No. 16-

IN THE

Supreme Court of the United States

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC.,

Petitioner,

v.

JEAN CHARLES, JR., as next friend and duly appointed guardian of his sister, MARIE CHARLES, *et al.*,

Respondents.

On Petition for a Writ of Certiorari to the Florida Supreme Court

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The federal Patient Safety Act created a national system for healthcare providers to share and analyze patient-safety information. Congress broadly defined this "patient safety work product" to include "any data, reports, records, memoranda, and analyses (such as root cause analyses)" a healthcare provider assembles for or reports to a "patient safety organization." 42 U.S.C. § 299b-21(7). Because state discovery laws might dissuade participation, Congress made patient safety work product privileged and confidential "[n]otwithstanding any other provision of Federal, State, or local law." § 299b-22(a).

The Florida Supreme Court, however, held that information was not patient safety work product "because Florida statutes and administrative rules require providers to create and maintain these records," and because a state constitutional amendment "provides patients with a constitutional right to access these records." Pet. App. 20a.

The question presented is:

Whether state law may override Congress's definition of patient safety work product by deeming healthcare information to be "collected, maintained, or developed separately" from the federal patient-safety system in which it resides.

CORPORATE DISCLOSURE STATEMENT

Southern Baptist Hospital of Florida, Inc. is a Florida not-for-profit corporation whose sole member is Baptist Health System, Inc. No publicly held company owns 10% or more of Southern Baptist Hospital of Florida, Inc. or Baptist Health System, Inc.

PARTIES TO THE PROCEEDINGS

Petitioner, Southern Baptist Hospital of Florida, Inc., was petitioner-appellee below. 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.; and John D. Pennington, M.D., were nominal respondents-appellees below.

Jean Charles, Jr., as next friend and duly appointed guardian of his sister, Marie Charles, and children, Angel Alston and Jazmin Houston, minors, and Pervin Alston, were respondents-appellants below.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Southern Baptist Hospital of Florida, Inc. ("Baptist") respectfully petitions for a writ of certiorari to review the judgment of the Florida Supreme Court in this case.

OPINIONS BELOW

The opinion of the Florida Supreme Court is reported at 209 So. 3d 1199 (Fla. 2017), and reproduced at Petition Appendix (Pet. App.) 1a-33a. The decision of the Florida First District Court of Appeal is reported at 178 So. 3d 102 (Fla. Dist. Ct. App. 2015), and reproduced at Pet. App. 34a-48a. The orders of the Duval County Circuit Court are reproduced at Pet. App. 49a-78a.

JURISDICTION

The Florida Supreme Court issued its opinion on January 31, 2017. Pet. App. 1a. This Court has jurisdiction pursuant to 28 U.S.C. § 1257. *Infra* pp. 31-34.

CONSTITUTIONAL AND STATUTORY PROVISIONS

The Supremacy Clause provides, in pertinent part, that "the Laws of the United States … shall be the supreme Law of the Land; … any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

The relevant provisions of the Patient Safety and Quality Improvement Act of 2005 ("Patient Safety Act" or "Act"), Pub. L. No. 109-41, 119 Stat. 424 (codified at 42 U.S.C. § 299b-21 *et seq.*), are reproduced at Pet. App. 79a-92a.

INTRODUCTION

The Florida Supreme Court held below that *state* discovery law nullifies a *federal* privilege. This interpretation of the Patient Safety Act contravenes the text of the statute, turns preemption on its head, and conflicts with other courts' interpretations of the privilege. The ruling also directly undermines a federal program designed by Congress to improve patient health by shielding "patient safety work product" "[n]otwithstanding any other provision of … State … law." 42 U.S.C. § 299b-22(a).

In 2005, Congress sought to reduce medical errors by establishing a nationwide system for the reporting, aggregation, and analysis of information about patient-safety events. To induce doctors and hospitals to participate in this federal program, Congress made the information collected for or contained within the system privileged and confidential. Otherwise, candid information about medical errors and near-misses would never be shared, for fear of its being discovered and used in malpractice lawsuits. Through the Patient Safety Act, Congress sought to create a "culture of safety" in which providers could share, analyze, and learn from adverse-event information without fear of increased liability exposure.

The Florida Supreme Court has drastically destabilized this federal privilege by subordinating it to state law. The Florida Constitution creates a right to access "any records … relating to any adverse medical incident"—a broad class of information that subsumes the materials Congress protected under federal law. The court below held that Congress did not displace this provision, or any other state laws or regulations that require reporting, maintaining, or disclosing such information. Thus, the court held that materials that

are "not privileged under state law or the state constitution" are not privileged under federal law either. Pet. App. 3a.

The effect of this backwards ruling is to leave in place the patchwork of inconsistent state laws that Congress deemed inadequate to permit the candid sharing and analysis of medical-error information. Indeed, given the breadth of the state laws at issue, the privilege is now all but nugatory in Florida, leaving healthcare providers with the dilemma of eschewing valuable patient-safety activities altogether or creating work product that may be used against them in litigation. That is not what Congress envisioned when it enacted a uniform federal privilege.

Unsurprisingly, other appellate courts have rejected this cramped construction of the Act. If this case had been litigated in Illinois, Kentucky, or several other states, the result would have been different. The breadth and error of the decision below, however, threaten the viability of the privilege throughout the country. Even the threat of disclosure will destroy the federal incentive offered to providers to voluntarily report all possible medical errors. Few providers are likely to create, much less share, self-critical analysis at the risk of court-ordered disclosure—precisely the reason Congress enacted the Patient Safety Act in the first place. The Court should grant the petition, resolve this conflict, and restore certainty to the patient-safety program Congress created.

STATEMENT OF THE CASE

I. LEGAL BACKGROUND

1. Patchwork of State-Law Rules. Before Congress enacted the Patient Safety Act, barriers to sharing healthcare information inhibited efforts to study

medical errors and improve patient safety. According to a seminal analysis by the Institute of Medicine, "fears about the legal discoverability of [patient-safety] information may undercut motivations to detect and analyze errors to improve safety. Unless such data are assured protection, information about errors will continue to be hidden and errors will be repeated." IOM, *To Err Is Human: Building a Safer System* 10 (1999) ("IOM Report"). Those errors, often preventable, kill or injure thousands of patients each year. And as Congress recognized, they impose huge costs—up to $29 billion—on the nation's health-care system and the broader economy every year. H.R. Rep. No. 109-197, at 9 (2005).

Existing state-law protections for information sharing were inadequate. Some states recognized a medical peer-review privilege, but protections were inconsistent, limited, and porous. The lack of a reliable privilege and the corresponding risk of discovery in malpractice litigation caused many providers not to engage in peer-review analysis at all. There were "few incentives and many barriers for providers to collect and report information regarding patient safety," specifically "concerns that information shared to promote patient safety would expose providers to liability." S. Rep. No. 108-196, at 7 (2003). And the analysis providers did produce was rarely shared with other institutions or researchers addressing similar safety issues. Rather, it remained siloed within the institution that created it, because disclosure to outside healthcare professionals could destroy any applicable state-law privilege. See 73 Fed. Reg. 8,112, 8,113 (proposed Feb. 12, 2008). This prevented any meaningful aggregation and study on a scale that would enable robust research. *Id.*; IOM Report at 120-21.

Florida's medical-record disclosure law, at issue in this case, illustrates how state law could stymie information sharing. "Amendment 7" is the ballot designation and common name of Article 10, section 25, of the Florida Constitution, added by referendum in 2004. It provides that "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." Fla. Const. art. X, § 25(a) (emphases added). Amendment 7 broadly defines "adverse medical incident" to include "any … act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient." *Id.* § 25(c)(3). This state-law disclosure right "has become an important discovery tool for medical malpractice plaintiffs" and the plaintiffs' bar, and has correspondingly diminished healthcare providers' ability to candidly and confidentially critique adverse medical incidents. Pet. App. 35a.

That threat of malpractice liability historically had been the principal policy check on medical errors. But Congress recognized it was insufficient. Indeed, the threat of litigation exacerbated the dearth of information sharing: fear of civil discovery discouraged hospitals, doctors, and other providers from recording or sharing information about adverse events and near-misses. See 73 Fed. Reg. at 8,113. More reliable protection was necessary to facilitate data sharing across the "decentralized and fragmented" healthcare system. IOM Report at 3, 90; see also 73 Fed. Reg. at 8,113.

2. The Patient Safety Act. Congress responded by enacting the Patient Safety Act of 2005. The system it launched allows healthcare providers and researchers to share and study medical-error data in a manner that is aggregated, anonymous, and protected from

disclosure. The goal was to replace the "culture of blame" associated with the liability system, 73 Fed. Reg. 70,732, 70,749 (Nov. 21, 2008); IOM Report at ix, with "a culture of safety and of providing feedback and assistance to effectively minimize patient risk," 42 U.S.C. § 299b-21(5)(D).

The Act created a federal system to facilitate robust nationwide sharing and analysis of safety data:

- Hospitals, doctors, and other healthcare providers may collect a broad swath of safety information for review, aggregation, and analysis: "any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements … which could result in improved patient safety, health care quality, or health care outcomes." This information is known as "patient safety work product," or PSWP. § 299b-21(7).
- Providers transmit this data to "patient safety organizations," or PSOs, which store, aggregate, and anonymize the data. §§ 299b-21(d)(4), -24(d). Once the data is organized, researchers mine and study it to understand why errors occur and how they can be prevented. Today more than 80 PSOs operate across all 50 states.[1]

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[1] The Act also discusses a "patient safety evaluation system" ("PSES"): a provider's in-house system for "collect[ing], manag[ing], or analy[zing]" information before reporting it to a PSO. § 299b-21(6). The distinction between a PSO and PSES is generally unimportant for this petition, which refers to the two collectively as the "patient-safety system." To avoid a gap in protection, HHS has clarified that information becomes protected PSWP as soon as it is stored in a provider's internal PSES, if it will later be reported externally to a PSO. 42 C.F.R. § 3.20(1)(i)(A).

- PSOs share data with one another through a central clearinghouse known as the Network of Patient Safety Databases. This is intended to recognize and disseminate trends and best practices at the national level. § 299b-23.
- Researchers and PSOs transmit the resulting feedback, findings, and reports to their doctor and hospital members, who incorporate the responses into patient care. PSO-derived research may also be published in peer-reviewed journals.[2]

The Act thus creates a positive feedback loop between providers and PSOs: the incentive to both supply and analyze data increases as more flows into the system. But providers must first be confident that the candid information they share will in fact remain confidential. *E.g.*, 73 Fed. Reg. at 70,741. Federal law requires many hospitals to participate in a PSO, including those with problematic readmission rates. 42 U.S.C. § 280j-3. For other providers, however, the decision whether and how much to participate is purely voluntary; absent a robust privilege, providers are deterred from gathering and reporting critical assessments of their own physicians, nurses, and systems involved in patient-safety events.

To provide this assurance, Congress offered "substantial and broad" protections for shared information, as HHS recognized in promulgating its final implementation rule. 73 Fed. Reg. at 70,741. The privilege allows "health care providers … to discuss errors openly and learn from them," H.R. Rep. No. 109-197,

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[2] *E.g.*, Williams et al., *Guidewires Unintentionally Retained During Central Venous Catheterization*, 19 J. Ass'n Vascular Access 29 (2014) (recommending device design change, later adopted by manufacturer, based on review of PSO reports).

at 9, by "enabl[ing] all health care providers … to share data within a protected legal environment, both within and across states, without the threat of information being used against [them]," 73 Fed. Reg. at 8,113.

Federal law protects this patient safety work product by treating it as privileged and confidential. It explicitly bars disclosure, even in response to a subpoena, discovery order, FOIA request, or disciplinary proceeding. § 299b-22(a)(1)-(5). And the protection expressly preempts contrary law: it applies "[n]otwithstanding any other provision of Federal, State, or local law." § 299b-22(a), (b). Indeed, unauthorized disclosure of PSWP is punishable by civil penalties of up to $11,000 per act. § 299b-22(f); 42 C.F.R. § 3.402-.408; 74 Fed. Reg. 42,777, 42,779 (Aug. 25, 2009). And given concerns about the existing patchwork of state laws, the federal protections do not depend on state law, but apply "uniform[ly] … in all states." 73 Fed. Reg. at 8,113.

3. The Scope of PSWP. The applicability of this protection turns on whether information falls within the definition of "patient safety work product." In deciding what would be treated as privileged and confidential, Congress defined "PSWP" broadly to include (as relevant):

> any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—
>
> (i) which—
>
> (I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; …
>
> ….

> and which could result in improved patient safety, health care quality, or health care outcomes.…

42 U.S.C. § 299b-21(7)(A).

The Act identifies two specific exclusions from this definition. First, "a patient's medical record, billing and discharge information, or any other original patient or provider record" is not protected PSWP. § 299b-21(7)(B)(i). Second, "information that is collected, maintained, or developed separately, or exists separately," from the patient-safety reporting process is not protected. § 299b-21(7)(B)(ii). These exclusions preserve patients' and states' ability to access the "original records underlying patient safety work product," 73 Fed. Reg. at 70,732, and also ensure that information kept outside the patient-safety system cannot later become privileged simply because a provider sent it to a PSO.

To qualify for protection as patient safety work product, therefore, information must meet three criteria:

1. It must fit into the broadly defined categories of material listed in the Act: "any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" which "could result in improved patient safety, … quality, or … outcomes." § 299b-21(7)(A).

2. It must be "assembled or developed" for reporting to a PSO and in fact be reported to a patient-safety system. *Id.*; 42 C.F.R. § 3.20(1)(i)(A); see *supra* p. 6 n.1.

3. And it must fall outside the statutory exceptions for original records or separately developed or maintained information. § 299b-21(7)(B).

II. PROCEEDINGS BELOW

1. Baptist's Information-Sharing under the Patient Safety Act. Petitioner Southern Baptist Hospital ("Baptist") has for years participated in the Patient Safety Act system. It "has established a [patient-safety] system in which it collects, manages, and analyzes [patient-safety] information for reporting to its PSO—PSO Florida." Pet. App. 38a. Baptist's staff is "instructed to enter information into the [patient-safety] system with the assurance of confidentiality based upon the … protections in the Act." *Id.* This information includes "occurrence reports" regarding "events that are not consistent with the routine operations of the hospital or the routine care of a patient or that could result in an injury." *Id.*

Baptist also creates and submits root cause analyses to its PSO. Root cause analyses identify causes and critique performance after deaths, serious injuries, or near-miss events. They are the only specific type of information expressly identified by the Act as within the definition of PSWP: "data, reports, records, memoranda, analyses (such as root cause analyses)." 42 U.S.C. § 299b-21(7)(A). And the Act contains an exception to its normal rule of non-disclosure that applies to root cause analyses in particular: given the requirement to conduct root cause analyses imposed by the nation's leading healthcare accreditation body (the Joint Commission), the Act expressly permits disclosure of PSWP to an accrediting body without destroying the privilege. § 299b-22(a)-(b), (c)(2)(E), (c)(3).

2. Plaintiffs' Demand for PSWP. Respondents, representatives of Marie Charles and her family, sued Baptist for medical malpractice after Charles suffered a neurological injury. Pet. App. 38a. During discovery, respondents demanded that Baptist produce documents related to *all* adverse medical incidents in the

hospital's history, or to *any* doctor, care, or treatment associated with Baptist during the three years before the discovery request. *Id.* at 38a-39a. In response, Baptist produced two occurrence reports related to Marie Charles, along with many other documents it had already disclosed or created pursuant to Florida health regulations. But Baptist invoked the protections of the Patient Safety Act and withheld other documents, including root-cause analyses and occurrence reports, which had not been disclosed and which met the definition of privileged PSWP.

Respondents moved to compel production of these materials, arguing that the Patient Safety Act "protects only documents created solely for the purpose of submission to a patient safety organization." Pet. App. 8a. The trial court agreed: it required Baptist to produce "[*a*]*ll* reports … created, or maintained pursuant to *any* statutory, regulatory, licensing, or accreditation requirements." Pet. App. 66a (emphases added). This order compelled production of more than 50,000 documents, including root cause analyses, internal quality documents, and records Baptist prepared for licensing and accreditation documents independent of any state regulatory requirement.

3. Court of Appeal Ruling. The Florida District Court of Appeal, in a unanimous opinion by Chief Judge Roberts, quashed the trial court's orders. The court's analysis was straightforward and textual: "the documents at issue clearly meet the definition of PSWP because they were placed into Baptist's PSE system where they remained pending submission to a PSO." Pet. App. 43a. Because the records "d[id] not exist outside of the PSE system," they "should be regarded as PSWP, which is privileged, confidential, and not discoverable." Pet. App. 46a.

Applying basic preemption principles, the court of appeal rejected Respondents' contention that state-law disclosure rights under Amendment 7 could overcome the federal PSWP privilege. The Act's bar against disclosure "notwithstanding any … provision of … State … law," § 299b-22(a), "expressly preempts any broad discovery right under Amendment 7 to documents meeting the definition of" patient safety work product, Pet. App. 47a. The Act also impliedly preempts Amendment 7, the court recognized, "because compliance with both federal and state law would be impossible." *Id.*

The court of appeal also emphasized the implementing rule promulgated by HHS after notice and comment. The Rule directly addressed concerns, like those raised by Respondents and the trial court, that the scope of the PSWP privilege might displace state regulatory and recordkeeping requirements. See 42 U.S.C. § 299b-21(7)(B)(iii)(II)-(III) (privilege does not limit a provider's reporting or recordkeeping obligations for federal, state, or local governments). HHS "assur[ed] providers that they may place information into their [patient-safety] system with the expectation of protection" even if such information might later be needed to meet state regulatory or reporting requirements. Pet. App. 44a (citing 73 Fed. Reg. at 70,742). And the court explained that, if a provider failed to satisfy such obligations, "the remedy would be to address the noncompliance of recordkeeping or reporting obligations itself" through applicable state regulatory remedies, rather than to permit a trial court "to 'rummage through' the provider's [patient-safety] system, in plain contravention to the purpose of the Act." *Id.* at 45a.

4. **Decision Below.** After Respondents appealed, but before argument, the parties resolved the underlying medical-malpractice claim and filed a stipulation of dismissal of the appeal. The Florida Supreme Court, however, rejected the stipulation of dismissal. It proceeded to hold argument and decide the appeal. Its opinion offered four reasons why: the statutory-interpretation question had statewide importance, the court of appeal's decision invalidated a provision of the Florida Constitution, the decision bound courts across the state, and "amici on both sides of the controversy have important interests in the outcome of this case." Pet. App. 2a n.2. Two justices dissented from the rejection of the stipulation, contending the appeal should have been dismissed without deciding the question presented. *Id.* at 33a.

The majority, however, reached the merits and reversed the court of appeal. *First*, it held that any state-regulated document was not developed for the "sole purpose" of submission to the federal patient-safety program. In the court's view, "Congress carved out broad exceptions" to the privilege that excluded the "adverse medical incident reports" covered by Florida's Amendment 7 from the scope of PSWP protections. Pet. App. 18a-19a. Specifically, it held that "adverse medical incident reports are not patient safety work product because Florida statutes and administrative rules require providers to create and maintain these records." *Id.* at 20a. The documents fell within the Act's exception for information that is "collected, maintained, or developed separately, or exists separately," from a patient-safety system, given that "Amendment 7 provides patients with a constitutional right to access these records." *Id.* (quoting § 299b-21(7)(B)(ii)). The records, according to the court, "were not created solely for the purpose of submission to a patient safety

evaluation system" "because Florida statutes and administrative rules require providers to create and maintain" adverse medical incident reports. *Id.* at 31a.

Second, the court held the Patient Safety Act did not preempt Amendment 7. Given the court's interpretation of the definition of PSWP not to include adverse incident reports, it concluded that "the Federal Act does not contain any express statement of preemption relating to Amendment 7." Pet. App. 24a. The court further decided that, even where the Act and Amendment 7 overlapped, the federal statute would give way based on the voluntary nature of the federal program. A "mandatory disclosure law in our state constitution is not preempted by a health care provider's *choice* to participate in the Federal Act, coupled with its choice to place documents into a patient safety evaluation system." *Id.* at 25a-26a. The Act, according to the majority opinion, "was intended by Congress … not to act as a shield to providers." *Id.* at 32a.

REASONS FOR GRANTING THE PETITION

The Florida Supreme Court's decision warrants this Court's review for three reasons. *First*, it decided an important question of federal law in a manner that contravenes the statutory text and turns preemption on its head. *Second*, the court's interpretation of the patient-safety work product privilege diverges from the decisions of other courts. *Third*, the errors and uncertainty introduced by the decision below threaten an important federal program.

Review is particularly justified given the state supreme court's aggressive effort to decide this question of federal law. Its decision binds lower courts, healthcare providers, and patients alike to an upside-

down interpretation of the Patient Safety Act with serious and ongoing consequences.

I. THE DECISION BELOW SUBORDINATES FEDERAL PROTECTION TO STATE LAW.

1. The "sole purpose" interpretation negates federal protection for any information created or maintained under state law. The Florida Supreme Court misinterpreted this "uniform" federal privilege, 73 Fed. Reg. at 8,113, as somehow intended to be subject to the disparate and changing contours of state law. It held that any healthcare records that must be created, kept, or disclosed under state law cannot be privileged under federal law.

To reach this counterintuitive conclusion, the court adopted an extremely broad interpretation of an exception to the Patient Safety Act's definition of patient safety work product. The Act excludes "information … collected, maintained, or developed separately, or [that] exists separately, from a patient safety evaluation system" from the PSWP privilege. 42 U.S.C. § 299b-21(7)(B)(ii). This means providers cannot resist discovery by placing records in a patient-safety system after the fact. The opinion below, however, equates records "collected, maintained, or developed separately," *id.*, with records "not created *solely* for the purpose of submission to a patient safety evaluation system," Pet. App. 31a (emphasis added).

This is a deep incursion on Congress's design and an inversion of the ordinary relationship between federal and state law. The state-court decision covers any reports and records that "Florida statutes and administrative rules require providers to create and maintain," including Amendment 7's state disclosure requirement. Pet. App. 31a; see also *id.* at 20a, 30a. And the scope of records covered by that Amendment is

practically limitless: "*any* records made or received in the course of business by a health care facility or provider relating to *any* adverse medical incident." Fla. Const. art. X, § 25(a) (emphases added). No document regarding the medical incidents that concerned Congress, therefore, may be shared, studied, and protected as Congress intended without exposing the medical provider who shares the information to disclosure to the plaintiffs' bar. This outcome is not textual; the statute makes no mention of state law in defining the privilege. Yet according to the Florida Supreme Court, any state can defeat the congressionally-enacted privilege simply by requiring providers to maintain or disclose federally protected records.

2. The decision below is irreconcilable with the Patient Safety Act. Subsection (7)(B)(ii)'s exception for "information collected, maintained, or developed separately, or [that] exists separately, from a patient safety evaluation system" cannot remotely bear the weight the court below assigned to it. Nothing in the statute's text, structure, or purpose suggests states may unilaterally contract the federal privilege by the simple expedient of expanding state disclosure requirements.

First, the plain text of the Patient Safety Act contradicts the state supreme court's interpretation. The text of the exception set forth in § 299b-21(7)(B)(ii) nowhere mentions a "sole purpose" requirement. Nor does it mention state law. "[I]nformation … collected, maintained, or developed separately, or [that] exists separately, from a patient safety evaluation system" merely refers to where information is stored—either inside or outside the patient-safety system. The reading adopted below transforms that simple factual inquiry (how were documents collected and maintained?)

into a multilayered legal inquiry (are documents subject to state-law reporting, recordkeeping, or disclosure requirements?). *Cf. Dep't of Fin. & Prof'l Regulation* v. *Walgreen Co.,* 970 N.E.2d 552, 557-58 (Ill. App. Ct. 2012) (privilege turns on whether documents were maintained outside of the patient-safety system).

Simply put, "exists separately" does not mean "required separately" or "used for a separate purpose." That view reads words into the statute that Congress did not and would not enact if it hoped to achieve its purpose of encouraging voluntary disclosures. Pet. App. 44a. As the court of appeal explained, a "document is [privileged] if"—as a matter of historical fact—"it is placed into a PSE system for reporting to a PSO and does not exist outside of the PSE system." *Id.* at 46a.

The point is not limited to the text of the specific exception relied on below; no part of the PSWP definition mentions state law or a sole purpose. Rather, the test Congress set forth is straightforward and factual: First, are the documents of the type eligible for the privilege? That is an expansive class that undoubtedly includes the root cause analyses and occurrence reports at issue here: "*any* data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" that "could result in improved patient safety, health care quality, or health care outcomes." § 299b-21(7)(A) (emphasis added). And second, has the provider created and maintained them in its patient-safety system for reporting to a PSO? Again, there is no doubt that Baptist complied with this textual duty.[3] If Congress intended the federally

[3] The opinion states, incorrectly, that Baptist "never submitted" the documents "to the patient safety organization." Pet. App.

created privilege to turn on state law, it surely would have said so.

Second, a "sole-purpose" test is at odds with the structure and effect of the Act. As the court of appeal recognized, the sole-purpose approach "gives the false impression that federal protection under the Act and state compliance have to be mutually exclusive." Pet. App. 44a. HHS's rulemaking flatly contradicts the state court's view: the Final Rule (and thus the Act) "does not limit the purpose for which patient safety work product may be shared internal to an entity." See 73 Fed. Reg. at 70,737. Moreover, the Act's other provisions foreclose reading "for" to mean "solely for"—because they recognize that privileged information may be used "for a variety of purposes." H.R. Rep. No. 109-197, at 14.

PSWP may be disclosed "to carry out patient safety activities"; for "research" and "demonstration projects" authorized by HHS; "to an accrediting body"; if "necessary for business operations"; and to law enforcement. § 299b-22(c)(2)(A)-(G). None of these disclosures destroys the privilege: "Patient safety work product that is disclosed under [these exceptions] shall continue to be privileged and confidential …." § 299b-22(d)(1). Congress recognized that providers "may disclose [patient safety] work product for a variety of purposes under subsection 922(c)," and that "despite such a disclosure, such work product remains confidential and privileged and does not lose its status as patient safety work product." H.R. Rep. No. 109-197, at 14. Thus, the Act explicitly contemplates the use of protected work product for more than one purpose. The sole-purpose interpretation of the Florida Supreme Court

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31a. That would be legally irrelevant in any event. The documents were part of Baptist's PSES, and therefore were privileged even before submission to the PSO. *Supra* p. 6 n.1.

would render Congress's list of permissible disclosures at best surplusage, and at worst outright contradictory. See Pet. App. 57a-61a.

Third, the decision below defeats Congress's manifest purpose in creating a federal privilege to protect information-sharing from state discovery laws. The Act *preempts* "any other provision of Federal, State, or local law" that might require the disclosure of such information. 42 U.S.C. § 299b-22(a). If the "exists separately" exception is read to cover information that "exists" in any part because of a state-law requirement, that broad carve-out would defeat Congress's purpose. Instead, it merely clarifies that "[s]uch separate information" cannot *become* privileged simply because a provider later opts to report it to a PSO. § 299b-21(7)(B)(ii). "'Where Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of evidence of a contrary legislative intent.'" *TRW Inc.* v. *Andrews*, 534 U.S. 19, 28 (2001) (quoting *Andrus* v. *Glover Constr. Co.,* 446 U.S. 608, 616-17 (1980)).

Fourth, the Act's provisions that *do* relate to state law offer no support to the interpretation below. The court attempted to bolster its reading by pointing to a "[c]larification" that the Act does not "limit" a provider's recordkeeping or reporting obligations under state law with respect to information excluded from the definition of PSWP. Pet. App. 20a, 43a (citing § 299b-21(7)(B)(iii)). Likewise, the Act includes a "[r]ule of construction" that "[n]othing … shall be construed" to "limit, alter, or affect the requirements of Federal, State, or local law pertaining to information *that is not privileged or confidential* under this section" or "as preempting or otherwise affecting any State law requiring a provider to report information *that is not patient safety work product*." 42 U.S.C. § 299b-

22(g)(2), (5) (emphases added); see Pet. App. 17a-19a. But treating certain state-regulated records as *privileged* is fully consistent with Congress's respect for state regulation of "information that is *not privileged*." 42 U.S.C. § 299b-22(g)(2) (emphasis added). Any state-law violations may be "remedied … in 'the same manner as'" before the Act. *Tibbs* v. *Bunnell*, 448 S.W. 3d 796, 815 (Ky. 2014) (Abramson, J., dissenting) (quoting 73 Fed. Reg. at 70,742), *cert. denied*, 136 S. Ct. 2504 (2016). The court of appeal agreed: "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." Pet. App. 44a-45a.

3. The court's preemption analysis inverts the Supremacy Clause. The decision below renders the federal privilege entirely dependent on the scope of "state law or the state constitution." Pet. App. 3a. Given Congress's express purpose to *preempt* state privilege and discovery rules it found inadequate, "[i]t is not easy to imagine that Congress meant to accomplish nothing more, and nothing uniform, by its effort." *Fid. Fin. Servs., Inc.* v. *Fink*, 522 U.S. 211, 218 (1998).

Rather, Congress's intent was to adopt, for the first time, "a uniform set of Federal protections that will be available in all states and U.S. territories and that extend to all health care practitioners and institutional providers." 73 Fed. Reg. at 8,113. The decision below, however, ratifies the preexisting patchwork of uneven State-law protections that Congress specifically aimed to overcome. See IOM Report at 91-93, 120-21, 127-28. It also contravenes the broader principle that "federal statutes are generally intended to have uniform nationwide application." *Miss. Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43-44 (1989); see also *Howlett ex rel. Howlett* v. *Rose*, 496 U.S. 356, 383

(1990) (refusing to adopt an approach allowing States to "nullify for their own people the legislative decisions that Congress has made on behalf of all the People").

The Florida Supreme Court's preemption analysis turns basic Supremacy Clause principles on their head. The court acknowledged the Act's express preemptive force—rendering documents privileged and confidential "[n]otwithstanding any other provision of Federal, State, or local law." 42 U.S.C. § 299b-22; Pet. App. 14a-15a, 24a. But its constricted interpretation of the PSWP definition did nothing but violence to Congress's clear aim.

As to implied preemption, the court's ruling was even stranger. Federal law must yield to state law, it held, because the patient-safety program is "voluntary," while Amendment 7 is "mandatory." Pet. App. 26a. That state constitutional provision, according to the court, was "not preempted by a health care provider's *choice* to participate in the Federal Act, [and] to place documents into a patient safety evaluation system." *Id.* That choice, of course, is precisely the one Congress encouraged (and sometimes required) healthcare providers to make. *Supra* pp. 5-9. As the court of appeal recognized, "compliance with both federal and state law would be impossible." Pet. App. 47a. At a minimum, therefore "the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,'" including where "it interferes with the methods by which the federal statute was designed to reach [its] goal." *Int'l Paper Co.* v. *Ouellette*, 479 U.S. 481, 492, 494 (1987). The federal privilege is essential to "the methods by which the [Patient Safety Act] was designed to reach [its] goal"; without that guarantee, the patient-safety system cannot function. *Supra* pp. 5-9.

It is no answer to say that providers can simply choose not to participate, see Pet. App. 26a; that outcome would entirely frustrate Congress's intent in passing the Act. See *Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000) ("If the purpose of the act cannot otherwise be accomplished—if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect—the state law must yield …."). The clear aim of the federal statute is to overcome contrary state law—even "an important right afforded to Florida citizens through Amendment 7," Pet. App. 32a—not to allow "state legislatures to nullify … unwanted federal legislation," *Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 105-06 (1992).

II. THE DECISION BELOW CONFLICTS WITH OTHER COURTS' CONSTRUCTION OF THE PRIVILEGE.

The decision below adopted a "sole purpose" construction of the "separately collected" exception that is at odds with the interpretations of several other courts and the U.S. government. This disagreement implicates an important question of federalism: the extent (if any) to which state law constrains the reach of a federal statute. Review is warranted to resolve the disagreement, confusion, and disparate outcomes evident in the lower courts' application of the Patient Safety Act.

1. The Kentucky Supreme Court recently considered and rejected an approach that is materially identical to the Florida Supreme Court's analysis.

In *Tibbs* v. *Bunnell*, a controlling plurality interpreted the privilege not to protect "information normally contained in" documents that states require health-care providers to create or maintain. 448

S.W.3d at 809. The opinion discerned this rule in the same exception relied on below, for information collected or maintained "separately … from a patient safety evaluation system." *Id.* at 803-04 (quoting 42 U.S.C. § 299b-21(7)(B)(ii)). The Court viewed this "clarification" as indicating that any information that falls under a state reporting or recordkeeping requirement cannot be privileged patient safety work product. *Id.* at 809. Two judges dissented on the ground that the "federal privilege … precludes an adverse party's—and a trial court's—invasion of the patient safety evaluation system itself, since … providers must be assured that their participation in the patient safety system will not subject them to adverse consequences." *Id.* at 815 (Abramson, J., dissenting).

Recently, however, the Kentucky Supreme Court revisited *Tibbs* and adopted a different approach. In *Baptist Health Richmond, Inc.* v. *Clouse*, a majority of the court held that a provider "may collect information within its patient safety evaluation system that complies with the Act and that also complies with state statutory and regulatory requirements." 497 S.W.3d 759, 766 (Ky. 2016). Only "if a provider fails to fulfill" its "statutory and regulatory reporting obligations" is a trial court authorized to conduct discovery of information that might be within the patient safety system. *Id.* The court did not rest its decision on the "exists separately" exception. And it rejected the plaintiff's argument for and lower court's adoption of the "sole purpose" test embraced by the Florida Supreme Court. *Id.* at 761. Instead, the court relied upon the "original-record" exception described in an HHS "guidance" document. *Id.* at 765 (purporting to exempt from the privilege "original records (e.g., reports or documents) that are required of a provider to meet any Federal, state,

or local public health or health oversight requirement").[4]

The decision below conflicts squarely with *Clouse* because it authorizes—indeed, mandates—broad discovery of patient safety work product, even absent any showing that the provider has failed to comply with any statutory or regulatory obligations. Compare Pet. App. 3a, 19a-20a, with 497 S.W.3d at 766. In Kentucky, medical providers who are in compliance with state regulatory requirements can participate in the patient-safety program without fear that privileged work product will later be used against them. See 497 S.W.3d at 764 (noting the concern that "broad protections are essential to encourage reporting").

In Florida, by contrast, no amount of regulatory compliance can insulate providers' patient-safety materials from discovery. The mere fact that such materials might be subject to Amendment 7, or to other regulatory requirements—even if the provider is *fully in compliance* with those requirements—means they are not privileged at all. Pet. App. 3a, 32a. Thus, in one State the federal program envisioned by Congress operates more or less as it should, and in the other, it has no force. As a result, this case would come out differently under the rule set forth in *Clouse*. The court below did not dispute that Baptist's "root cause" analyses are not

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[4] The HHS guidance did not undergo notice-and-comment rulemaking, even though it contradicts implementing regulations which did. Its statutory interpretation therefore warrants no deference, *Christopher* v. *SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2166 (2012), and incorrectly interprets the statute for the reasons above, *supra* pp. 15-22. In any event, the decision below did not rely on the guidance document, which rested on the original-record exception and did not purport to address root cause analyses. *See* 81 Fed. Reg. 32,655, 32,660 (May 24, 2016); Pet. App. 28a.

subject to any Florida reporting or recordkeeping obligation. Nor did it indicate Baptist was noncompliant with any state regulation. The only basis for affirming the trial court's order to disclose thousands of root-cause analyses and occurrence reports, was the court's ruling that *any* state-law disclosure obligation—even one as broad as Amendment 7—displaced the federal Patient Safety Act.

2. Other courts have construed the Act, consistent with its plain language, to protect any eligible patient-safety information that is collected for and reported to a PSO, without regard to state regulatory requirements. The Florida District Court of Appeal's decision in this case, reversed by the decision below, clearly explained why the federal privilege turns on providers' compliance with *federal* rather than state-law requirements. Pet. App. 34a-48a.

Likewise, in *Department of Financial & Professional Regulation* v. *Walgreen Co.*, a state agency issued administrative subpoenas seeking quality-improvement reports related to three of the company's pharmacists. 970 N.E.2d at 555. The Illinois Appellate Court rejected the agency's attempt to enforce subpoenas under state law because the reports in question had been submitted to a PSO. *Id.* at 557-58. The court distinguished these reports from other, potentially discoverable materials that the pharmacy maintained *outside* the PSO program for non-PSO purposes. See *id.* at 558. The *Walgreen* court's focus on the key statutory question—whether the reports were created for and provided to a PSO—reflects a proper application of the Act's privilege. And in that case—unlike *Charles* or *Clouse*—the patient safety work product was protected even though the state agency pursued it under its regulatory authority.

Several other decisions, moreover, have properly construed the Patient Safety Act according to its text and structure. Although these decisions have not all addressed whether state discovery rules may displace the federal statute, each recognizes the proper preemptive scope and effect of the PSWP privilege. See *Tinal* v. *Norton Healthcare, Inc.*, No. 11-cv-596, slip op. at 21-22 (W.D. Ky. July 15, 2014) (ECF No. 59) (each document at issue was privileged because it qualified as patient safety work product and was reported to a PSO); *KD ex rel. Dieffenbach* v. *United States*, 715 F. Supp. 2d 587, 595-96 (D. Del. 2010) ("the [Act] protects all … data, reports, records, memoranda, analyses, or written or oral statements which … are assembled or developed by a provider for reporting to a [PSO] and are reported to a [PSO]"); *Willard* v. *State*, 893 N.W.2d 52, 63-64 (Iowa 2017) (similar); *Lee Med., Inc.* v. *Beecher*, 312 S.W.3d 515, 535 (Tenn. 2010) (similar).

Both the Florida and Kentucky approaches conflict with these decisions, as they look to the contours of state law, rather than the text of the federal statute, to determine whether the privilege applies. Indeed, under the Florida Supreme Court's reasoning in *Charles*, the state regulatory subpoena at issue in *Walgreen* surely would have trumped the federal privilege: the state agency's subpoena power—even more so than a private litigant's access rights under Amendment 7—is a state rule that mandates access to information. See Pet. App. 19a.

3. Federal courts have rejected the position of the Florida Supreme Court in closely related contexts. An analogous federal statute, 23 U.S.C. § 409, establishes a federal privilege for materials "compiled or collected for the purpose of" enumerated highway-safety activities. Courts have recognized the privilege does not

turn on whether these materials were compiled for the *sole* purpose of federal reporting. *E.g.*, *Lusby* v. *Union Pac. R.R.*, 4 F.3d 639, 641 (8th Cir. 1993) ("materials do not fall outside the scope of [the statute] merely because they are not compiled solely for federal reporting purposes and are available for other uses"). Courts have likewise rejected a "sole purpose" standard under the attorney-client privilege. *E.g.*, *In re Kellogg Brown & Root, Inc.*, 756 F.3d 754, 759 (D.C. Cir. 2014) (communications remained privileged despite being partly motivated by business and regulatory considerations).

III. THE DECISION BELOW THREATENS AN IMPORTANT FEDERAL PROGRAM.

The Patient Safety Act represents a significant and refined effort by Congress to address the pressing question of healthcare quality and medical errors. The Florida Supreme Court's decision, however, leaves almost no information subject to the Act's protection and analysis. Providers there and elsewhere thus can have little confidence that patient-safety materials will remain protected from discovery.

First, the ruling stymies the Patient Safety Act's goal of creating a culture of safety through information sharing without fear of discovery. See 42 U.S.C. § 299b-21(5)(d); H.R. Rep. No. 109-197, at 9; IOM Report at 15. That aim is plainly frustrated by this rule. The robust protection Congress codified for patient safety work product—as evidenced by the breadth of the statutory definition, the construction provision, and the strong preemptive language, see 42 U.S.C. §§ 299b-21(7)(A), 299b-22(a), (d)(3)[5]—is to little effect

[5] *See, e.g.*, 73 Fed. Reg. at 8,121 ("[T]his expansive list [of patient safety work product] will maximize provider flexibility in operating its patient safety evaluation system by enabling the

if courts simply ask whether *state law* renders the information discoverable. This is particularly true given the program's dependence on the voluntary participation of providers. Without the protection of confidentiality, providers have little incentive to report peer-review information that plaintiffs may one day obtain in discovery. 73 Fed. Reg. at 70,741.

Particularly in Florida, the decision below renders the Act a "dead letter." Pet. App. 48a. Amendment 7 reaches "*any* records made or received in the course of business by a health care facility or provider relating to *any* adverse medical incident," which in turn includes not only "medical negligence, intentional misconduct, and *any other act, neglect, or default* of a … provider that caused or could have caused injury … or death," but also "incidents 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." Fla. Const. art. X, § 25(a), (c)(3) (emphases added). It is difficult to imagine anything a Florida doctor might assemble or develop "for reporting to a patient safety organization … which could result in improved patient safety, health care quality, or health care outcomes," 42 U.S.C. § 299b-21(7)(A)(i)(I), that would *not* fall within the scope of Amendment 7, to say nothing of the other regulatory requirements the court indicated would also vitiate the privilege, Pet. App. 19a. Unless "Florida healthcare providers can … secure [Patient Safety Act] privilege and confidentiality

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broadest possible incorporation and protection of information by providers and PSOs.").

protections as a way of avoiding the disclosure mandated by Amendment 7," the PSO system in Florida will atrophy and ultimately disappear.[6]

Second, this constriction of the privilege will have an intense impact on the primary conduct of healthcare providers. In enacting the Patient Safety Act, Congress sought to induce the participation of doctors and hospitals that would prefer to engage in peer review, but who were deterred by the prospect of civil discovery. S. Rep. No. 108-196, at 7 ("Currently, there are few incentives and many barriers for providers to collect and report information regarding patient safety. The primary barrier relates to concerns that information shared to promote patient safety would expose providers to liability."). Congress broadly articulated the protections of the Patient Safety Act precisely to overcome those fears. But the Florida Supreme Court read into the Act an atextual exception that makes nearly all written information concerning any patient-safety activity fair game for plaintiffs and their lawyers.

Under this rule, providers have little comfort ex ante—when the decision whether to collect or report work product to a PSO must be made—whether federal protection will suffice if the documents are later subpoenaed. Florida's decision, moreover, serves as a blueprint for any state legislature or regulator seeking statewide nullification of an Act of Congress: Simply pass a statute, amendment, or regulation that, like

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[6] Michael Arnold, *Peer Review Is Threatened, but (P)So What: Patient Safety Organization Utilization in Florida After Amendment 7 As A Troubling Sign for PSQIA*, 46 Colum. J.L. & Soc. Probs. 291, 317 (2013) (recognizing that "the disclosure[s] mandated by [the Florida constitution] and forbidden by [the Act] are clearly in conflict").

Amendment 7, purports to guarantee access to the materials covered by the Patient Safety Act. Providers cannot have any confidence in the federal privilege that can be overridden at any time by a change in *state* law.

Third, because a privilege is involved, it is not only the fact but the *perception* of protection that shapes primary conduct. As this Court has made clear, an "uncertain privilege, or one which purports to be certain but results in widely varying applications by the courts, is little better than no privilege at all." *Upjohn Co.* v. *United States*, 449 U.S. 383, 393 (1981) (the "very terms of the test adopted by the court below suggest the unpredictability of its application"). For "if the purpose of the … privilege is to be served, the [provider] must be able to predict with some degree of certainty whether particular [materials] will be protected." *Id.*; see also *Jaffee* v. *Redmond*, 518 U.S. 1, 15-17 (1996) (similar); *United States* v. *Jicarilla Apache Nation*, 131 S. Ct. 2313, 2328 (2011) (similar); *Swidler & Berlin* v. *United States*, 524 U.S. 399, 409 (1998) (similar).

Fourth, the ruling below will adversely affect the conduct of PSOs, which are now subject to conflicting legal obligations. Pet. App. 47a The decision below contemplates that a state court could compel a PSO to violate its federal-law obligation not to release patient safety information. See 42 U.S.C. § 229b-22(a)-(b), (d)(4)(A)(i). Violations of this rule are punishable by civil monetary penalties of up to $11,000 per act. *Supra* p. 8. PSOs should not need to rely on the forbearance of federal regulators to avoid incurring such penalties as a result of state-court-ordered discovery. The need for federal uniformity is particularly acute for the many PSOs that operate across multiple states; their operations could be subject to not just two, but many

more differing legal requirements. 73 Fed. Reg. at 8,113.

Unless the Patient Safety Act's protections are restored, fewer doctors and hospitals will participate in the patient-safety activities envisioned by the Act. See*, e.g.*, Hospital Quality Inst., *Why Are Some Organizations Reluctant to Participate in a PSO?* (July 2013), http://www.hqinstitute.org/post/why-are-some-organizations-reluctant-participate-pso ("Some organizations question the strength of the protections promised by the [Act]" in light of "recent court cases"). Such a reaction is unfortunate but completely rational, given the exposure providers face when they surrender patient safety materials. After all, the "confidentiality provisions are included in the Patient Safety Act to encourage provider participation. Without such protections, providers will be reluctant to participate in the expanded reporting and analysis of patient safety events, and low participation will severely inhibit the opportunity to reap the benefits from efforts to improve patient safety." See 73 Fed. Reg. at 8,170.

IV. THE STATE COURT'S BINDING INTERPRETATION OF FEDERAL LAW WARRANTS REVIEW.

The Florida Supreme Court's decision drastically constricts the scope of a federal privilege in order to promote state disclosure law. The court recognized the "important interests in the outcome of this case" for litigants on both sides, and then issued a ruling that purports to bind "all trial courts in th[e] State." Pet. App. 2a n.2. The court did so despite the parties' attempt to dismiss the appeal. Far from mooting this petition, the state court's aggressive response and attempt to neuter a federal statute cries out for this Court's intervention. Moreover, because the judgment

unquestionably has a significant "prospective effect on the parties," it satisfies Article III's case-or-controversy requirement. *Camreta* v. *Greene*, 563 U.S. 692, 702 (2011).

Baptist possesses a strong and ongoing stake in reversal because it "regularly engages in … conduct"—namely, producing and sharing patient-safety work product with its PSO—that could expose it to liability under the decision below. *Id.* at 703. "[S]o long as [the decision below] continues in effect," Baptist "must either change the way [it] performs [its] duties or risk [many] meritorious" lawsuits leading to disclosure and increased liability. *Id.* Unless the decision is overturned, Baptist will be "barred from enforcing" its rights under the Patient Safety Act—an interest "sufficient to prevent the case from being moot." *City of Erie* v. *Pap's A.M.*, 529 U.S. 277, 288 (2000).

In *Camreta*, this Court reviewed a qualified-immunity decision that "specifically instructed" public officials "in no uncertain terms" that they could no longer conduct warrantless student interviews. 563 U.S. at 700, 707. Even though the lower court had absolved the officers of liability in that proceeding, its warrant-requirement holding was reviewable. Otherwise, a defendant must "either acquiesce in a ruling he had no opportunity to contest in this Court," or "defy the views of the lower court, adhere to practices that have been declared illegal, and thus invite new suits." *Id.* at 708 (quoting *Pearson* v. *Callahan,* 555 U.S. 223, 240-41 (2009)). Baptist is similarly situated: acquiescence would mean changing hospital operations, shrinking PSO participation, and limiting the candor and frequency of post-incident analyses, while defiance would invite immediate challenge under the unreviewed decision below.

Respondents, too, have an ongoing "interest in preserving the judgment" below. Along with other Floridians, they will receive the "ongoing protection" of Amendment 7 "[o]nly if th[at] ruling remains good law." *Camreta*, 563 U.S. at 703. The Florida Constitution's disclosure right broadly establishes that "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." Fla. Const., art. X, § 25(a). This right is not limited to medical-malpractice plaintiffs, but applies to *any* "individual who has sought, is seeking, is undergoing, or has undergone care or treatment in a health care facility or by a health care provider." *Id.* § 25(c)(2). Thus, Respondents could now demand the same documents they sought during the underlying litigation.

There is little reason to suspect Respondents—who presently can depend on the "ongoing protection" of Amendment 7—will refuse to defend the judgment below. *Camreta*, 563 U.S. at 703. And even if they did, the conflict between federal and state rights would persist—implicating the State of Florida's own interest in defending the constitutionality of its laws. Of course, should Respondents decline to defend the judgment, the Court can invite the Florida Attorney General or other counsel to do so.

At a minimum, this Court should vacate the judgment below. "[V]acatur 'clears the path for future relitigation'" when a civil case becomes moot before this Court can review it. *U.S. Bancorp Mortg. Co.* v. *Bonner Mall P'ship*, 513 U.S. 18, 22 (1994) (quoting *United States* v. *Munsingwear, Inc.*, 340 U.S. 36, 40 (1950)). The remedy "prevent[s] an unreviewable decision 'from spawning any legal consequences,' so that no party is harmed by … a 'preliminary' adjudication."

Camreta, 563 U.S. at 713 (quoting *Munsingwear*, 340 U.S. at 40-41). Those considerations militate in favor of vacatur here, with a binding but potentially unreviewable decision threatening to control Baptist's conduct and undermine a federal program.

The vacatur "determination is an equitable one," even if the circumstances hindering review flow from the parties' own conduct. *Bonner Mall*, 513 U.S. at 29 (recognizing vacatur may be appropriate despite the parties' settlement). While a settlement ordinarily will prevent this Court's review, see *id.*, the situation facing Baptist is not ordinary: the parties' settlement *preceded* the Florida Supreme Court's decision that controls Baptist's future conduct and restricts its federal rights. These unusual circumstances warrant vacatur of the state court's judgment interpreting federal law. See, *e.g.*, *Lake Coal Co.* v. *Roberts & Schaefer Co.*, 474 U.S. 120 (1985) (per curiam); *DeFunis* v. *Odegaard*, 416 U.S. 312 (1974) (per curiam).

CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be granted.

Respectfully submitted,

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May 31, 2017

APPENDIX

APPENDIX A

SUPREME COURT OF FLORIDA

No. SC15-2180

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

Appellants,

v.

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

Appellees.

An Appeal from the District Court of Appeal—Statutory or Constitutional Invalidity, First District—Case No. 1D15-109, (Duval County)

January 31, 2017

OPINION

PARIENTE, J.

The important constitutional issue at the heart of this dispute is whether the records that patients in this State have a right to access under article X, section 25, of the Florida Constitution ("Amendment 7"), specifically records relating to "adverse medical incidents," are privileged and confidential under the Federal Patient Safety and Quality Improvement Act ("the Federal Act"),[1] such that Amendment 7 has been

[1] 42 U.S.C. § 299b-22 (2005).

preempted by federal law. The First District Court of Appeal, in *Southern Baptist Hospital of Florida, Inc. v. Charles*, 178 So.3d 102 (Fla. 1st DCA 2015), concluded that adverse medical incident reports requested by the Appellants pursuant to Amendment 7 in the Appellants' medical malpractice action constituted privileged and confidential "patient safety work product," pursuant to the Federal Act and that the Federal Act preempted Amendment 7. *Id*. at 108-10. We accepted this appeal under our mandatory jurisdiction of appeals from a decision of a district court of appeal "declaring invalid a state statute or a provision of the state constitution." *See* art. V, § 3(b)(1), Fla. Const.[2]

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[2] After briefing in this case was complete and the day before Oral Argument, the parties filed a stipulation of dismissal, which we rejected because this case not only involves an issue of statewide importance, but also involves a decision of the First District holding that article X, section 25, of the Florida Constitution has been preempted by federal law and is therefore invalid. Absent an opinion from this Court, all trial courts in this State would be bound by the opinion of the First District, until there is a contrary decision from the appellate court in their own district. *See Pardo v. State*, 596 So.2d 665, 667 (Fla. 1992). Our decision not to accept the stipulation of dismissal in this case is even more compelling when not only has briefing been completed, but when the stipulation was also filed on the eve of Oral Argument and the briefing includes several amici on both sides of the controversy who have important interests in the outcome of this case. *See Pino v. Bank of N.Y.*, 76 So.3d 927, 927 (Fla. 2011) ("It cannot be questioned that our well-established precedent authorizes this Court to exercise its discretion to deny the requested dismissal of a review proceeding, even where both parties to the action agree to the dismissal in light of an agreed-upon settlement."); *see also State v. Schopp*, 653 So.2d 1016, 1018 (Fla. 1995) ("Even where a notice of voluntary dismissal is timely filed, a reviewing court has discretion to retain jurisdiction and proceed with the appeal."); *Holly v. Auld*, 450 So.2d 217, 218 n.1 (Fla. 1984) ("It is well settled that mootness does not destroy an

We disagree with the First District both as to its statutory interpretation of the Federal Act and its resulting conclusion on preemption. We hold that the Federal Act was never intended as a shield to the production of documents required by Amendment 7 and other provisions of Florida law, and Amendment 7 and other provisions of Florida law are not preempted by the Federal Act, which set up a voluntary system for hospitals to improve patient safety. Moreover, the health care provider or facility, in this case Southern Baptist Hospital of Florida ('Southern Baptist"), cannot shield documents not privileged under state law or the state constitution by virtue of its unilateral decision of where to place the documents under the voluntary reporting system created by the Federal Act. Accordingly, we reverse the decision of the First District.

BACKGROUND

Article X, section 25, of the Florida Constitution, which is generally referred to by its ballot designation, Amendment 7, was proposed by citizen initiative and adopted in 2004. It provides 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. "Adverse medical incident" is defined broadly to include "any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient . . . ." Art. X, § 25(c)(3), Fla. Const. Amendment 7 gives patients, including those who become medical malpractice plaintiffs, access to any adverse medical

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appellate court's jurisdiction . . . when the questions raised are of great public importance or are likely to recur.").

incident record, including incidents involving other patients, sometimes called occurrence reports, created by health care providers.

As this Court discussed in *Florida Hospital Waterman, Inc. v. Buster*, 984 So.2d 478 (Fla. 2008), the purpose of Amendment 7 "was to do away with the legislative restrictions on a Florida patient's access to a medical provider's 'history of acts, neglects, or defaults' because such history 'may be important to a patient.'" *Id*. at 488 (quoting *Advisory Op. to the Att'y Gen. re Patients' Right to Know About Adverse Med. Incidents*, 880 So.2d 617, 618 (Fla. 2004)).[3]

As the First District stated:

> In 2005, Congress . . . [passed] the Patient Safety and Quality Improvement Act of 2005 (the [Federal] Act), Pub. L. No. 109-41, 119 Stat. 424, codified at 42 U.S.C. § 299b-21 *et seq.*, . . . following a 1999 Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health System*, . . . estimat[ing] 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

[3] The Amendment's appearance in the November 2004 election came after decades of frustration because citizens could not access information they needed in order to make informed decisions about their health care. *Fla. Hosp. Waterman*, 984 So.2d at 480. Out of 7.2 million Florida voters, more than 5.8 million people (or over 80%) voted in favor of this state constitutional right. *See* Fla. Dep't of State, Division of Elections, *Patient's Right to Know About Adverse Medical Incidents*, http://dos.elections.myflorida.com/initiatives/initdetail.asp?account=35169 & seqnum=3 (last visited on Jan. 23, 2017).

> 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); H.R. Rep. No. 109-197, at 9 (2005). Through passage of the [Federal] Act, . . . 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). *See also* Patient Safety and Quality Improvement, 73 Fed. Reg. 8,112, 8,113 (proposed Feb. 12, 2008).

S. Baptist Hosp. of Fla., 178 So.3d at 105.

The Federal Act creates a voluntary, confidential, non-punitive system of data sharing of health care errors for the purpose of improving the quality of medical care and patient safety. The Federal Act envisions a system in which each participating health care provider or member establishes a patient safety evaluation system,[4] in which relevant information would be collected, managed, and analyzed. 42 U.S.C. § 299b-21(6). After the information is collected in the patient safety evaluation system, the provider forwards the information to its patient safety organization, which then collects and analyzes the data and provides feedback and recommendations to providers on ways to improve patient safety and quality of care. *See id.* § 299b-24; 73 Fed. Reg. at 70,733. Information reported to patient safety organizations is also shared with a central clearing house, the Network of Patient Safety Databases, which aggregates the data and

[4] The terms used throughout this opinion are sometimes referred to by other sources through the use of acronyms: PSES for "patient safety evaluation system," PSO for "patient safety organization," and PSWP for "patient safety work product." For clarity, we will refer to the terms by their full names and not the acronyms used by other courts.

makes it available to providers as an "evidence-based management resource." *See* 42 U.S.C. § 299b-23.

In order to encourage and incentivize participation, within the Federal Act Congress created a protected legal environment in which providers would be comfortable sharing data "both within and across state lines, without the threat that the information will be used against [them]." 73 Fed. Reg. at 70,732. Privilege and confidentiality protections attach to the shared information, termed "patient safety work product," "to encourage providers to share this information without fear of liability." *Id.*; *see* 42 U.S.C. § 299b-22(a)-(b). These protections are "the foundation to furthering the overall goal of the statute to develop a national system for analyzing and learning from patient safety events." 73 Fed. Reg. at 70,741.

The potential burden to providers of maintaining duplicate systems to separate federally protected patient safety work product from information required to fulfill state reporting obligations was addressed in the final rule documents from the Department of Health and Human Services. *See id*. at 70,742-43. The solution was to allow providers to collect all information in one patient safety evaluation system where the information remains protected unless and until the provider determines it must be removed from the patient safety evaluation system and reported to the State. *Id*. at 70,742; 42 C.F.R. § 3.20 (2009) (defining patient safety work product and providing that patient safety work product removed from a patient safety evaluation system is no longer protected).

Turning to this case, Southern Baptist participates in information sharing under the Federal Act and has established a patient safety evaluation system in

which it collects, manages, and analyzes such information for reporting to its patient safety organization—PSO Florida. Southern Baptist's employees enter information into the patient safety evaluation system. Southern Baptist collects and maintains reports, which it calls "occurrence reports," of events that are not consistent with the routine operations of the hospital or the routine care of a patient or that could result in an injury.

Jean Charles, Jr., initiated a medical malpractice action, as next friend and duly appointed guardian of his sister, Marie Charles, and her minor children. Charles claims that Marie Charles suffered a severe neurological injury due to Southern Baptist's negligence.

Discovery commenced in the litigation between Charles and Southern Baptist, and Charles filed three requests for production pursuant to Amendment 7. Charles requested documents: 1) related to adverse medical incidents in Southern Baptist's history, and 2) either related to any physician who worked for Southern Baptist or arising from care and treatment rendered by Southern Baptist during the three-year period preceding Marie Charles' care and treatment through the time when the discovery request was filed. Southern Baptist ultimately produced certain responsive documents, which included Code 15 Reports (required by section 395.0197(7), Florida Statutes (2014)), Annual Reports (required by section 395.0197(6), Florida Statutes (2014)), and two occurrence reports specific to Marie Charles that were extracted from Southern Baptist's patient safety evaluation system before they were reported to the patient safety organization. Southern Baptist claimed that certain other

documents, primarily occurrence reports, while potentially responsive because they were adverse incident reports, were not subject to production because they were privileged and confidential under the Federal Act as patient safety work product.

Charles moved to compel production of the documents that Southern Baptist refused to produce based on its claim of privilege under the Federal Act. In response to Southern Baptist's refusal, Charles argued that the Federal Act protects only documents created solely for the purpose of submission to a patient safety organization, and such information is not privileged and confidential if it was collected and maintained for another purpose or for dual purposes, or if the information is in any way related to a health care provider's obligation to comply with federal, state, or local laws or accrediting or licensing requirements. In a series of three orders, the circuit court agreed with Charles, finding that the adverse medical incident reports requested were not patient safety work product if they were collected or maintained for a purpose other than submission to a patient safety organization or for dual purposes. The circuit court held, "All reports of adverse medical incidents, as defined by Amendment 7, which are created, or maintained pursuant to any statutory, regulatory, licensing, or accreditation requirements are not protected from discovery under [the Federal Act.]" The circuit court found that Southern Baptist was entitled to a reasonable fee for production that Charles was to pay prior to production, and upon payment, Southern Baptist "shall produce . . . all records in its possession relating to adverse medical incidents during the time period set forth in [the] third request for production."

Southern Baptist then filed a petition for writ of certiorari in the First District, which was granted. *S. Baptist Hosp. of Fla.*, 178 So.3d at 104, 111. On the merits, after examining what it termed "the plain language" of the Federal Act, the First District concluded that "[t]he record here shows that the documents at issue clearly meet the definition of [patient safety work product] because they were placed into [Southern Baptist's patient safety evaluation] system where they remained pending submission to a [patient safety organization]." *Id*. at 108. The First District further concluded that "[t]he documents at issue also do not meet the [Federal] Act's definition of what is *not* [patient safety work product]. That is, they are not original patient records and were not collected, maintained, or developed separately from the [patient safety evaluation] system." *Id*. (emphasis in original). Accordingly, the First District concluded that "[b]ecause they meet the definition of [patient safety work product], the documents are entitled to the federal protection under the [Federal] Act." *Id*. at 108-09. In sum, the First District held that "[t]he plain language of the [Federal Act] is clear. A document is [patient safety work product] if it is placed into a [patient safety evaluation] system for reporting to a [patient safety organization] and does not exist outside of the [patient safety evaluation] system. The documents here meet that definition and should be regarded as [patient safety work product], which is privileged, confidential, and not discoverable." *Id*. at 110 (citations omitted).

The First District also held that under the Supremacy Clause of the United States Constitution, "the [Federal Act] expressly preempts any broad discovery right under Amendment 7 to documents meeting the definition of [patient safety work product,]" and "Amendment 7 is also impliedly preempted by the [Federal]

Act because compliance with both federal and state law would be impossible." *Id*. Thus, the First District held that Amendment 7 "has been preempted by the [Federal] Act." *Id*. This appeal followed.[5]

ANALYSIS

Because the First District concluded that the documents Charles requested were entitled to protection from discovery under the plain language of the Federal Act, we first examine the language of the Federal Act. We then determine whether the Federal Act expressly or impliedly preempts Amendment 7 and other provisions of Florida law, as the First District held.

Statutory Construction

Because this case involves an issue of statutory construction, our review is de novo. *W. Fla. Reg'l Med. Ctr., Inc. v. See*, 79 So.3d 1, 8 (Fla. 2012) ("Statutory and constitutional construction are questions of law subject to a de novo review."). "The object of statutory interpretation is to determine legislative intent." *Crews v. State*, 183 So.3d 329, 332 (Fla. 2015). "To discern legislative intent, this Court looks first to the plain and obvious meaning of the statute's text[.]" *W. Fla. Reg'l Med. Ctr., Inc.*, 79 So.3d at 9. "When the statute is clear and unambiguous, courts will not look behind the statute's plain language for legislative intent or resort to rules of statutory construction to ascertain

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[5] The Florida Consumer Action Network, the Association for the Advancement of Retired Persons, and the Florida Justice Association filed amicus briefs on behalf of the Appellants, and the Patient Safety Organization of Florida joined by the ECRI Institute PSO, the Alliance for Quality Improvement and Patient Safety, the Joint Commission, the American Medical Association joined by the Florida Medical Association and the Clarity PSO and others, filed amicus briefs in support of the Appellees.

intent." *Daniels v. Fla. Dept. of Health*, 898 So.2d 61, 64 (Fla. 2005).

However, we have also made clear that statutes cannot be read in isolation. "Every statute must be read as a whole with meaning ascribed to every portion and due regard given to the semantic and contextual interrelationship between its parts." *Fla. Dep't of Env. Pro. v. ContractPoint Fla. Parks, LLC*, 986 So.2d 1260, 1265 (Fla. 2008) (quoting *Fleischman v. Dep't of Prof'l Reg.*, 441 So.2d 1121, 1123 (Fla. 3d DCA 1983)). A "statute should be interpreted to give effect to every clause in it, and to accord meaning and harmony to all of its parts" and is not to be read in isolation, but in the context of the entire section. *Jones v. ETS of New Orleans, Inc.*, 793 So.2d 912, 914-15 (Fla. 2001) (quoting *Acosta v. Richter*, 671 So.2d 149, 153-54 (Fla. 1996)).

The Federal Act "creates a tightly crafted federal privilege for 'patient safety work product' actually reported to a 'patient safety organization.'" *Lee Med., Inc. v. Beecher*, 312 S.W.3d 515, 535 (Tenn. 2010) (footnotes omitted). "Such information is not subject to discovery in legal proceedings." *Rasor v. Nw. Hosp., LLC*, 239 Ariz. 546, 373 P.3d 563, 573 (App. 2016). "The Patient Safety Act 'announces a more general approval of the medical peer review process and more sweeping evidentiary protections for materials used therein.'" *Dep't of Fin. & Prof'l Regulation v. Walgreen Co.*, 361 Ill.Dec. 186, 970 N.E.2d 552, 557 (Ill. App. Ct. 2012) (quoting *KD ex rel. Dieffenbach v. United States*, 715 F.Supp.2d 587, 595 (D. Del. 2010)). Congress enacted the Federal Act "to encourage health care providers to voluntarily associate and communicate privileged patient safety work product . . . among themselves through in-house patient safety evaluation

systems . . . and with and through affiliated patient safety organizations[.]" *Tibbs v. Bunnell*, 448 S.W.3d 796, 800 (Ky. 2014).

The Federal Act defines the term "provider" in relevant part as an "entity licensed or otherwise authorized under State law to provide health care services, including . . . a hospital[.]" 42 U.S.C. § 299b-21(8)(A)(i). The Federal Act defines the term "patient safety evaluation system" as "the collection, management, or analysis of information for reporting to or by a patient safety organization." *Id*. § 299b-21(6). A "patient safety organization" is one certified by the Secretary of the Department of Health and Human Services whose "mission and primary activity . . . [is] to conduct activities that are to improve patient safety and the quality of health care delivery." *Id*. §§ 299b-21(4), 299b-24(a), (b)(1)(A). Patient safety organizations engage in a number of "patient safety activities," including "[t]he collection and analysis of patient safety work product." *Id*. § 299b-21(5)(B). The Federal Act defines patient safety work product as follows:

> (7) Patient safety work product
>
> (A) In general
>
> Except as provided in subparagraph (B), the term "patient safety work product" means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—
>
> (i) which—
>
> (I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

(II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or

(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

Id. § 299b-21(7). The Federal Act also excludes certain information from the definition of patient safety work product and addresses a provider's duties with respect to non-patient safety work product, as follows:

(B) Clarification

(i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.

(ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

(iii) *Nothing in this part shall be construed to limit—*

(I) *the discovery of or admissibility of information described in this subparagraph in*

a criminal, *civil*, or administrative *proceeding*;

(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

(III) *a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.*

Id. § 299b-21(7)(B) (emphasis added). After describing what constitutes patient safety work product and what does not, the Federal Act then explains that, in general, patient safety work product is privileged and confidential:

(a) Privilege

Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be privileged and shall not be—

(1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

(2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

. . .

(b) Confidentiality of patient safety work product

Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be confidential and shall not be disclosed.

Id. § 299b-22(a)-(b). Patient safety work product may only be disclosed under certain circumstances:

(c) Exceptions

Except as provided in subsection (g)(3) of this section—

(1) Exceptions from privilege and confidentiality Subsections (a) and (b) of this section shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(A) Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an in camera determination that such patient safety work product contains evidence of a criminal act and that such patient safety work product is material to the proceeding and not reasonably available from any other source.

(B) Disclosure of patient safety work product to the extent required to carry out subsection (f)(4)(A) of this section.

(C) Disclosure of identifiable patient safety work product if authorized by each provider identified in such work product.

(2) Exceptions from confidentiality Subsection (b) of this section shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(A) Disclosure of patient safety work product to carry out patient safety activities.

(B) Disclosure of nonidentifiable patient safety work product.

(C) Disclosure of patient safety work product to grantees, contractors, or other entities carrying out research, evaluation, or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research to the extent that disclosure of protected health information would be allowed for such purpose under the HIPAA confidentiality regulations.

(D) Disclosure by a provider to the Food and Drug Administration with respect to a product or activity regulated by the Food and Drug Administration.

(E) Voluntary disclosure of patient safety work product by a provider to an accrediting body that accredits that provider.

(F) Disclosures that the Secretary may determine, by rule or other means, are necessary for business operations and are consistent with the goals of this part.

(G) Disclosure of patient safety work product to law enforcement authorities relating to the commission of a crime (or to an

event reasonably believed to be a crime) if the person making the disclosure believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

(H) With respect to a person other than a patient safety organization, the disclosure of patient safety work product that does not include materials that—

(i) assess the quality of care of an identifiable provider; or

(ii) describe or pertain to one or more actions or failures to act by an identifiable provider.

Id. § 299b-22(c). However, unless an "exception" exists under 42 U.S.C. § 299b-22(d)(2), "[p]atient safety work product that is disclosed under subsection (c) of this section shall continue to be privileged and confidential as provided for in subsections (a) and (b) of this section, and such disclosure shall not be treated as a waiver of privilege or confidentiality[.]" *Id*. § 299b-22(d)(1). Finally the Federal Act provides the following rules of construction:

(g) Rule of construction

Nothing in this section shall be construed—

(1) to limit the application of other Federal, State, or local laws that provide greater privilege or confidentiality protections than the privilege and confidentiality protections provided for in this section;

(2) *to limit, alter, or affect the requirements of Federal, State, or local law pertaining to*

information that is not privileged or confidential under this section;

(3) except as provided in subsection (i) of this section, to alter or affect the implementation of any provision of the HIPAA confidentiality regulations or section 1320d-5 of this title (or regulations promulgated under such section);

(4) to limit the authority of any provider, patient safety organization, or other entity to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with this section;

(5) *as preempting or otherwise affecting any State law requiring a provider to report information that is not patient safety work product*; or

(6) to limit, alter, or affect any requirement for reporting to the Food and Drug Administration information regarding the safety of a product or activity regulated by the Food and Drug Administration.

Id. § 299b-22(g) (emphasis added).

Charles asserts that the Federal Act expressly preserves and incorporates, rather than preempts, a provider's reporting and recordkeeping obligations under state law. *See id.* §§ 299b-21(7)(B)(iii)(II)-(III), 299b-22(g)(2)&(5). We agree.

Congress carved out broad exceptions to the Federal Act's definition of patient safety work product. For example, patient safety work product "does not include

a patient's medical record, billing and discharge information, or any other original patient or provider record." *Id.* § 299b-21(7)(B)(i). Significantly, patient safety work product also "does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product." *Id.* § 299b-21(7)(B)(ii). Moreover, the Federal Act clearly states that it should not be construed to "limit, alter, or affect the requirements of Federal, State, or local law pertaining to information that is not privileged or confidential under [the Federal Act]." *Id.* § 299b-22(g)(2).

Consistent with these provisions of the Federal Act, Florida has various statutes and rules, many of which pre-date the Federal Act, that require a health care provider to create and maintain adverse medical incident reports. *See* § 395.0197(4)-(7), Fla. Stat. (2015) (requiring risk program that includes adverse incident reports); *see also* Fla. Admin. Code r. 59A-10.0055 (establishing risk management system to report adverse incidents to the Florida Agency for Health Care Administration). Amendment 7 provides individuals the right to access "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. In other words, health care providers are required by state law to keep adverse medical incident reports, and the right of patients to access those adverse medical incident reports is enshrined in Florida's Constitution.

Despite the above, the First District concluded that "[t]he plain language of the [Federal] Act is clear. A

document is [patient safety work product] if it is placed into a [patient safety evaluation] system for reporting to a [patient safety organization] and does not exist outside of the [patient safety evaluation] system. The documents here meet that definition and should be regarded as [patient safety work product], which is privileged, confidential, and not discoverable." *S. Baptist Hosp. of Fla.*, 178 So.3d at 110. However, the First District's reading of the Federal Act was in error because it failed to consider the statute as a whole. There are numerous exceptions and limitations placed on the Federal Act. Though the Federal Act generally states that documents placed into a patient safety evaluation system that do not exist outside the system are privileged and confidential work product, it also makes clear that the provisions of the Federal Act shall not be construed to limit "the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding," or "a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law." 42 U.S.C. § 299b-21(7)(B)(iii).

Simply put, adverse medical incident reports are not patient safety work product because Florida statutes and administrative rules require providers to create and maintain these records and Amendment 7 provides patients with a constitutional right to access these records. Thus, they fall within the exception of information "collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system." *See id*. § 299b-21(7)(B)(ii). In addition, their disclosure fits squarely within the providers' recordkeeping obligations under state law. *Id*. § 299b-21(7)(B)(iii)

The Kentucky Supreme Court reached the same conclusion when deciding whether records required to be reported to the State by local laws were privileged and confidential patient safety work product in the case of *Baptist Health Richmond, Inc. v. Clouse*, 497 S.W.3d 759 (Ky. 2016). There, the Kentucky Supreme Court stated:

> [A] provider who participates in the [Federal] Act may collect information within its patient safety evaluation system that complies with the [Federal] Act and that also complies with state statutory and regulatory requirements. However, doing so does not relieve the provider from complying with those state requirements and, to the extent information collected in the provider's internal patient safety evaluation system is needed to comply with those state requirements, it is not privileged.
>
> . . . .
>
> The information that is usually contained in state-mandated reports is not protected by the patient safety work product privilege provided in the [Federal] Act and will be discoverable.

Id. at 766.

In conclusion, the records do not become patient safety work product simply because they were placed in a patient safety evaluation system or submitted to a patient safety organization because providers have an independent obligation under Florida law to create and maintain them, and Amendment 7 provides patients with a constitutional right to access them. *See* 42 U.S.C. § 299b-21(7)(B)(ii). Consequently, adverse medical incident reports produced in conformity with state law and requested by patients under Amendment 7

cannot be classified as confidential and privileged patient safety work product under the Federal Act.

Preemption

The next issue addressed is whether Amendment 7 and other Florida statutes are preempted by the Federal Act. This Court's review is de novo. *W. Fla. Reg'l Med. Ctr.*, 79 So.3d at 8. "Under the Supremacy Clause of the U.S. Constitution, a federal law may preempt state law." *Id*. at 15. "Preemption occurs when Congress intentionally enacts legislation that is intended to supersede state law on the same subject." *Id*. The United States Supreme Court has recognized three forms of preemption: express preemption, implied field preemption, and implied conflict preemption. *Id*. "Express preemption exists where a federal statute explicitly preempts state law." *Id*.

"The ultimate touchstone in every preemption case is the purpose of Congress." *Id*. at 16. This Court "begin[s] with a presumption against preemption, unless preemption has been expressed in the clear and manifest purpose of Congress." *Id*. When express preemption exists, courts "focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." *Chamber of Commerce of U.S. v. Whiting*, 563 U.S. 582, 594, 131 S.Ct. 1968, 179 L.Ed.2d 1031 (2011) (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664, 113 S.Ct. 1732, 123 L.Ed.2d 387 (1993)). But even when "a federal law contains an express pre-emption clause, it does not immediately end the inquiry because the question of the substance and scope of Congress' displacement of state law still remains." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76, 129 S.Ct. 538, 172 L.Ed.2d 398 (2008).

Moreover, for nearly seventy years, the United States Supreme Court has applied the "assumption" that States' historic police powers "were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947). Because States have historically regulated health and welfare, the Federal Act cannot preempt Florida's constitutional amendment and laws related to the disclosure of adverse medical incidents in the absence of Congress' clear intent to do so. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) ("In all pre-emption cases, and particularly in those in which Congress has legislated . . . in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." (internal citations and quotation omitted)); *see* U.S. Const. amend. X.

First we address whether the Federal Act preempts Amendment 7 through express preemption. To that end, the First District stated:

> As to express preemption, the Act specifically provides, "Notwithstanding any other provision of Federal, State, or local law . . . [patient safety work product] shall be privileged," and goes on to state that [patient safety work product] is not subject to disclosure in various ways including discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, among other ways. 42 U.S.C. § 299b-22. The Act also mandates a civil monetary penalty for improper disclosure of [patient safety work

> product]. 42 U.S.C. § 299b-22(f)(1). Thus, the Act expressly preempts any broad discovery right under Amendment 7 to documents meeting the definition of [patient safety work product].

S. Baptist Hosp. of Fla., 178 So.3d at 110. It is clear that the First District based its conclusion on an erroneous interpretation of the definition of patient safety work product. As stated above, the documents to which citizens have a right to access pursuant to Amendment 7 are not patient safety work product under the Federal Act's definition. Accordingly, the Federal Act does not contain any express statement of preemption relating to Amendment 7.

However, in its opinion, the First District went on to state: "Amendment 7 is also impliedly preempted by the [Federal] Act because compliance with both federal and state law would be impossible[,]" and "we find [that Amendment 7] has been preempted by the [Federal] Act." *Id*. This conclusion is also based on the First District's erroneous interpretation of the statute, as described above.

Absent an express statement of preemption, preemption may still be implied if a state law "interferes with the methods by which the federal statute was designed to reach [its] goal." *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494, 107 S.Ct. 805, 93 L.Ed.2d 883 (1987). To this end, the United States Supreme Court has stated:

> We begin the analysis by noting that it is not necessary for a federal statute to provide explicitly that particular state laws are pre-empted. *Hillsborough [Cty.] v. Automated Medical [Labs.], Inc.*, 471 U.S. 707, 713, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985). Although courts should not lightly

> infer pre-emption, it may be presumed when the federal legislation is "sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation." [*Id*. at 713, 105 S.Ct. 2371] (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)). In addition to express or implied pre-emption, a state law also is invalid to the extent that it "actually conflicts with a . . . federal statute." *Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 158, 98 S.Ct. 988, 55 L.Ed.2d 179 (1978). Such a conflict will be found when the state law "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" [*Hillsborough Cty.*,] 471 U.S. at 713, 105 S.Ct. 2371 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S.Ct. 399, 85 L.Ed. 581 (1941)).

Ouellette, 479 U.S. at 491-92, 107 S.Ct. 805 (footnotes omitted).

Amendment 7, which was enacted before the Federal Act, gives patients a constitutional right to broad access to adverse medical incident records. Art. X, § 25(a), Fla. Const. This citizen-initiated constitutional amendment provides critical information for injured parties who have filed a medical malpractice suit as a result of negligent care, and it also allows individuals to make informed decisions when choosing future health care providers. Thus, this area of regulation is directly within the states' traditional role of regulating the health, safety, and welfare of its citizens. *See* U.S. Const. amend. X.

It is antithetical to the idea of preemption, which requires a clear expression of Congressional intent, that the Federal Act, which permits, but does not require provider participation, would preempt a state

constitutional amendment. In the context of the Federal Act's scheme allowing for voluntary participation, it is clear that a mandatory disclosure law in our state constitution is not preempted by a health care provider's *choice* to participate in the Federal Act, coupled with its choice to place documents into a patient safety evaluation system.

The legislative history of the Federal Act reveals that Congress did not intend to strip citizens of their pre-existing state right to information through the passage of the act. The House Report on the Federal Act highlights this fact in describing how documents that were created and maintained separately from a patient safety evaluation system would not become patient safety work product and confidential simply because a health care provider, in its discretion, decided to send those documents to a patient safety organization:

> [T]here may be documents or communications that are part of traditional health care operations or record keeping (including but not limited to . . . primary information at the time of events). Such information may be in communications or copies of documents sent to a patient safety organization. Originals or copies of such documents are both original provider records and separate information that is developed, collected, maintained or exist separately from any patient safety evaluation system. Both these original documents and ordinary information about health care operations may be relevant to a patient safety evaluation system but are not themselves patient safety work product.

H.R. Rep. No. 109-197, 14 (2005).

Several Senators also echoed that Congress never intended to take away patients' rights to hold negligent providers accountable. For example, Senator Ted Kennedy conveyed Congress' intent that the Federal Act should not be used to protect providers who have harmed patients:

> The legislation also creates a legal privilege for information reported to the safety organizations, but still guaranteeing that original records, such as patients' charts will remain accessible to patients.
>
> Drawing the boundaries of this privilege requires a careful balance, and I believe the legislation has found that balance. The bill is intended to make medical professionals feel secure in reporting errors without fear of punishment, and it is right to do so. But the bill tries to do so carefully, so that it does not accidentally shield persons who have negligently or intentionally caused harm to patients. The legislation also upholds existing state laws on reporting patient safety information.

151 Cong. Rec. S8713-02 (daily ed. July 21, 2005) (statement of Sen. Kennedy)

In a recent report, the Department of Health and Human Services explained that the Federal Act did not replace or destroy existing state laws and requirements:

> The Patient Safety Act 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 as well as voluntary reporting

> activities that occur for the purpose of maintaining accountability in the health care system.

73 Fed. Reg. at 70,742.

Recently, the Department of Health and Human Services further explained in a guidance document:

> As such, the Patient Safety Act recognizes the goal of accountability and transparency, and it attempts to balance this goal with that of improving patient safety and reducing medical errors. While Congress was aware of the chilling effect the fear of being sued had on providers, the Patient Safety Act was not designed to prevent patients who believed they were harmed from obtaining the records about their care that they were able to obtain prior to the enactment of the Patient Safety Act. Nor was the Patient Safety Act intended to insulate providers from demonstrating accountability through fulfilling their external obligations. Therefore, when interpreting the Patient Safety Act and Patient Safety Rule, [the Department of Health and Human Services] does so with the objective of maintaining balance between these two policy goals, consistent with the intent of the Patient Safety Act.

Patient Safety and Quality Improvement Act of 2005—HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations, 81 Fed. Reg. 32,655, 32,655-56 (May 24, 2016) (footnotes omitted).

Clearly, Congress did not intend to deprive Florida citizens of such an important constitutional measure. Rather, a review of the plain meaning of the Federal Act, coupled with the statements of Congress and the Department of Health and Human Services, which is

in charge of implementing the Federal Act, in light of Florida's Amendment 7, shows that the two systems can coexist harmoniously. Both support the ultimate congressional goal of improving this country's health care system, albeit through different means. One does not necessarily make the other unworkable. Indeed, if the First District's view were to become law, then medical providers would be free to determine for themselves what information was available in litigation through their own strategic use of the benefits in the Federal Act by placing all of their reports, regardless of any other state requirements, in the patient safety evaluation system and therefore making them confidential patient safety work product. Allowing such action would be antithetical not only to the purpose of Amendment 7, but also to the Congressional purpose of improving the health care system.

Moreover, the First District's opinion reflects a view that somehow the Federal Act is inconsistent with medical malpractice actions and that often medical malpractice actions are punitive, stating:

> Amendment 7 has become an important discovery tool for medical malpractice plaintiffs as it gives broad access to adverse medical incident records from medical providers. Amendment 7 provides a means, albeit often a punitive one, to improve the quality of healthcare by bringing medical errors to light.
>
> While medical malpractice litigation is one tool to address medical errors, other tools have emerged that seek to proactively prevent, rather than punish, medical errors.

S. Baptist Hosp. of Fla., 178 So.3d at 105. We reject the two premises of the First District's opinion. First,

the primary purpose of medical malpractice actions is not to punish the health care provider, but to compensate the victim of medical malpractice who is many times severely injured. Second, the creation of a Federal Act to provide a voluntary system for health care providers is not at all inconsistent with Amendment 7 or Florida law, and medical malpractice actions can and should coexist with the Federal Act. The Department of Health and Human Services explained how providers have been attempting to use the confidentiality and privilege provisions in the Federal Act to their advantage:

> First, some providers with recordkeeping or record maintenance requirements appear to be maintaining the required records only in their [patient safety evaluation system] and then refusing to disclose the records, asserting that the records in their [patient safety evaluation system] fulfill the applicable regulatory requirements while at the same time maintaining that the records are privileged and confidential [patient safety work product]. Second, some providers appear to develop records to meet external obligations outside of the [patient safety evaluation system], place a duplicate copy of the required record into the [patient safety evaluation system], then destroy the original outside of the [patient safety evaluation system] and refuse to disclose the remaining copy of the information, asserting that the copy is confidential and privileged [patient safety work product]. The Patient Safety Act was not intended to give providers such methods to evade their regulatory obligations.

81 Fed. Reg. 32,655-01, 32,657-58.

This Case

The documents at issue in this case were primarily adverse medical incident reports requested by Charles. Southern Baptist acknowledged that some of its occurrence reports would have been discoverable pursuant to that request, but for the Federal Act. The documents were placed in Southern Baptist's patient safety evaluation system, likely by an employee of the hospital. However, they were never submitted to the patient safety organization by Southern Baptist. Under this Court's interpretation of the Federal Act, the reports are not privileged and confidential patient safety work product because Florida statutes and administrative rules require providers to create and maintain them, and thus, they were not created solely for the purpose of submission to a patient safety evaluation system. *See* § 395.0197(4)-(7), Fla. Stat. (2015) (requiring risk management program that includes adverse incident reports); *see also* Fla. Admin. Code r. 59A-10.0055. The records fall squarely within the exception of information "collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system." *See* 42 U.S.C. § 299b-21(7)(B)(ii). Thus, the trial court was correct to conclude that the documents in this case were discoverable pursuant to Amendment 7. Accordingly, we reject the First District's conclusion that "the documents at issue clearly meet the definition of [patient safety work product] because they were placed into Baptist's [patient safety evaluation] system where they remained pending submission to a [patient safety organization]." *S. Baptist Hosp. of Fla.*, 178 So.3d at 108.

CONCLUSION

In conclusion, we hold that Congress did not intend to preempt state laws or Amendment 7 through the passage of the Federal Act creating a voluntary reporting system. Rather, the clear intent of the Federal Act, as set forth in the actual language of the Federal Act, was for the voluntary reporting system to function harmoniously within existing state reporting and discovery laws. The Federal Act was intended by Congress to improve the overall health care in this system, not to act as a shield to providers, thereby dismantling an important right afforded to Florida citizens through Amendment 7. Moreover, health care providers should not be able to unilaterally decide which documents will be discoverable and which will not in medical malpractice cases. Accordingly, we reverse the decision of the First District below.

It is so ordered.

LABARGA, C.J., and LEWIS, and QUINCE, JJ., and PERRY, Senior Justice, concur.

CANADY, J., dissents with an opinion, in which POLSTON, J., concurs.

CANADY, J., dissenting.

I dissent from the majority's disapproval of the stipulation for dismissal. The parties are entitled to a dismissal because they filed a stipulation for dismissal under Florida Rule of Appellate Procedure 9.350(a) before this Court issued a decision on the merits. I adhere to my view that a stipulation for dismissal filed under rule 9.350(a) before a decision on the merits is not subject to disapproval:

> Florida Rule of Appellate Procedure 9.350(a) provides that "[w]hen any cause pending in the court is settled before a decision on the merits, the parties shall immediately notify the court by filing a signed stipulation for dismissal." The rule does not appear to contemplate that such a stipulation for dismissal is subject to disapproval by the Court. The very designation "stipulation for dismissal"—as opposed to "motion for dismissal"—suggests that the act of the parties is dispositive. The committee note to the rule recognizes that dismissal of the case is the clerk's ministerial duty: "On the filing of a stipulation of dismissal, the clerk of the court will dismiss the case as to the parties signing the stipulation."

Pino v. Bank of New York, 76 So.3d 927, 931 (Fla. 2011) (Canady, C.J., dissenting) (alteration in original).

The decision of the majority here, which can have no impact on this settled case, is a purely advisory opinion. Our job is to decide live controversies presented by the parties to a case that is before us. It is not to opine on the issues in a case that has been settled and that the parties have agreed should be dismissed.

POLSTON, J., concurs.

APPENDIX B

DISTRICT COURT OF APPEAL OF FLORIDA,
FIRST DISTRICT

No. 1D15-0109

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC.,

Petitioner,

v.

JEAN CHARLES, JR., AS NEXT FRIEND AND DULY APPOINTED GUARDIAN OF HIS SISTER, MARIE CHARLES, AND HER CHILDREN, ANGEL ALSTON AND JAZMIN HOUSTON, MINORS, AND ERVIN ALSTON; KRISTIN FERNANDEZ, D.O.; YUVAL Z. NAOT, M.D.; SAFEER A. ASHRAF, M.D.; INTEGRATED COMMUNITY ONCOLOGY NETWORK, LLC; ANDREW NAMEN, M.D.; GREGORY J. SENGSTOCK, M.D.; JOHN D. PENNINGTON, M.D.; AND EUGENE R. BEBEAU, M.D.; AND ROBERT E. ROSEMUND, M.D.,

Respondents.

Oct. 28, 2015.
As Corrected Oct. 29, 2015.
Rehearing Denied Nov. 24, 2015.

OPINION

ROBERTS, C.J.

This case concerns the intersection of Florida's Amendment 7, found in Article 10, section 25, of the Florida Constitution and the federal Patient Safety and Quality Improvement Act of 2005. The petitioner

seeks certiorari review of three discovery orders from the circuit court, arguing that the court erroneously compelled the production of documents that were privileged and confidential under federal law. We find the case ripe for review, grant the petition, and quash the orders below.

Background

Article 10, section 25, of the Florida Constitution, which is generally referred to by its ballot designation (Amendment 7), was proposed by citizen initiative and adopted in 2004. It provides "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. "Adverse medical incident" is defined broadly to include "any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient[.]" Art. X, § 25(c)(3), Fla. Const. Amendment 7 has become an important discovery tool for medical malpractice plaintiffs as it gives broad access to adverse medical incident records from medical providers. Amendment 7 provides a means, albeit often a punitive one, to improve the quality of healthcare by bringing medical errors to light.

While medical malpractice litigation is one tool to address medical errors, other tools have emerged that seek to proactively prevent, rather than punish, medical errors. In 2005, Congress took action to improve patient safety in the healthcare industry as a whole with the passage of the Patient Safety and Quality Improvement Act of 2005 (the Act), Pub.L. No. 109-41, 119 Stat. 424, codified at 42 U.S.C. § 299b-21 *et seq*. 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); 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). *See also* Patient Safety and Quality Improvement, 73 Fed.Reg. 8,112, 8,113 (proposed February 12, 2008).[1]

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); 73 Fed.Reg. at 70,749. The Act creates a voluntary, confidential, non-punitive system of data sharing of healthcare errors for the purpose of improving the quality of medical care and patient safety. The Act envisions that each participating provider or member would establish a patient safety evaluation system (PSE system) in which relevant information would be collected, managed, and analyzed. 42 U.S.C. § 299b-21(6). After the information is

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[1] The United States Department of Health and Human Services (HHS) adopted rules to implement the Act. On February 12, 2008, HHS published a Notice of Proposed Rulemaking. *See* 73 Fed.Reg. 8,112. After receiving substantial comment, the comment period closed on April 14, 2008. The Final Rule was published on November 21, 2008, and codified at 42 C.F.R., Part 3. *See* 73 Fed.Reg. 70,732-01.

collected in the PSE system, the provider would forward it to its patient safety organization (PSO), which serves to collect and analyze the data and provide feedback and recommendations to providers on ways to improve patient safety and quality of care. *See* 42 U.S.C. § 299b-24; 73 Fed.Reg. at 70,733. Information reported to PSOs would also be shared with a central clearing house, the Network of Patient Safety Databases, which aggregates the data and makes it available to providers as an "evidence-based management resource." *See* 42 U.S.C. § 299b-23.

In order to encourage and incentivize participation, a protected legal environment was created in which providers would be comfortable sharing data both within and across state lines "without the threat of information being used against [them]." *See* 73 Fed.Reg. at 70,732. Privilege and confidentiality protections attach to the shared information, termed "patient safety work product" (PSWP), "to encourage providers to share this information without fear of liability[.]" 73 Fed.Reg. at 70,732; 42 U.S.C. § 299b-22(a)-(b). The protections are "the foundation to furthering the overall goal of the statute to develop a national system for analyzing and learning from patient safety events." 73 Fed.Reg. at 70,741.

The potential burden to providers of maintaining duplicate systems to separate federally protected PSWP from information required to fulfill state reporting obligations was addressed in the final rule documents from HHS. *See* 73 Fed.Reg. at 70,742. The solution was to allow providers to collect all information in one PSE system where the information remains protected unless and until the provider determines it must be removed from the PSE system for reporting to the State. 73 Fed.Reg. at 70,742; 42 C.F.R. § 3.20(2)(ii)

(defining PSWP and providing that PSWP removed from a PSE system is no longer protected). The information becomes PSWP upon collection within a PSE system, but loses PSWP protection once the information is removed from the PSE system by the provider.

In this particular case, the petitioner hospital, Southern Baptist Hospital of Florida, Inc. (Baptist), participates in information sharing under the Act and has established a PSE system in which it collects, manages, and analyzes such information for reporting to its PSO—PSO Florida. The record shows that Baptist's employees are instructed to enter information into the PSE system with the assurance of confidentiality based upon the PSWP protections in the Act. Baptist collects and maintains reports, which it calls "occurrence reports," of events that are not consistent with the routine operations of the hospital or the routine care of a patient or that could result in an injury. Occurrence reports are collected regardless of whether an event might constitute an "adverse medical incident."

Facts

This case began as a medical malpractice action initiated by the respondents, Jean Charles, Jr., as next friend and duly appointed guardian of his sister, Marie Charles, and her minor children, Ervin Alston, Angel Alston, and Jazmin Houston (the respondents). The respondents claimed that Marie Charles suffered a catastrophic neurological injury due to Baptist's negligence.

Discovery commenced in the case, and the respondents filed three requests for production pursuant to Amendment 7 in which they requested documents that:

(1) related to adverse medical incidents and (2) either related to any physician who worked for Baptist or arose from care and treatment rendered by Baptist during the three-year period preceding Marie-[sic] Charles' care and treatment and through the date of the third request. Baptist ultimately produced certain responsive documents, which included Code 15 Reports (required by section 395.0197(7), Florida Statutes (2014)), Annual Reports (required by section 395.0197(6), Florida Statutes (2014)), and two occurrence reports specific to Marie Charles that had been extracted from Baptist's PSE system before they were reported the PSO. Baptist claimed that certain other documents, primarily occurrence reports, while potentially responsive, were not subject to production because they were privileged and confidential under the Act.

The respondents moved to compel production, arguing that the Act only protects documents created *solely* for the purpose of submission to a PSO and that information does not constitute PSWP if it was collected or maintained for another purpose or for dual purposes or if the information is "in any way related" to a healthcare provider's obligation to comply with federal, state, or local laws or accrediting or licensing requirements.

In a series of three orders, the circuit court agreed with the respondents, finding that information is not PSWP if it was collected or maintained for a purpose other than submission to a PSO or for "dual purposes." The circuit court found this was true even if the information was collected in a PSE system for submission to a PSO and did not exist outside of the PSE system. The circuit court held that "all reports of adverse medical incidents, as defined by Amendment 7, which are created, or maintained pursuant to any statutory, regulatory, licensing, or accreditation requirements

are not protected from discovery under [the Act]." The circuit court found that Baptist was entitled to a reasonable fee for production that was to be paid prior to production, and, upon payment, Baptist "shall produce to [the respondents] . . . all records in its possession relating to adverse medical incidents during the time periods set forth in [the respondents'] third request for production." The instant petition for writ of certiorari followed.

Jurisdiction

Certiorari is an extraordinary remedy, not to be used as a "piecemeal review of non-final trial court orders [that would] impede the orderly administration of justice and serve only to delay and harass." *Bd. of Tr. of the Int'l Improvement Trust Fund v. Am. Educ. Enters., LLC*, 99 So.3d 450, 454 (Fla.2012) (citations omitted). Orders granting discovery have traditionally been reviewed by certiorari because, once discovery is wrongfully granted, the complaining party is "beyond relief." *Martin-Johnson, Inc. v. Savage*, 509 So.2d 1097, 1099 (Fla.1987). "Orders requiring disclosure of material not subject to discovery by reason of privilege are commonly reviewed by certiorari petition because the harm caused by wrongly compelling the petitioner to disclose the protected material is irreparable." *SCI Funeral Srvs. of Fla., Inc. v. Walthour*, 165 So.3d 861, 863 (Fla. 1st DCA 2015) (citing *Barker v. Barker*, 909 So.2d 333, 336-37 (Fla. 2d DCA 2005)).

Certiorari review of an order compelling discovery is appropriate when the order departs from the essential requirements of law, causing irreparable harm that cannot be remedied on appeal. This Court must first conduct a jurisdictional analysis to determine whether the petitioner has made a prima facie showing of

irreparable harm. *See Poston v. Wiggins*, 112 So.3d 783, 785 (Fla. 1st DCA 2013) (citations omitted).

As an initial matter, we find that Baptist has made a sufficient showing of irreparable harm to invoke this Court's jurisdiction. Although judicial labor remains below, that labor is confined to a determination, if necessary, of the reasonableness of Baptist's fee for production. The circuit court has given no indication that it intends to otherwise revisit its rulings on the interaction between Amendment 7 and the Act. While there are still steps to be taken before the documents have to be produced, once those steps are taken, production is inevitable, and no further remedy would remain. The threshold irreparable harm has been shown. We now turn to the merits of the petition.

The Plain Language of the Act

The petitioner argues that the circuit court orders contradict the plain language of federal law and undermine the important federal policies that Congress intended to advance. Indeed, the plain language of the Act is our starting point and guidepost. *See Krause v. Textron Fin. Corp.*, 59 So.3d 1085, 1089 (Fla.2011). We need not resort to the rules of statutory interpretation and construction here because the Act is clear and unambiguous such that the language must be given its plain and obvious meaning. *Id.*

The Act clearly and unambiguously defines what is PSWP:

> (7) Patient safety work product
>
> (A) In general
>
> Except as provided in subparagraph (B), the term "patient safety work product" means any data, reports, records, memoranda, analyses

(such as root cause analyses), or written or oral statements—

(i) which—

(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

(II) are developed by a patient safety organization for the conduct of patient safety activities;

and which could result in improved patient safety, health care quality, or health care outcomes; or

(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

42 U.S.C. § 299b-21(7)(A).

The Act also specifically defines what type of information is *not* protected PSWP:

(i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.

(ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

42 U.S.C. § 299b-21(7)(B)(i)-(ii).

Finally, the Act makes clear that the definition of PSWP should not be construed to relieve a provider's duty to respond to federal, state, or local law obligations with information that is not privileged or confidential:

> (iii) Nothing in this part shall be construed to limit—
>
> (I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;
>
> (II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or
>
> (III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

42 U.S.C. § 299b-21(7)(B)(iii).

The record here shows that the documents at issue clearly meet the definition of PSWP because they were placed into Baptist's PSE system where they remained pending submission to a PSO. *See* 42 U.S.C. § 299b-21(7)(A). The documents at issue also do not meet the Act's definition of what is *not* PSWP. That is, they are not original patient records and were not collected, maintained, or developed separately from the PSE system. *See* 42 U.S.C. § 299b-21(7)(B)(i)-(ii). Because

they meet the definition of PSWP, the documents are entitled to the federal protection under the Act.

The circuit court and the respondents place a heavy focus on subpart (iii). The respondents argue that because some of the documents at issue may serve a "dual purpose," i.e., they may also be required under a state statute, rule, licensing provision, or accreditation requirement, PSWP status is removed, and the documents are stripped of any federal protection. The respondents primarily focus on the occurrence reports, which they claim are the same as the incident reports required to be prepared and maintained under section 395.0197, Florida Statutes (2014). They also argue that even if the incident/occurrence reports do not have to be physically produced to the State, Florida statutes and administrative code rules provide that the Agency for Healthcare Administration has access to these documents, which access effectively means the documents are "reported" under state law.

This argument and the circuit court's interpretation incorrectly impose additional terms into the definition of PSWP. Nowhere does the definition state that a document may not simultaneously be PSWP and also meet a state reporting requirement. HHS's rule guidance specifically addresses this scenario by assuring providers that they may place information into their PSE system with the expectation of protection and may later remove the information if the provider determines that it must be reported to the State. *See* 73 Fed.Reg. at 70,742. The circuit court's "dual purpose" language gives the false impression that federal protection under the Act and state compliance have to be mutually exclusive—they do not. Rather, the 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 non-compliance with state or federal reporting requirements. Notably, the respondents have not alleged that Baptist failed to comply with any reporting or recordkeeping requirements.

It could be suggested that the provider's unilateral, unreviewable decision as to what is placed in its PSE system could open the doors to "gamesmanship." That is, a provider could potentially dump everything into its PSE system, rendering it privileged and confidential, in an effort to thwart discovery. First, it is unlikely that this would occur as the Act clearly defines what can and what cannot constitute PSWP. Even if gamesmanship were to occur, the true issue to be corrected, as pointed out by the dissent in *Tibbs v. Bunnell,* would be the provider's failure to comply with state or federal reporting requirements. 448 S.W.3d 796, 809 (Ky.2014) (Abramson, J., dissenting). The remedy would not be for the trial court to "rummage through" the provider's PSE system, in plain contravention to the purpose of the Act, in search of documents that could possibly serve a "dual purpose." *See id*. at 815. Rather, the remedy would be to address the noncompliance of recordkeeping or reporting obligations itself, which, as pointed out by the dissent in *Tibbs,* could be remedied in the same manner as it could have been prior to the passage of the Act. *Id.* Again, the respondents have not alleged that Baptist has failed to comply with any reporting or recordkeeping requirements in the instant case. In fact, Baptist has already produced the Code 15 Reports and Annual Reports that are

required to be reported to the State under Florida law.[2]

The plain language of the Act is clear. A document is PSWP if it is placed into a PSE system for reporting to a PSO and does not exist outside of the PSE system. The documents here meet that definition and should be regarded as PSWP, which is privileged, confidential, and not discoverable. *Cf. Dep't of Fin. & Prof'l Reg. v. Walgreen Co.,* 361 Ill.Dec. 186, 970 N.E.2d 552 (2012) (interpreting the privilege under the Act as turning on whether documents were maintained outside of the PSE system). The fact that some documents may also satisfy state reporting or recordkeeping requirements is not the relevant inquiry. The provider is charged with complying with state requirements, and, absent an allegation that the provider has failed to comply, the circuit court should not be involved in the provider's participation under the Act.

Federal Preemption

Under the Supremacy Clause, the Constitution and federal laws are the "supreme Law of the Land." Art. VI, cl. 2, U.S. Const. The United States Supreme Court has recognized three categories of preemption, two of which are relevant here: (1) express preemption where a federal statute contains explicit preemptive language and (2) implied conflict preemption where it would be impossible to comply with both the federal and state regulations. *See State v. Harden*, 938 So.2d 480, 486 (Fla.2006) (citation omitted). As to express preemption, the Act specifically provides, "Notwithstanding any other provision of Federal, State, or local

[2] At oral argument, Baptist did not dispute that the Code 15 Reports and Annual Reports were subject to production as they were not housed within Baptist's PSE system.

law . . . [PSWP] shall be privileged," and goes on to state that PSWP is not subject to disclosure in various ways including discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, among other ways. 42 U.S.C. § 299b-22. The Act also mandates a civil monetary penalty for improper disclosure of PSWP. 42 U.S.C. § 299b-22(f)(1). Thus, the Act expressly preempts any broad discovery right under Amendment 7 to documents meeting the definition of PSWP.

In addition to express preemption, Amendment 7 is also impliedly preempted by the Act because compliance with both federal and state law would be impossible. That is, documents that meet the definition of PSWP under the Act are categorically protected and excluded from production. To produce PSWP in response to an Amendment 7 discovery request would be in contravention to the Act.

Conclusion

The plain language of the Act is clear. The dispositive question that should have been asked below is whether or not the documents met the definition of PSWP in the Act. The record showed that the documents met this definition and were, thus, protected from disclosure. The circuit court's heavy focus on state reporting and recordkeeping requirements erroneously placed state law above federal law. Absent an allegation that Baptist was in some way not complying with its reporting or recordkeeping requirements, there was no need for the court to consider whether the documents at issue simultaneously satisfied any state law obligations. The language in subpart (iii) is cautionary to the provider's decision on how to create and maintain its records. While Amendment 7 can provide a litigant with broad access to records relating

to "adverse medical incidents," we find it has been preempted by the Act. The respondents' interpretation of the Act would render it a "dead letter" and is contrary to Congress's intent to cultivate a culture of safety to improve and better the healthcare community as a whole. Accordingly, we grant the petition and quash the orders on review.

GRANTED.

THOMAS and RAY, JJ., concur.

APPENDIX C

IN THE CIRCUIT COURT,
FOURTH JUDICIAL CIRCUIT,
IN AND FOR DUVAL COUNTY, FLORIDA

[Filed: 12/09/2014]

Case No.: 16-2012-CA-2677
Division: CV-H

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 ERVIN ALSTON,

Plaintiffs,

vs.

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC. d/b/a BAPTIST MEDICAL CENTER-SOUTH and BAPTIST MEDICAL CENTER-DOWNTOWN, KRISTIN FERNANDEZ, D.O., Gynecologist, YUVAL Z. NAOT, M.D., Hematologist/Oncologist, SAFEER A. ASHRAF, M.D., Hematologist/ Oncologist, INTEGRATED COMMUNITY ONCOLOGY NETWORK, LLC., a Florida limited liability corporation, ANDREW NAMEN, M.D., Pulmonologist, GREGORY J. SENGSTOCK, M.D., Neurologist, JOHN D. PENNINGTON, M.D., Internist, EUGENE R. BEBEAU, M.D., Anesthesiologist, and ROBERT E. ROSEMUND, M.D., Family Practitioner,

Defendants.

ORDER ON BREADTH, SCOPE, TIMING AND COST OF PRODUCTION OF AMENDMENT 7 DOCUMENTS

This action came before this Court August 25, 2014, for a hearing on the Motion for Clarification or Reconsideration and Emergency Motion to Vacate Order Pending Clarification or Reconsideration filed by Defendant Southern Baptist Hospital of Florida, Inc., doing business as Baptist Medical Center-South and Baptist Medical Center-Downtown ("Baptist"). On August 28, 2014, this Court entered its Amended Order on Plaintiffs' Motion to Compel the Production of Amendment 7 Documents. In that Amended Order, this Court informed that a subsequent order would address the breadth and scope of the Amendment 7 documents to be produced, the timing of production, and Baptist's demand for reimbursement of costs of identifying and producing the Amendment 7 documents. This is that order.

1. Article X, Section 25 of the Constitution of the State of Florida ("Amendment 7") provides that, "[i]n addition to any other similar rights provided herein or by general law, 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." Art. X, § 25(a), Fla. Const.

> The phrase "adverse medical incident" means medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient, including, but not limited to, those incidents that are reported to or reviewed by any health care facility peer review, risk management, quality assurance, credential, or similar committee, or any representative of any such committees.

Art. X, § 25(c)(3), Fla. Const. Plaintiffs argue that the constitution's definition of "adverse medical incident"

makes all reports submitted to Baptist's risk management department reports of adverse medical incidents, without regard to the subject matter of the report, and that, therefore, they are entitled to have access to all of that information. This Court disagrees. Under the plain meaning of the above-quoted language, "including, but not limited to, *those* incidents that are reported" refers to the incidents described in the preceding words of the definition, i.e., incidents of "medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient . . . ." Were the intended meaning the one urged by Plaintiffs, it might have read, "including, but not limited to, *any* incidents that are reported . . . ."

2. Even were this Court to find the definition of adverse medical incident ambiguous, it would interpret it the same way. The constitution is to be interpreted by application of "principles parallel to those of statutory interpretation." *Advisory Opinion to Att'y Gen. Re Use of Med. Marijuana for Certain Med. Conditions*, 132 So. 3d 786, 799 (Fla. 2014)(internal quotation marks omitted). The well-recognized principle of statutory interpretation, *ejusdem generis*, instructs that "where general words or phrases follow an enumeration of specific words or phrases, 'the general words are construed as applying to the same kind or class as those that are specifically mentioned.'" *Id*. at 801 (citation omitted). Applying that principle, this Court concludes that records of "incidents that are reported to or reviewed by" the listed committees are accessible under Amendment 7 only to the extent that they are records of adverse medical incidents. In short, "Amendment 7 does not require production of . . . documents that do not contain information about particular adverse medical incidents." *Morton Plant*

Hosp. Ass'n, Inc. v. Shahbas, 960 So. 2d 820, 827 (Fla. 2d DCA 2007).

3. Under Amendment 7,

> [t]he phrase "have access to any records" means, in addition to any other procedure for producing such records provided by general law, making the records available for inspection and copying upon formal or informal request by the patient or a representative of the patient, provided that current records which have been made publicly available by publication or on the Internet may be "provided" by reference to the location at which the records are publicly available.

Art. X, § 25(c)(4), Fla. Const. Section 381.028(7)(c)1., Florida Statutes, provides:

> Fees charged by a health care facility for copies of records requested by a patient under s. 25, Art. X of the State Constitution may not exceed the reasonable and actual cost of complying with the request, including a reasonable charge for the staff time necessary to search for records and prevent the disclosure of the identity of any patient involved in the adverse medical incident through redaction or other means as required by the Health Insurance Portability and Accountability Act of 1996 or its implementing regulations. The health care facility may require payment, in full or in part, before acting on the records request.

§ 381.028(7)(c)1., Fla. Stat. (2012). Plaintiffs argue that the statute is a general law providing "[an]other procedure for producing" Amendment 7 records and that they are proceeding, not under the statute, but under Amendment 7 itself. Therefore, they assert that

they are entitled to production of Amendment 7 documents without cost. However, section 381.028, Florida Statutes, does not provide a procedure for producing Amendment 7 documents in addition to, or separate from, the constitution (it certainly was not a general law in existence at the time Amendment 7 passed, *see* Ch. 2005-265, § 1, Laws of Fla., creating section 381.028, Florida Statutes); rather, it implements Amendment 7. *Fla. Hosp. Waterman, Inc. v. Buster*, 984 So. 2d 478, 492 (Fla. 2008). Subsection 381.028(7)(c)1., specifically, has withstood constitutional challenge as a valid implementation of Amendment 7. *Buster*, 984 So. 2d at 493; *see also W. Fla. Reg'l Hosp. v. See*, 79 So. 3d 1, 14 (Fla. 2012)(recognizing that *Buster* upheld section 381.028(7)(c)); *see also Columbia Hosp. Corp. of S. Broward v. Fain*, 16 So. 3d 236, 241 (Fla. 4th DCA 2009)(same). Therefore, the implementing statute regarding reasonable fees applies to Plaintiffs' request for production of Amendment 7 documents.

4. Plaintiffs' contention that Amendment 7 requires Baptist to maintain its records relating to adverse medical incidents in a format ready for public perusal is belied by section 381.028(7)(c)1., Florida Statutes. As recognized in the statute, provision of copies may require staff time "to *search for records* and *prevent the disclosure* of the identity of any patient involved in the adverse medical incident *through redaction* or other means . . . ." § 381.028(7)(c)1., Fla. Stat. (2012)(emphasis added). That those tasks may be required as part of a response to a request for documents indicates that the request itself is the catalyst for identifying and redacting Amendment 7 records. Therefore, this Court concludes that the necessity of staff time for those tasks applies equally to "making the records available for inspection and copying" under Amendment 7. Art. X, § 25(c)(4), Fla. Const.

Therefore, it is

ORDERED as follows:

A. Plaintiffs have a right to access Baptist's records relating to "adverse medical incidents" as that term is defined in Article X, section 25, Florida Constitution.

B. Baptist is entitled to receive from Plaintiffs a reasonable fee for: searching for and identifying records responsive to Plaintiffs' request for production of Amendment 7 documents; redacting confidential information from those documents; and producing those documents to Plaintiffs. Baptist may require payment, in full or in part, before acting on Plaintiffs' request for production.

C. Upon prepayment by Plaintiffs of a reasonable fee, Baptist shall produce to Plaintiffs, within a reasonable time and by a procedure which complies with applicable law, all records in its possession relating to adverse medical incidents during the time periods set forth in Plaintiffs' third request for production.

DONE AND ORDERED in chambers at Jacksonville, Duval County, Florida, this 9th day of December, 2014.

/s/ Waddell A. Wallace, III
Waddell A. Wallace, III
Circuit Judge

APPENDIX D

IN THE CIRCUIT COURT,
FOURTH JUDICIAL CIRCUIT,
IN AND FOR DUVAL COUNTY, FLORIDA

Case No.: 16-2012-CA-002677
Division: CV-H

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

Plaintiffs,

vs.

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC. d/b/a BAPTIST MEDICAL CENTER-SOUTH, KRISTIN FERNANDEZ, D.O., Gynecologist, YUVAL Z. NAOT, M.D., Hematologist/ Oncologist, SAFEER A. ASHRAF, M.D., Hematologist/ Oncologist, INTEGRATED COMMUNITY ONCOLOGY NETWORK, LLC., a Florida limited liability corporation, ANDREW NAMEN, M.D., Pulmonologist, GREGORY J. SENGSTOCK, M.D., Neurologist, JOHN D. PENNINGTON, M.D. Internist, EUGENE R. BEBEAU, M.D., Anesthesiologist, and ROBERT E. ROSEMUND, M.D., Family Practitioner,

Defendants.

AMENDED ORDER ON PLANTIFFS' MOTION TO COMPEL THE PRODUCTION OF AMENDMENT 7 DOCUMENTS

This case is before the Court for consideration of the Motion for Clarification or Reconsideration and Emergency Motion to Vacate filed on behalf of defendant Southern Baptist Hospital of Florida, Inc. ("BMC"), directed to the Order on Plaintiffs' Motion to Compel the Production of Amendment 7 Documents, signed by the Court July 30, and entered in this action July 31, 2014. BMC's motions are granted and the order regarding amendment 7 documents is VACATED and SUPERCEDED by the amended order set forth below.

I. Background and Procedural Posture

This is a medical malpractice case. The Plaintiffs have alleged that Marie Charles suffered neurological injuries as the result of the negligence of the Defendants while she was a patient at Baptist Medical Center - South and Baptist Medical Center - Downtown. Specifically, the Plaintiffs allege that Marie Charles was subject to an unnecessary, and contra-indicated, surgery while under the care of the Defendants at Baptist Medical Center - South. They further allege that, due to complicating medical factors known to the Defendants, Marie Charles suffered a stroke while undergoing this surgery. Finally, the Plaintiffs allege that the treatment given to Marie Charles at Baptist Medical Center - South and Baptist Medical Center - Downtown after suffering her stroke was untimely and negligent.

On July 24, 2013, the Plaintiff served a third set of requests for production on Defendant Baptist. In brief, these requests asked, pursuant to Art. 10 Sec. 25 of the Florida Constitution (Amendment 7), for adverse incident reports (as defined by Amendment 7) relating to the following:

1. Marie Charles;

2. The defendant doctors;
3. Any physicians working at Baptist Medical Center - South between 2007 and the present;
4. Any physicians working at any Baptist Medical Center facility between 2007 and the present;
5. Emergency care at any Baptist Medical Center facility between 2007 and the present;
6. Any care and/or treatment at any Baptist Medical Center facility between 2007 and the present;
7. Any care and/or treatment at Baptist Medical Center - South between 2007 and the present;

In addition, each request contained the following explanatory language:

> This request is limited to adverse incident documents (as described above) that are ***created*** by you, or ***maintained*** by you, or provided by you to any state or federal agency, pursuant to any obligation or requirement in any state or federal law, rule, or regulation. As limited, this request includes, but is not limited to, documents ***created*** by you, or ***maintained*** by you pursuant to Fla. Stat. § 395.0197, 766.010, and 395.0193. This request, as limited, specifically includes, but is not limited to, your annual adverse incident summary report and any and all Code 15 Reports.

(Emphasis added).

On August, 23 2013, Baptist responded to Plaintiffs' Third Request For Production. Baptist stated it had no documents responsive to Requests 1 and 2, and agreed to produce documents responsive to Requests 3 through 7. Baptist then produced Code 15 Reports

and Annual Reports. Baptist and the Plaintiffs then exchanged a number of letters regarding Baptist's response to the Plaintiffs' Third Request for Production. At the end of this exchange, Baptist acknowledged that it had other potentially responsive documents, but claimed that these documents were protected from discovery under the Federal Patient Safety and Quality Improvement Act ("PSQIA") - 42 U.S.C. § 299b-21 et. seq.

The Plaintiffs then filed a motion to compel the production of all remaining Amendment 7 documents responsive to their Third Request For Production. Following the filing of this motion, the Court heard argument regarding the production of Amendment 7 documents on several occasions, and both the Plaintiff and Baptist submitted case law and other authority for the Court's consideration. In addition, the parties engaged in negotiations, attempting to work out a compromise on this issue. During these negotiations, Baptist produced two incident reports relating directly to the care of Marie Charles that gives rise to this case.

The parties have now reached an impasse. Baptist has produced Annual Reports, Code 15 Reports, and two incident reports relating to Marie Charles. It maintains its objection under the PSQIA to the production of any other documents. On June 24, 2014 the Plaintiffs brought this issue back before the Court. The Plaintiffs seek an order granting their motion to compel the production of all Amendment 7 Documents that were created or maintained by Baptist as required by state or federal law or regulation or credentialing entity requirements, or which were provided by Baptist to any state or federal agency or other credentialing entity pursuant to any obligation or requirement in any state or federal law, rule, regulation, or licensing

or accreditation obligation. Baptist asks that the Court deny the Plaintiffs' motion to the extent it seeks documents not already produced.

II. Analysis

The Plaintiffs' Motion to Compel Production of Amendment 7 Documents deals with the interaction of Amendment 7 and the PSQIA. Amendment 7 gave Floridians broad access to adverse incident records from medical providers. The PSQIA creates a privilege protecting documents that qualify as so called "Patient Safety Work Product."

Passed in 2004, Amendment 7 provides that patients have a right to any records made or received in the course of business by a health care facility or provider relating to any adverse incident. *Fla. Const. Art. 10 § 25,* "Adverse incidents" are broadly defined to include: medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or the death of a patient. *Id.* These categories include, but are not limited to, those incidents that are required by state or federal law to be reported to any governmental agency or body, and incidents 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. *Id.*

Since 2004, Amendment 7 has been the subject of extensive litigation. Florida appellate courts have ruled on issues relating to Amendment 7, turning back several common law and statutory challenges to the law. *See: Cedars Healthcare Group v. Martinez*, 39 Fla. L. Weekly, S60 (Fla. Jan. 30, 2014); *Florida Hospital Waterman v. Buster*, 984 So.2d 478 (Fla. 2008); *West Florida Regional Medical Center v. Lynda See, et al.*,

70 So.3d 1 (Fla. 2012); *Morton Plant Hospital Association, Inc. v. Shabhas*, 960 So.2d 820 (Fla. 2nd DCA 2007); *Columbia Hospital Corporation of South Broward v. Fain*, 16 So.3d 236 (Fla. 4th DCA 2009); *Baldwin v. Shands Teaching Hospital and Clinics, Inc.*, 45 So.3d 119 (Fla. 1st DCA 2010); *Dania Acevedo v. Doctors Hospital, Inc.*, 68 So.3d 949 (Fla. 3rd DCA 2011); *Lakeland Regional Medical Center v. Neely*, 8 So.3d 1268 (Fla. 2nd 2009); *Florida Eye Clinic v. Mary T. Gmash*, 14 So.3d [sic] (Fla 5th DCA 2009).

In this case, Baptist has argued that the documents sought by the Plaintiffs are protected from discovery by the PSQIA. The PSQIA authorizes the creation of patient safety organizations (PSO's). A healthcare provider may collect information through a patient safety evaluation system (PSES) and then share that information with a PSO. The information thus collected and shared may be classified as Patient Safety Work Product (PSWP), but only if the information fits within the Act's definition of PSWP, which is as follows:

> (A) IN GENERAL —
>
> Except as provided in subparagraph (B), the term "patient safety work product" means any data, reports, records, memoranda, analysis (such as root cause analyses), or written or oral statement —
>
> (I) which —
>
> (I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or
>
> (II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in

improved patient safety, health care quality, or health care outcomes; or

(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

42 U.S.C. §299b-21(7)(A) (2006). The PSQIA grants privilege from discovery and confidentiality protection to PSWP. *See:* 42 U.S.C. §299b-22(A) and (B) (2006).

However, the Act contains significant restrictions on the definition of PSWP and the applicability of the privilege and confidentiality protections. These restrictions are found under the heading "CLARIFICATION" in § 299b-21(7)(B) and provide in pertinent part as follows:

(B) CLARIFICATION

(i) . . .

(ii) Information described in subparagraph (A) *does not* include information that is *collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system*. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

(iii) Nothing in this part shall be construed to limit —

(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

(II) *the reporting of information described in this subparagraph to a Federal, State, or local government agency for public health surveillance, investigation, or other public health purposes*; or

(III) *a provider's record keeping obligation with respect to information described in this subparagraph under Federal, State, or local law.*

42 U.S.C. §299b-21(7)(B) (emphasis added).

Under the plain language of the PSQIA, information collected, maintained, or developed for purposes other than submission to a PSO does not constitute PSWP and is not privileged or confidential under the Act. Specifically, information collected, maintained, or developed to fulfill obligations under federal, state, or local law does not constitute PSWP.

The U.S. Department of Health and Human Services, during the rule making process surrounding the implementation of the PSQIA, gave significant guidance to what is and is not PSWP. Both Baptist and the Plaintiff cited extensively to the rule summary found in Fed. Reg. Vol 73, No. 226, 70732 et. seq. (Nov. 21, 2008). In that Summary, HHS explains that reporting obligations under state and federal laws must be met with non-privileged materials:

> Even when laws or regulations require the reporting of the information regarding the type of events also reported to PSOs, the Patient Safety Act does not shield providers from their obligation to comply with such requirements. *These external obligations must be met with information that* ***is not patient safety work product*** *and oversight entities continue to have access to this*

> *original information in the same manner as such entities have had access prior to the passage of the Patient Safety Act.*

Id. at 70742 (emphasis added). HHS goes on to explain that information collected for state or federal record keeping or reporting requirements is not PSWP:

> The Patient Safety Act establishes a protected space or system that is separate, distinct, and resides alongside but does not replace other information collecting activities mandated by laws, regulations, and accrediting and licensing requirements as well as voluntary reporting activities that occur for the purposes of maintaining accountability in the health care system. *Information is not patient safety work product if it is* ***collected*** *to comply with external obligations, such as: state incident reporting requirements; [or] . . . certification or licensing records for compliance with health oversight agency requirements . . . .*

Id. (emphasis added). HHS Further explained that PSWP is limited only to information obtained by a healthcare provider's PSES for the sole purpose of reporting to its PSO, and information collected for other purposes does not become PSWP by virtue of the fact that it was submitted to a PSO:

> Providers should be cautioned to consider whether there are other purposes for which an analysis may be used to determine whether protection as patient safety work product is necessary or warranted. *Further, the definition of patient safety work product is clear that information collected for a purpose other than reporting to a PSO may not*

> *become patient safety work product only based upon the reporting of that information to a PSO.*

Id. at 70744 (Emphasis added).

The final rules promulgated by HHS reaffirm the limitations referred to above. "Patient safety work product does not . . . include information that is *collected, maintained*, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered patient safety work product." 42 C.F.R. § 3.20, *Patient safety work product* (2)(i) (emphasis added). Sec. 3.20 goes on to state that: "Nothing in this part shall be construed to limit information that is not patient safety work product from being . . . reported to a Federal, State, local or Tribal government agency for public health oversight purposes; or ***maintained*** as part of a providers' record keeping obligation under Federal, State, local or Tribal law. [sic] 42 C.F.R. §3.20, *Patient safety work product* (2)(iii) (emphasis added).

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. [sic] 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.

Florida's statutes and administrative rules contain numerous requirements for record keeping and reporting of adverse incidents by healthcare providers. For instance, Section 395.0197, Florida Statutes and Fla. Admin. Code 59A-10.0055 establish a system whereby reports of adverse incident are to be created, main-

tained and reported to ACHA. Section 395.0197(4) mandates that health care providers establish a risk management program that includes written incident reports. Rule 59A-10.0055 describes what information these incident reports must contain. Both Section 395.0197(13) and Rule 59A-10.0055(3)(b) mandate that ACHA shall have access to these reports and can review them upon request. Other statutes that trigger record keeping and/or reporting requirement include Sections 766.101 and 395.0193. Documents created or maintained pursuant to statutory or regulatory schemes such as these are not PSWP.

The language of the Plaintiffs' Third Request for Production is tailored to ask for only those documents created or maintained pursuant to statutory, regulatory, licensing, or accreditation requirements. Since these documents are not PSWP, they are not privileged or protect from discovery under the PSQIA.

Baptist argues that, regardless of the purpose behind the collection of information in its possession, only information actually provided to the government entities is not privileged under the PSQIA. However, in referring to non-privileged information, the terms used repeatedly by the statutes and other authorities is "collected" and "maintained." It is the collection and maintenance of information and records for a regulatory purpose, not the actual provision of that information to the government, that takes information out of the ambit of the PSQIA. In the words of the HHS information "***collected*** to comply with external obligations, such as: state incident reporting requirements; [or] . . . certification or licensing records for compliance with health oversight agency requirements . . ." is not privileged. Federal Register, Part III, Vol. 73, No. 226, at 70742 (Nov. 21, 2008) (emphasis added).

Finally, there is a dispute between Baptist and the Plaintiffs on who should bear the cost of the production of the documents at issue. The Plaintiffs argue that no costs are appropriate under the language of Amendment 7, and that the costs asked for by Baptist for similar documents in similar cases is excessive. They have expressed a desire to do discovery on the issue of such costs. Baptist, for its part, claims entitlement to costs under the provisions of Florida Statutes. The Court is not ruling, at this point, on either entitlement to costs of production or the amount of these costs should they be ordered,

Accordingly, it is

ORDERED:

1. Plaintiffs' Motion to Compel the Production of Amendment 7 Documents is GRANTED in part, as stated in paragraphs 2 and 3.

2. All reports of adverse medical incidents, as defined by Amendment 7, which are created, or maintained pursuant to any statutory, regulatory, licensing, or accreditation requirements are not protected from discovery under the Federal Patient Safety and Quality Improvement Act ("PSQIA").

3. By subsequent order, the Court will address the breath and scope of the Amendment 7 documents to be produced, the timing of the production and Baptist's demand for reimbursement of the cost of identifying and producing the Amendment 7 documents.

DONE AND ORDERED in chambers at Jacksonville, Duval County, Florida, this 28th day of August, 2014.

/s/ Wadell A. Wallace, III
Wadell A. Wallace, III
Circuit Judge

Copies furnished to all counsel of record.

APPENDIX E

IN THE CIRCUIT COURT,
FOURTH JUDICIAL CIRCUIT,
IN AND FOR DUVAL COUNTY, FLORIDA

Case No.: 16-2012-CA-002677
Division: CV-H

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

Plaintiffs,

vs.

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC. d/b/a BAPTIST MEDICAL CENTER-SOUTH, KRISTIN FERNANDEZ, D.O., Gynecologist, YUVAL Z. NAOT, M.D., Hematologist/ Oncologist, SAFEER A. ASHRAF, M.D., Hematologist/ Oncologist, INTEGRATED COMMUNITY ONCOLOGY NETWORK, LLC., a Florida limited liability corporation, ANDREW NAMEN, M.D., Pulmonologist, GREGORY J. SENGSTOCK, M.D., Neurologist, JOHN D. PENNINGTON, M.D. Internist, EUGENE R. BEBEAU, M.D., Anesthesiologist, and ROBERT E. ROSEMUND, M.D., Family Practitioner,

Defendants.

ORDER ON PLAINTIFFS' MOTION TO COMPEL THE PRODUCTION OF AMENDMENT 7 DOCUMENTS

I. Background and Procedural Posture

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5. Emergency care at any Baptist Medical Center facility between 2007 and the present;

6. Any care and/or treatment at any Baptist Medical Center facility between 2007 and the present;

7. Any care and/or treatment at Baptist Medical Center - South between 2007 and the present;

In addition, each request contained the following explanatory language:

> This request is limited to adverse incident documents (as described above) that are ***created*** by you, or ***maintained*** by you, or provided by you to any state or federal agency, pursuant to any obligation or requirement in any state or federal law, rule, or regulation. As limited, this request includes, but is not limited to, documents ***created*** by you, or ***maintained*** by you pursuant to Fla. Stat. § 395.0197, 766.010, and 395.0193. This request, as limited, specifically includes, but is not limited to, your annual adverse incident summary report and any and all Code 15 Reports.

(Emphasis added).

On August, 23 2013, Baptist responded to Plaintiffs' Third Request For Production. Baptist stated it had no documents responsive to Requests 1 and 2, and agreed to produce documents responsive to Requests 3 through 7. Baptist then produced Code 15 Reports and Annual Reports. Baptist and the Plaintiffs then exchanged a number of letters regarding Baptist's response to the Plaintiffs' Third Request for Production. At the end of this exchange, Baptist acknowledged that it had other potentially responsive documents, but claimed that these documents were protected from discovery under the Federal Patient Safety and Quality Improvement Act ("PSQIA") - 42 U.S.C. § 299b-21 et. seq.

The Plaintiffs then filed a motion to compel the production of all remaining Amendment 7 documents responsive to their Third Request For Production. Following the filing of this motion, the Court heard argument regarding the production of Amendment 7 documents on several occasions, and both the Plaintiff and Baptist submitted case law and other authority for the Court's consideration. In addition, the parties engaged in negotiations, attempting to work out a compromise on this issue. During these negotiations, Baptist produced two incident reports relating directly to the care of Marie Charles that gives rise to this case.

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protecting documents that qualify as so called "Patient Safety Work Product."

Passed in 2004, Amendment 7 provides that patients have a right to any records made or received in the course of business by a health care facility or provider relating to any adverse incident. *Fla. Const. Art. 10 § 25.* "Adverse incidents" are broadly defined to include: medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or the death of a patient. *Id.* These categories include, but are not limited to, those incidents that are required by state or federal law to be reported to any governmental agency or body, and incidents 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. *Id.*

Since 2004, Amendment 7 has been the subject of extensive litigation. Florida appellate courts have ruled on issues relating to Amendment 7, turning back several common law and statutory challenges to the law. *See: Cedars Healthcare Group v. Martinez*, 39 Fla. L. Weekly, S60 (Fla. Jan. 30, 2014); *Florida Hospital Waterman v. Buster*, 984 So.2d 478 (Fla. 2008); *West Florida Regional Medical Center v. Lynda See, et al.*, 70 So.3d 1 (Fla. 2012); *Morton Plant Hospital Association, Inc. v. Shabhas*, 960 So.2d 820 (Fla. 2nd DCA 2007); *Columbia Hospital Corporation of South Broward v. Fain*, 16 So.3d 236 (Fla. 4th DCA 2009); *Baldwin v. Shands Teaching Hospital and Clinics, Inc.*, 45 So.3d 119 (Fla. 1st DCA 2010); *Dania Acevedo v. Doctors Hospital, Inc.*, 68 So.3d 949 (Fla. 3rd DCA 2011); *Lakeland Regional Medical Center v. Neely*,

8 So.3d 1268 (Fla. 2nd 2009); *Florida Eye Clinic v. Mary T. Gmash*, 14 So.3d [sic] (Fla 5th DCA 2009).

In this case, Baptist has argued that the documents sought by the Plaintiffs are protected from discovery by the PSQIA. The PSQIA authorizes the creation of patient safety organizations (PSO's). A healthcare provider may collect information through a patient safety evaluation system (PSES) and then share that information with a PSO. The information thus collected and shared may be classified as Patient Safety Work Product (PSWP), but only if the information fits within the Act's definition of PSWP, which is as follows:

> (A) IN GENERAL —
>
> Except as provided in subparagraph (B), the term "patient safety work product" means any data, reports, records, memoranda, analysis (such as root cause analyses), or written or oral statement —
>
> (I) which —
>
> (I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or
>
> (II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or
>
> (ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

42 U.S.C. §299b-21(7)(A) (2006). The PSQIA grants privilege from discovery and confidentiality protection to PSWP. *See:* 42 U.S.C. § 299b-22(A) and (B) (2006).

However, the Act contains significant restrictions on the definition of PSWP and the applicability of the privilege and confidentiality protections. These restrictions are found under the heading "CLARIFICATION" in § 299b-21(7)(B) and provide in pertinent part as follows:

> (B) CLARIFICATION
>
> (i) . . .
>
> (ii) Information described in subparagraph (A) *does not* include information that is ***collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system***. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.
>
> (iii) Nothing in this part shall be construed to limit —
>
> (I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;
>
> (II) *the reporting of information described in this subparagraph to a Federal, State, or local government agency for public health surveillance, investigation, or other public health purposes*; or
>
> (III) *a provider's record keeping obligation with respect to information described in this subparagraph under Federal, State, or local law.*

42 U.S.C. § 299b-21(7)(B) (emphasis added).

Under the plain language of the PSQIA, information collected, maintained, or developed for purposes other than submission to a PSO does not constitute PSWP and is not privileged or confidential under the Act. Specifically, information collected, maintained, or developed to fulfill obligations under federal, state, or local law does not constitute PSWP.

The U.S. Department of Health and Human Services, during the rule making process surrounding the implementation of the PSQIA, gave significant guidance to what is and is not PSWP. Both Baptist and the Plaintiff cited extensively to the rule summary found in Fed. Reg. Vol 73, No. 226, 70732 et. seq. (Nov. 21, 2008). In that Summary, HHS explains that reporting obligations under state and federal laws must be met with non-privileged materials:

> Even when laws or regulations require the reporting of the information regarding the type of events also reported to PSOs, the Patient Safety Act does not shield providers from their obligation to comply with such requirements. *These external obligations must be met with information that* ***is not patient safety work product*** *and oversight entities continue to have access to this original information in the same manner as such entities have had access prior to the passage of the Patient Safety Act.*

Id. at 70742 (emphasis added). HHS goes on to explain that information collected for state or federal record keeping or reporting requirements is not PSWP:

> The Patient Safety Act establishes a protected space or system that is separate, distinct, and resides alongside but does not replace other information collecting activities mandated by laws,

> regulations, and accrediting and licensing requirements as well as voluntary reporting activities that occur for the purposes of maintaining accountability in the health care system. *Information is not patient safety work product if it is* ***collected*** *to comply with external obligations, such as: state incident reporting requirements; [or] . . . certification or licensing records for compliance with health oversight agency requirements . . . .*

Id. (emphasis added). HHS Further explained that PSWP is limited only to information obtained by a healthcare provider's PSES for the sole purpose of reporting to its PSO, and information collected for other purposes does not become PSWP by virtue of the fact that it was submitted to a PSO:

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

Id. at 70744 (Emphasis added).

The final rules promulgated by HHS reaffirm the limitations referred to above. "Patient safety work product does not . . . include information that is *collected, maintained*, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered patient safety work product." 42 C.F.R. §3.20, *Patient safety work product* (2)(i) (emphasis

added). Sec. 3.20 goes on to state that: "Nothing in this part shall be construed to limit information that is not patient safety work product from being . . . reported to a Federal, State, local or Tribal government agency for public health oversight purposes; or ***maintained*** as part of a providers' record keeping obligation under Federal, State, local or Tribal law. [sic] 42 C.F.R. §3.20, *Patient safety work product* (2)(iii) (emphasis added).

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. [sic] 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.

Florida's statutes and administrative rules contain numerous requirements for record keeping and reporting of adverse incidents by healthcare providers. For instance, Section 395.0197, Florida Statutes and Fla. Admin. Code 59A-10.0055 establish a system whereby reports of adverse incident are to be created, maintained and reported to ACHA. Section 395.0197(4) mandates that health care providers establish a risk management program that includes written incident reports. Rule 59A-10.0055 describes what information these incident reports must contain. Both Section 395.0197(13) and Rule 59A-10.0055(3)(b) mandate that ACHA shall have access to these reports and can review them upon request. Other statutes that trigger record keeping and/or reporting requirement include Sections 766.101 and 395.0193. Documents created or maintained pursuant to statutory or regulatory schemes such as these are not PSWP.

The language of the Plaintiffs' Third Request for Production is tailored to ask for only those documents created or maintained pursuant to statutory, regulatory, licensing, or accreditation requirements. Since these documents are not PSWP, they are not privileged or protect from discovery under the PSQIA.

Baptist argues that, regardless of the purpose behind the collection of information in its possession, only information actually provided to the government entities is not privileged under the PSQIA. However, in referring to non-privileged information, the terms used repeatedly by the statutes and other authorities is "collected" and "maintained." It is the collection and maintenance of information and records for a regulatory purpose, not the actual provision of that information to the government, that takes information out of the ambit of the PSQIA. In the words of the HHS information "***collected*** to comply with external obligations, such as: state incident reporting requirements; [or] . . . certification or licensing records for compliance with health oversight agency requirements . . ." is not privileged. Federal Register, Part III, Vol. 73, No. 226, at 70742 (Nov. 21, 2008) (emphasis added).

Finally, there is a dispute between Baptist and the Plaintiffs on who should bear the cost of the production of the documents at issue. The Plaintiffs argue that no costs are appropriate under the language of Amendment 7, and that the costs asked for by Baptist for similar documents in similar cases is excessive. They have expressed a desire to do discovery on the issue of such costs. Baptist, for its part, claims entitlement to costs under the provisions of Florida Statutes. The Court is not ruling, at this point, on either entitlement to costs of production or the amount of these costs should they be ordered.

Accordingly, it is

ORDERED:

1. Plaintiffs' Motion to Compel the Production of Amendment 7 Documents is GRANTED.

2. All adverse incident reports, as defined by Amendment 7, which are created, or maintained pursuant to any statutory, regulatory, licensing, or accreditation requirements are not protected from discovery under the Federal Patient Safety and Quality Improvement Act ("PSQIA").

3. By subsequent Order, the Court will address the breath and scope of the Amendment 7 documents to be produced, the timing of the production and Baptist's demand for reimbursement of the cost of identifying and producing the Amendment 7 documents.

DONE AND ORDERED in chambers at Jacksonville, Duval County, Florida, this ____ day of July, 2014.

ORDER ENTERED
JUL 30, 2014

/s/ Waddell A. Wallace, III
Waddell A. Wallace, III
Circuit Judge

Copies furnished to all counsel of record.

APPENDIX F

FEDERAL STATUTES

42 U.S.C. § 299b-21. Definitions

In this part:

* * * *

(4) Patient safety organization

The term "patient safety organization" means a private or public entity or component thereof that is listed by the Secretary pursuant to section 299b-24(d) of this title.

(5) Patient safety activities

The term "patient safety activities" means the following activities:

(A) Efforts to improve patient safety and the quality of health care delivery.

(B) The collection and analysis of patient safety work product.

(C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

(D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.

(E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.

(F) The provision of appropriate security measures with respect to patient safety work product.

(G) The utilization of qualified staff.

(H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

(6) Patient safety evaluation system

The term "patient safety evaluation system" means the collection, management, or analysis of information for reporting to or by a patient safety organization.

(7) Patient safety work product

(A) In general

Except as provided in subparagraph (B), the term "patient safety work product" means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—

(i) which—

(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

(II) are developed by a patient safety organization for the conduct of patient safety activities;

and which could result in improved patient safety, health care quality, or health care outcomes; or

(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

(B) Clarification

(i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.

(ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

(iii) Nothing in this part shall be construed to limit—

(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

(8) Provider

The term "provider" means—

(A) an individual or entity licensed or otherwise authorized under State law to provide health care services, including—

(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

(B) any other individual or entity specified in regulations promulgated by the Secretary.

42 U.S.C. § 299b-22. Privilege and confidentiality protections

(a) Privilege

Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be privileged and shall not be—

(1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

(2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

(3) subject to disclosure pursuant to section 552 of Title 5 (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;

(4) admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding,

or administrative adjudicatory proceeding, including any such proceeding against a provider; or

(5) admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

(b) Confidentiality of patient safety work product

Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be confidential and shall not be disclosed.

(c) Exceptions

Except as provided in subsection (g)(3) of this section—

(1) Exceptions from privilege and confidentiality

Subsections (a) and (b) of this section shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(A) Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an in camera determination that such patient safety work product contains evidence of a criminal act and that such patient safety work product is material to the proceeding and not reasonably available from any other source.

(B) Disclosure of patient safety work product to the extent required to carry out subsection (f)(4)(A) of this section.

(C) Disclosure of identifiable patient safety work product if authorized by each provider identified in such work product.

(2) Exceptions from confidentiality

Subsection (b) of this section shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(A) Disclosure of patient safety work product to carry out patient safety activities.

(B) Disclosure of nonidentifiable patient safety work product.

(C) Disclosure of patient safety work product to grantees, contractors, or other entities carrying out research, evaluation, or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research to the extent that disclosure of protected health information would be allowed for such purpose under the HIPAA confidentiality regulations.

(D) Disclosure by a provider to the Food and Drug Administration with respect to a product or activity regulated by the Food and Drug Administration.

(E) Voluntary disclosure of patient safety work product by a provider to an accrediting body that accredits that provider.

(F) Disclosures that the Secretary may determine, by rule or other means, are necessary for business operations and are consistent with the goals of this part.

(G) Disclosure of patient safety work product to law enforcement authorities relating to the commission of a crime (or to an event reasonably believed to be a crime) if the person making the

disclosure believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

(H) With respect to a person other than a patient safety organization, the disclosure of patient safety work product that does not include materials that—

(i) assess the quality of care of an identifiable provider; or

(ii) describe or pertain to one or more actions or failures to act by an identifiable provider.

(3) Exception from privilege

Subsection (a) of this section shall not apply to (and shall not be construed to prohibit) voluntary disclosure of nonidentifiable patient safety work product.

(d) Continued protection of information after disclosure

(1) In general

Patient safety work product that is disclosed under subsection (c) of this section shall continue to be privileged and confidential as provided for in subsections (a) and (b) of this section, and such disclosure shall not be treated as a waiver of privilege or confidentiality, and the privileged and confidential nature of such work product shall also apply to such work product in the possession or control of a person to whom such work product was disclosed.

(2) Exception

Notwithstanding paragraph (1), and subject to paragraph (3)—

(A) if patient safety work product is disclosed in a criminal proceeding, the confidentiality protections provided for in subsection (b) of this section shall no longer apply to the work product so disclosed; and

(B) if patient safety work product is disclosed as provided for in subsection (c)(2)(B) of this section (relating to disclosure of nonidentifiable patient safety work product), the privilege and confidentiality protections provided for in subsections (a) and (b) of this section shall no longer apply to such work product.

(3) Construction

Paragraph (2) shall not be construed as terminating or limiting the privilege or confidentiality protections provided for in subsection (a) or (b) of this section with respect to patient safety work product other than the specific patient safety work product disclosed as provided for in subsection (c) of this section.

(4) Limitations on actions

(A) Patient safety organizations

(i) In general

A patient safety organization shall not be compelled to disclose information collected or developed under this part whether or not such information is patient safety work product unless such information is identified, is not patient safety work product, and is not reasonably available from another source.

(ii) Nonapplication

The limitation contained in clause (i) shall not apply in an action against a patient safety organization or with respect to disclosures pursuant to subsection (c)(1) of this section.

(B) Providers

An accrediting body shall not take an accrediting action against a provider based on the good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety work product in accordance with this part. An accrediting body may not require a provider to reveal its communications with any patient safety organization established in accordance with this part.

(e) Reporter protection

(1) In general

A provider may not take an adverse employment action, as described in paragraph (2), against an individual based upon the fact that the individual in good faith reported information—

(A) to the provider with the intention of having the information reported to a patient safety organization; or

(B) directly to a patient safety organization.

(2) Adverse employment action

For purposes of this subsection, an "adverse employment action" includes—

(A) loss of employment, the failure to promote an individual, or the failure to provide any other employment-related benefit for which the individual would otherwise be eligible; or

(B) an adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of the individual.

(f) Enforcement

(1) Civil monetary penalty

Subject to paragraphs (2) and (3), a person who discloses identifiable patient safety work product in knowing or reckless violation of subsection (b) of this section shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation.

(2) Procedure

The provisions of section 1320a-7a of this title, other than subsections (a) and (b) and the first sentence of subsection (c)(1), shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a of this title.

(3) Relation to HIPAA

Penalties shall not be imposed both under this subsection and under the regulations issued pursuant to section 264(c)(1) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note) for a single act or omission.

(4) Equitable relief

(A) In general

Without limiting remedies available to other parties, a civil action may be brought by any aggrieved individual to enjoin any act or practice that violates subsection (e) of this section and to obtain other appropriate equitable relief (includ-

ing reinstatement, back pay, and restoration of benefits) to redress such violation.

(B) Against State employees

An entity that is a State or an agency of a State government may not assert the privilege described in subsection (a) of this section unless before the time of the assertion, the entity or, in the case of and with respect to an agency, the State has consented to be subject to an action described in subparagraph (A), and that consent has remained in effect.

(g) Rule of construction

Nothing in this section shall be construed—

(1) to limit the application of other Federal, State, or local laws that provide greater privilege or confidentiality protections than the privilege and confidentiality protections provided for in this section;

(2) to limit, alter, or affect the requirements of Federal, State, or local law pertaining to information that is not privileged or confidential under this section;

(3) except as provided in subsection (i) of this section, to alter or affect the implementation of any provision of the HIPAA confidentiality regulations or section 1320d-5 of this title (or regulations promulgated under such section);

(4) to limit the authority of any provider, patient safety organization, or other entity to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with this section;

(5) as preempting or otherwise affecting any State law requiring a provider to report information that is not patient safety work product; or

(6) to limit, alter, or affect any requirement for reporting to the Food and Drug Administration information regarding the safety of a product or activity regulated by the Food and Drug Administration.

(h) Clarification

Nothing in this part prohibits any person from conducting additional analysis for any purpose regardless of whether such additional analysis involves issues identical to or similar to those for which information was reported to or assessed by a patient safety organization or a patient safety evaluation system.

(i) Clarification of application of HIPAA confidentiality regulations to patient safety organizations

For purposes of applying the HIPAA confidentiality regulations—

(1) patient safety organizations shall be treated as business associates; and

(2) patient safety activities of such organizations in relation to a provider are deemed to be health care operations (as defined in such regulations) of the provider.

(j) Reports on strategies to improve patient safety

(1) Draft report

Not later than the date that is 18 months after any network of patient safety databases is operational, the Secretary, in consultation with the Director, shall prepare a draft report on effective strategies

for reducing medical errors and increasing patient safety. The draft report shall include any measure determined appropriate by the Secretary to encourage the appropriate use of such strategies, including use in any federally funded programs. The Secretary shall make the draft report available for public comment and submit the draft report to the Institute of Medicine for review.

(2) Final report

Not later than 1 year after the date described in paragraph (1), the Secretary shall submit a final report to the Congress.

42 U.S.C. § 299b-23. Network of patient safety databases

(a) In general

The Secretary shall facilitate the creation of, and maintain, a network of patient safety databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other entities. The network of databases shall have the capacity to accept, aggregate across the network, and analyze nonidentifiable patient safety work product voluntarily reported by patient safety organizations, providers, or other entities. The Secretary shall assess the feasibility of providing for a single point of access to the network for qualified researchers for information aggregated across the network and, if feasible, provide for implementation.

(b) Data standards

The Secretary may determine common formats for the reporting to and among the network of patient safety databases maintained under subsection (a) of this section of nonidentifiable patient safety work product,

including necessary work product elements, common and consistent definitions, and a standardized computer interface for the processing of such work product. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act [42 U.S.C. § 1320d et seq.].

(c) Use of information

Information reported to and among the network of patient safety databases under subsection (a) of this section shall be used to analyze national and regional statistics, including trends and patterns of health care errors. The information resulting from such analyses shall be made available to the public and included in the annual quality reports prepared under section 299b-2(b)(2) of this title.

APPENDIX G

FEDERAL REGULATIONS

42 C.F.R. § 3.10. Purpose.

The purpose of this part is to implement the Patient Safety and Quality Improvement Act of 2005 (Pub.L. 109–41), which amended Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) by adding sections 921 through 926, 42 U.S.C. 299b–21 through 299b–26.

42 C.F.R. § 3.20. Definitions.

* * * *

Patient Safety Act means the Patient Safety and Quality Improvement Act of 2005 (Pub.L. 109–41), which amended Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) by inserting a new Part C, sections 921 through 926, which are codified at 42 U.S.C. 299b–21 through 299b–26.

Patient safety activities means the following activities carried out by or on behalf of a PSO or a provider:

(1) Efforts to improve patient safety and the quality of health care delivery;

(2) The collection and analysis of patient safety work product;

(3) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;

(4) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;

(5) The maintenance of procedures to preserve confidentiality with respect to patient safety work product;

(6) The provision of appropriate security measures with respect to patient safety work product;

(7) The utilization of qualified staff; and

(8) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

Patient safety evaluation system means the collection, management, or analysis of information for reporting to or by a PSO.

Patient safety organization (PSO) means a private or public entity or component thereof that is listed as a PSO by the Secretary in accordance with subpart B. A health insurance issuer or a component organization of a health insurance issuer may not be a PSO. See also the exclusions in § 3.102 of this part.

Patient safety work product:

(1) Except as provided in paragraph (2) of this definition, patient safety work product means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material)

(i) Which could improve patient safety, health care quality, or health care outcomes; and

(A) Which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a patient safety evaluation system for reporting to a PSO, and such

documentation includes the date the information entered the patient safety evaluation system; or

(B) Are developed by a PSO for the conduct of patient safety activities; or

(ii) Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

(2)(i) Patient safety work product does not include a patient's medical record, billing and discharge information, or any other original patient or provider information; nor does it include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered patient safety work product.

(ii) Patient safety work product assembled or developed by a provider for reporting to a PSO may be removed from a patient safety evaluation system and no longer considered patient safety work product if:

(A) The information has not yet been reported to a PSO; and

(B) The provider documents the act and date of removal of such information from the patient safety evaluation system.

(iii) Nothing in this part shall be construed to limit information that is not patient safety work product from being:

(A) Discovered or admitted in a criminal, civil or administrative proceeding;

(B) Reported to a Federal, State, local or Tribal governmental agency for public health or health oversight purposes; or

(C) Maintained as part of a provider's recordkeeping obligation under Federal, State, local or Tribal law.

Person means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Provider means:

(1) An individual or entity licensed or otherwise authorized under State law to provide health care services, including—

(i) A hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office (includes a group practice), long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

(ii) A physician, physician assistant, registered nurse, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner;

(2) Agencies, organizations, and individuals within Federal, State, local, or Tribal governments that deliver health care, organizations engaged as contractors by the Federal, State, local, or Tribal governments to deliver health care, and individual health care

practitioners employed or engaged as contractors by the Federal State, local, or Tribal governments to deliver health care; or

(3) A parent organization of one or more entities described in paragraph (1)(i) of this definition or a Federal, State, local, or Tribal government unit that manages or controls one or more entities described in paragraphs (1)(i) or (2) of this definition.

Research has the same meaning as the term is defined in the HIPAA Privacy Rule at 45 CFR 164.501.

Respondent means a provider, PSO, or responsible person who is the subject of a complaint or a compliance review.

Responsible person means a person, other than a provider or a PSO, who has possession or custody of identifiable patient safety work product and is subject to the confidentiality provisions.

Workforce means employees, volunteers, trainees, contractors, or other persons whose conduct, in the performance of work for a provider, PSO or responsible person, is under the direct control of such provider, PSO or responsible person, whether or not they are paid by the provider, PSO or responsible person.

42 C.F.R. § 3.204. Privilege of patient safety work product.

(a) Privilege. Notwithstanding any other provision of Federal, State, local, or Tribal law and subject to paragraph (b) of this section and § 3.208 of this subpart, patient safety work product shall be privileged and shall not be:

(1) Subject to a Federal, State, local, or Tribal civil, criminal, or administrative subpoena or order, including in a Federal, State, local, or Tribal civil or

administrative disciplinary proceeding against a provider;

(2) Subject to discovery in connection with a Federal, State, local, or Tribal civil, criminal, or administrative proceeding, including in a Federal, State, local, or Tribal civil or administrative disciplinary proceeding against a provider;

(3) Subject to disclosure pursuant to section 552 of Title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal, State, local, or Tribal law;

(4) Admitted as evidence in any Federal, State, local, or Tribal governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or

(5) Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

(b) Exceptions to privilege. Privilege shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(1) Disclosure of relevant patient safety work product for use in a criminal proceeding, subject to the conditions at § 3.206(b)(1) of this subpart.

(2) Disclosure to the extent required to permit equitable relief subject to the conditions at § 3.206(b)(2) of this subpart.

(3) Disclosure pursuant to provider authorizations subject to the conditions at § 3.206(b)(3) of this subpart.

(4) Disclosure of non-identifiable patient safety work product subject to the conditions at § 3.206(b)(5) of this subpart.

(c) Implementation and enforcement by the Secretary. Privilege shall not apply to (and shall not be construed to prohibit) disclosures of relevant patient safety work product to or by the Secretary if such patient safety work product is needed to investigate or determine compliance, or to seek or impose civil money penalties, with respect to this part or the HIPAA Privacy Rule, or to make or support decisions with respect to listing of a PSO.

42 C.F.R. § 3.206. Confidentiality of patient safety work product.

(a) Confidentiality. Subject to paragraphs (b) through (e) of this section, and §§ 3.208 and 3.210 of this subpart, patient safety work product shall be confidential and shall not be disclosed.

(b) Exceptions to confidentiality. The confidentiality provisions shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(1) Disclosure in criminal proceedings. Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an in-camera determination that:

(i) Such patient safety work product contains evidence of a criminal act;

(ii) Such patient safety work product is material to the proceeding; and

(iii) Such patient safety work product is not reasonably available from any other source.

(2) Disclosure to permit equitable relief for reporters. Disclosure of patient safety work product to the extent required to permit equitable relief under section 922 (f)(4)(A) of the Public Health Service Act, provided the court or administrative tribunal has issued a protective order to protect the confidentiality of the patient safety work product in the course of the proceeding.

(3) Disclosure authorized by identified providers.

(i) Disclosure of identifiable patient safety work product consistent with a valid authorization if such authorization is obtained from each provider identified in such work product prior to disclosure. A valid authorization must:

(A) Be in writing and signed by the provider from whom authorization is sought; and

(B) Contain sufficient detail to fairly inform the provider of the nature and scope of the disclosures being authorized;

(ii) A valid authorization must be retained by the disclosing entity for six years from the date of the last disclosure made in reliance on the authorization and made available to the Secretary upon request.

(4) Disclosure for patient safety activities—

(i) Disclosure between a provider and a PSO. Disclosure of patient safety work product for patient safety activities by a provider to a PSO or by a PSO to that disclosing provider.

(ii) Disclosure to a contractor of a provider or a PSO. A provider or a PSO may disclose patient safety work product for patient safety activities to

an entity with which it has contracted to undertake patient safety activities on its behalf. A contractor receiving patient safety work product for patient safety activities may not further disclose patient safety work product, except to the provider or PSO with which it is contracted.

(iii) Disclosure among affiliated providers. Disclosure of patient safety work product for patient safety activities by a provider to an affiliated provider.

(iv) Disclosure to another PSO or provider. Disclosure of patient safety work product for patient safety activities by a PSO to another PSO or to another provider that has reported to the PSO, or, except as otherwise permitted in paragraph (b)(4)(iii) of this section, by a provider to another provider, provided:

(A) The following direct identifiers of any providers and of affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the workforce, or household members of such providers are removed:

(1) Names;

(2) Postal address information, other than town or city, State and zip code;

(3) Telephone numbers;

(4) Fax numbers;

(5) Electronic mail addresses;

(6) Social security numbers or taxpayer identification numbers;

(7) Provider or practitioner credentialing or DEA numbers;

(8) National provider identification number;

(9) Certificate/license numbers;

(10) Web Universal Resource Locators (URLs);

(11) Internet Protocol (IP) address numbers;

(12) Biometric identifiers, including finger and voice prints; and

(13) Full face photographic images and any comparable images; and

(B) With respect to any individually identifiable health information in such patient safety work product, the direct identifiers listed at 45 CFR 164.514(e)(2) have been removed.

(5) Disclosure of nonidentifiable patient safety work product. Disclosure of nonidentifiable patient safety work product when patient safety work product meets the standard for nonidentification in accordance with § 3.212 of this subpart.

(6) Disclosure for research.

(i) Disclosure of patient safety work product to persons carrying out research, evaluation or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research.

(ii) If the patient safety work product disclosed pursuant to paragraph (b)(6)(i) of this section is by a HIPAA covered entity as defined at 45 CFR 160.103 and contains protected health information as defined by the HIPAA Privacy Rule at 45 CFR 160.103, such patient safety work product may only be disclosed under this exception in the

same manner as would be permitted under the HIPAA Privacy Rule.

(7) Disclosure to the Food and Drug Administration (FDA) and entities required to report to FDA.

(i) Disclosure by a provider of patient safety work product concerning an FDA–regulated product or activity to the FDA, an entity required to report to the FDA concerning the quality, safety, or effectiveness of an FDA–regulated product or activity, or a contractor acting on behalf of FDA or such entity for these purposes.

(ii) Any person permitted to receive patient safety work product pursuant to paragraph (b)(7)(i) of this section may only further disclose such patient safety work product for the purpose of evaluating the quality, safety, or effectiveness of that product or activity to another such person or the disclosing provider.

(8) Voluntary disclosure to an accrediting body.

(i) Voluntary disclosure by a provider of patient safety work product to an accrediting body that accredits that provider, provided, with respect to any identified provider other than the provider making the disclosure:

(A) The provider agrees to the disclosure; or

(B) The identifiers at § 3.206(b)(4)(iv)(A) are removed.

(ii) An accrediting body may not further disclose patient safety work product it receives pursuant to paragraph (b)(8)(i) of this section.

(iii) An accrediting body may not take an accrediting action against a provider based on a

good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety work product in accordance with this Part. An accrediting body may not require a provider to reveal its communications with any PSO.

(9) Disclosure for business operations.

(i) Disclosure of patient safety work product by a provider or a PSO for business operations to attorneys, accountants, and other professionals. Such contractors may not further disclose patient safety work product, except to the entity from which they received the information.

(ii) Disclosure of patient safety work product for such other business operations that the Secretary may prescribe by regulation as consistent with the goals of this part.

(10) Disclosure to law enforcement.

(i) Disclosure of patient safety work product to an appropriate law enforcement authority relating to an event that either constitutes the commission of a crime, or for which the disclosing person reasonably believes constitutes the commission of a crime, provided that the disclosing person believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

(ii) Law enforcement personnel receiving patient safety work product pursuant to paragraph (b)(10)(i) of this section only may disclose that patient safety work product to other law enforcement authorities as needed for law enforcement

activities related to the event that gave rise to the disclosure under paragraph (b)(10)(i) of this section.

(c) Safe harbor. A provider or responsible person, but not a PSO, is not considered to have violated the requirements of this subpart if a member of its workforce discloses patient safety work product, provided that the disclosure does not include materials, including oral statements, that:

(1) Assess the quality of care of an identifiable provider; or

(2) Describe or pertain to one or more actions or failures to act by an identifiable provider.

(d) Implementation and enforcement by the Secretary. The confidentiality provisions shall not apply to (and shall not be construed to prohibit) disclosures of relevant patient safety work product to or by the Secretary if such patient safety work product is needed to investigate or determine compliance or to seek or impose civil money penalties, with respect to this part or the HIPAA Privacy Rule, or to make or support decisions with respect to listing of a PSO.

(e) No limitation on authority to limit or delegate disclosure or use. Nothing in subpart C of this part shall be construed to limit the authority of any person to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with this subpart.

42 C.F.R. § 3.402. Basis for a civil money penalty.

(a) General rule. A person who discloses identifiable patient safety work product in knowing or reckless

violation of the confidentiality provisions shall be subject to a civil money penalty for each act constituting such violation.

(b) Violation attributed to a principal. A principal is independently liable, in accordance with the federal common law of agency, for a civil money penalty based on the act of the principal's agent, including a workforce member, acting within the scope of the agency if such act could give rise to a civil money penalty in accordance with § 3.402(a) of this subpart.

42 C.F.R. § 3.404. Amount of a civil money penalty.

(a) The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section and § 3.408 of this subpart.

(b) The Secretary may impose a civil money penalty in the amount of not more than $11,000.

42 C.F.R. § 3.408. Factors considered in determining the amount of a civil money penalty.

In determining the amount of any civil money penalty, the Secretary may consider as aggravating or mitigating factors, as appropriate, any of the following:

(a) The nature of the violation.

(b) The circumstances, including the consequences, of the violation, including:

(1) The time period during which the violation(s) occurred; and

(2) Whether the violation caused physical or financial harm or reputational damage;

(c) The degree of culpability of the respondent, including:

(1) Whether the violation was intentional; and

(2) Whether the violation was beyond the direct control of the respondent.

(d) Any history of prior compliance with the Patient Safety Act, including violations, by the respondent, including:

(1) Whether the current violation is the same or similar to prior violation(s);

(2) Whether and to what extent the respondent has attempted to correct previous violations;

(3) How the respondent has responded to technical assistance from the Secretary provided in the context of a compliance effort; and

(4) How the respondent has responded to prior complaints.

(e) The financial condition of the respondent, including:

(1) Whether the respondent had financial difficulties that affected its ability to comply;

(2) Whether the imposition of a civil money penalty would jeopardize the ability of the respondent to continue to provide health care or patient safety activities; and

(3) The size of the respondent.

(f) Such other matters as justice may require.

APPENDIX H

STATE CONSTITUTION

Fla. Const. art. X, § 25: Patients' right to know about adverse medical incidents

(a) In addition to any other similar rights provided herein or by general law, 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.

(b) In providing such access, the identity of patients involved in the incidents shall not be disclosed, and any privacy restrictions imposed by federal law shall be maintained.

(c) For purposes of this section, the following terms have the following meanings:

(1) The phrases "health care facility" and "health care provider" have the meaning given in general law related to a patient's rights and responsibilities.

(2) The term "patient" means an individual who has sought, is seeking, is undergoing, or has undergone care or treatment in a health care facility or by a health care provider.

(3) The phrase "adverse medical incident" means medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient, including, but not limited to, those incidents that are required by state or federal law to be reported to any governmental agency or body, and incidents 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.

(4) The phrase "have access to any records" means, in addition to any other procedure for producing such records provided by general law, making the records available for inspection and copying upon formal or informal request by the patient or a representative of the patient, provided that current records which have been made publicly available by publication or on the Internet may be "provided" by reference to the location at which the records are publicly available.