Supreme Court of Florida

No. SC15-2180

JEAN CHARLES, JR., etc., et al.,
Appellants,
vs.

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

[January 31, 2017]

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 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

1. 42 U.S.C. § 299b-22 (2005).

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]

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

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

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 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 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).

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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 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

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.

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, 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]

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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

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

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the Florida Medical Association and the Clarity PSO and others, filed amicus briefs in support of the Appellees.

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, 373 P.3d 563, 573 (Ariz. Ct. 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., 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 (2011) (quoting CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (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 (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 (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 (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 (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 (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] (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (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 (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 (quoting Hines v. Davidowitz, 312 U.S. 52, 67, 61 (1941)).

Ouellette, 479 U.S. at 491-92 (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.

NOT FINAL UNTIL TIME EXPIRES TO FILE REHEARING MOTION, AND IF FILED, DETERMINED.

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.

An Appeal from the District Court of Appeal – Statutory or Constitutional Invalidity

First District - Case No. 1D15-109

(Duval County)

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