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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.

No. 1D15–0109.

District Court of Appeal of Florida, First District.

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

2015. [178 So.3d 103]

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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

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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.

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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 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–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

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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

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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 noncompliance 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

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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 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

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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.

Notes:

[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.

[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.
