UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

FLORIDA HEALTH SCIENCES CENTER, INC. d/b/a TAMPA GENERAL HOSPITAL,

Plaintiff,

v. **Case No. 8:18-cv-238-T-30CPT**

ALEX AZAR, Secretary of the United States Department of Health and Human Service,

Defendant.
_____/

ORDER

THIS CAUSE comes before the Court upon the dispositive Motions for Summary Judgment filed by Plaintiff Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital ("TGH") (Dkt. 58) and Plaintiff-Intervenor Patient Safety Organization of Florida ("PSO Florida") (Dkt. 60), and Defendant's Motion to Dismiss, or, in the Alternative, for Summary Judgment (Dkt. 59). The Court also reviewed AdventHealth's Brief of Amici Curiae (Dkt. 57) and all responses and replies. Upon review of these filings, and being otherwise advised in the premises, the Court concludes that declaratory relief is appropriate because it is undisputed that the documents at issue are patient safety work product and thus entitled to the protection of the Patient Safety Quality Improvement Act of 2005. It is also undisputed that, in the state court action, TGH has been ordered to produce the subject documents. Notably, all of the parties to this action, including the Amici Curiae, agree that the Patient Safety Act preempts Florida's Amendment 7. The Court agrees with respect to the documents at issue in this case.

BACKGROUND

In this action for declaratory relief, TGH seeks a declaration enjoining Defendant the Secretary of the Department of Health and Human Service from imposing mandatory penalties pursuant to the federal Patient Safety and Quality Improvement Act of 2005 ("the Patient Safety Act"). TGH argues that the Patient Safety Act, 42 United States Code, sections 299b-21 through 26, preempts Article X, section 25 of the Florida Constitution (commonly referred to as "Amendment 7") with respect to the documents at issue in the state court action.

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 [.]" Amendment 7 gives patients, including those who become medical malpractice plaintiffs, access to any adverse medical incident record, including incidents involving other patients, created by health care providers. Amendment 7's purpose "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.'" *Florida Hospital Waterman, Inc. v. Buster*, 984 So. 2d 478, 488 (Fla. 2008) (quoting Advisory Op. to the Att'y Gen. Re Patients' Right to Know about Adverse Med. Incidents, 880 So. 2d 617, 618 (Fla. 2004)).

The Patient Safety Act established a system under which health care providers can voluntarily collect and report medical errors in an attempt to educate themselves on preventable medical errors. Specifically:

> 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). 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).

Charles v. S. Baptist Hosp. of Fla., Inc., 209 So. 3d 1199, 1204 (Fla. 2017), cert. denied, 138 S. Ct. 129, 199 L. Ed. 2d 185 (2017) (internal quotations omitted).

The Patient Safety Act created 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. It envisioned that each participating provider or member would establish a patient safety evaluation system ("PSES") in which relevant information would be collected, managed, and analyzed. 42 U.S.C. § 299b–21(6). After the information is collected in the PSES, 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 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," "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.

As explained by the Department of Health and Human Services ("HHS"):

> By establishing strong protections, providers may engage in more detailed discussions about the causes of adverse events without the fear of liability from information and analyses generated from those discussions. Greater participation by health care providers will ultimately result in more opportunities to identify and address the causes of adverse events, thereby improving patient safety overall.

HHS, Agency for Healthcare Research and Quality Patient Safety Organization Program Frequently Asked Questions, https://pso.ahrq.gov/faq, accessed September 4, 2019.

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 HHS. *See* 73 Fed.Reg. at 70,742. The solution was to allow providers to collect all information in one PSES where the information remains protected unless and until the provider determines it must be removed from the PSES for reporting to the State. 73 Fed.Reg. at 70,742; 42 C.F.R. §

3.20(2)(ii) (defining patient safety work product and providing that patient safety work product removed from a PSES is no longer protected).

The Patient Safety Act provides, "[A] person who discloses identifiable patient safety work product in knowing or reckless violation of [the confidentiality provisions] of this section *shall be subject to* a civil monetary penalty of not more than $10,000 for each act constituting such violation." § 299b-22(f)(1) (emphasis added). The regulations implementing the Federal Act provide for the same mandatory penalty. 42 C.F.R. § 3.402(a).

The facts are undisputed that TGH is a member of a certified PSO, the Patient Safety Organization of Florida. On or about December 27, 2017, Lawrence Brawley, a plaintiff in a medical malpractice action pending in the Circuit Court of the Thirteenth Judicial Circuit in and for Hillsborough County, Florida, served an Adverse Medical Incident Request to Produce on TGH. The Request to Produce was served pursuant to Amendment 7 and demanded production of records related to "any adverse medical incident" concerning Brawley and patients other than Brawley.

The record reflects that there are 241 documents potentially responsive to Brawley's Request to Produce that are protected under the Patient Safety Act as patient safety work product. The documents were created within TGH's federally required PSES for submitting to the Patient Safety Organization of Florida ("PSO of Florida") and were submitted to PSO of Florida.

TGH filed a motion for protective order in the state court action, seeking a stay of discovery as to the documents while TGH pursued this action against the Secretary of the United States' Department of Health and Human Services (the "Secretary"). The state court denied the motion and entered an order holding TGH in "willful civil contempt" based on

TGH's failure to produce the documents. The state court ordered TGH to pay into the registry of the court $100.00 per day until such time as TGH complied with the order and produced the documents. (Dkt. 58-1). TGH subsequently appealed the state court's order and that appeal remains pending at this time.

TGH's motion for summary judgment requests, in relevant part, that the Court enjoin the Secretary from enforcing the Patient Safety Act in the state court action. The Secretary's only opposition in this case is that this Court lacks subject matter jurisdiction because TGH "does not face an imminent threat of an enforcement action." (Dkt. 64). The Secretary asserts that it is not obligated to impose a penalty if TGH discloses the documents pursuant to the state court's order. The Secretary also states that it takes no position as to whether the documents are patient safety work product. As to the issue of preemption, the Secretary "agrees that Amendment 7 is preempted by the Patient Safety Act."

As explained below, the Court concludes that Plaintiffs are entitled to summary judgment in their favor because the Court has subject matter jurisdiction over this action. This is the only dispute at issue because all the parties agree that the Patient Safety Act preempts Amendment 7—and it is undisputed that the subject documents are patient safety work product. Also, because the Secretary refuses to stipulate in this case that it will not penalize TGH when TGH produces the patient safety work product in the state court action, the Court must enter a declaration that enjoins the Secretary from imposing the mandatory penalty.

DISCUSSION

I. Subject Matter Jurisdiction

This Court has already determined, on two occasions, that it has jurisdiction to consider this controversy and will not rehash that analysis. *See* (Dkts. 32, 43). The Court adds that, since these rulings (Dkts. 32, 43), TGH has established that it is now faced with daily sanctions in the state court action. It is undisputed that if TGH produces the patient safety work product documents in the state court action, it would be a knowing disclosure subject to the Patient Safety Act's mandatory penalty. The federal statutory penalty is expressed in mandatory terms in both the Patient Safety Act and the HHS's implementing rule. *See* 42 U.S.C. § 299b-21(f)(1); 42 C.F.R. § 3.402(1).

The Secretary's claim that he has not actually taken enforcement action does not eliminate this case or controversy. This is especially true because TGH has not yet disclosed any protected patient safety work product. TGH also points out that the Secretary has refused, throughout this litigation, to "simply assure TGH that it would not be penalized if it produces the PSWP in the state court action," which would end this controversy. (Dkt. 63).

Under these circumstances, the Court agrees with TGH that the Court continues to have subject matter jurisdiction over this action. As the Court noted previously, "TGH is stuck between a rock and a hard place because its production of those documents would then subject it to penalties from HHS for knowingly disclosing patient safety work product in violation of the Federal Act. This threatened enforcement establishes the injury-in-fact requirement that is imminent enough to establish ripeness." (Dkt. 32). Accordingly, the Secretary's motion is denied.

II. Preemption

There is no dispute in this action about whether The Patient Safety Act expressly preempts Amendment 7. Specifically, Plaintiffs and AdventHealth discussed preemption in their well-written filings and the Court agrees with their reasoning. This is because "[a] fundamental principle of the Constitution is that Congress has the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). "[W]hen Congress has made its intent known through explicit statutory language, the courts' task is an easy one." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990); *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 517 (1992) (noting that "a provision explicitly addressing" preemption "provides a reliable indicium of congressional intent with respect to state authority"). "[B]ecause the statute 'contains an express pre-emption clause,' we do not invoke any presumption against pre-emption but instead 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016) (quoting *Chamber of Commerce of United States of Am. v. Whiting*, 563 U.S. 582, 594 (2011)).

The Patient Safety Act states:

> Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), 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[.]

42 U.S.C. § 299b–22(a)(1), (2). This language is clearly an express preemption clause.

"The express preemption clause in the Patient Safety Act demonstrates Congress's intent to supersede any court order requiring the production of documents that meet the definition of patient safety work product." *Daley v. Teruel*, 107 N.E.3d 1028, 1045–46 (Ill. App. Ct. 1st Dist. 2018) (citing *Quimbey v. Cmty. Health Sys. Prof'l Servs. Corp.*, 222 F. Supp. 3d 1038, 1043 (D.N.M. 2016) (finding that "the express language of the [the Patient Safety Act] demonstrates Congressional intent to preempt" any state laws providing for less protection of documents that constitute patient safety work product)); *see also* Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,774 (Nov. 21, 2008) (stating that the Patient Safety Act "generally preempt[s] State or other laws that would permit or require disclosure of information contained within patient safety work product").

Here, it is undisputed that the documents at issue in the state court action are patient safety work product. Accordingly, the Court concludes that the Patient Safety Act preempts Amendment 7 with respect to these documents. The Florida Supreme Court's opinion in *Charles v. Southern Baptist Hospital of Florida, Inc.*, 209 So. 3d 1199 (Fla. 2017), does not persuade the Court otherwise because the documents at issue in *Charles* had not been submitted to a patient safety organization. *See* 209 So. 3d at 1216. The Florida Supreme Court held that the documents at issue were not privileged and confidential patient safety work product. *Id.* Thus, the issue of preemption was not directly at issue, as it is in this case.

In sum, because the Patient Safety Act and its regulations mandate enforcement—and the state court has initiated sanctions for contempt—TGH is entitled to an injunction that enjoins the Secretary from enforcing the Patient Safety Act's privilege and confidentiality provisions in the state court action.

It is therefore **ORDERED AND ADJUDGED** that:

1. Defendant's Motion to Dismiss, or, in the Alternative, for Summary Judgment (Dkt. 59) is denied.

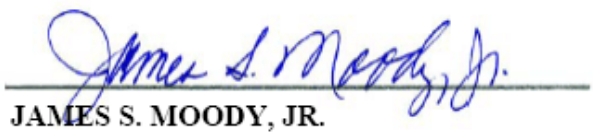
2. The dispositive Motions for Summary Judgment filed by Plaintiff Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital ("TGH") (Dkt. 58) and Plaintiff-Intervenor Patient Safety Organization of Florida ("PSO Florida") (Dkt. 60) are granted to the extent stated herein.

3. The Court declares that: (1) the 241 documents at issue in the state court action are protected patient safety work product; (2) the federal Patient Safety and Quality Improvement Act preempts Article X, section 25 of the Florida Constitution with respect to these 241 documents; and (3) Defendant the Secretary of the United States Department of Health and Human Services is enjoined from enforcing the Patient Safety Act in the state court action, which includes being enjoined from imposing the mandatory penalty against TGH.

4. The Clerk of Court is directed to enter final judgment in favor of Plaintiffs and against Defendant.

5. The Clerk of Court is directed to close this case and terminate any pending motions as moot.

DONE and **ORDERED** in Tampa, Florida on September 5, 2019.



JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel/Parties of Record