UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
GAINESVILLE DIVISION

SHANDS TEACHING HOSPITAL & CLINICS, INC. d/b/a UF HEALTH SHANDS, a Florida non-profit corporation,

Plaintiff,

v. Case No.: 1:17-cv-245-MW-GRJ

THOMAS E. PRICE, in his official capacity as SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES and GEORGE LORENZO MORGAN, an individual,

Defendants.
_____/

NOTICE OF FILING STATEMENT OF INTEREST OF THE UNITED STATES

COMES NOW, Plaintiff, SHANDS TEACHING HOSPITAL & CLINICS, INC. d/b/a UF HEALTH SHANDS (Shands), through its undersigned counsel, and hereby files the attached Statement of Interest of the United States, which was filed in Case No. 2017-CA-000119, *Brawley v. Smith, et al.*, in the Circuit Court of the Thirteenth Judicial Circuit for Hillsborough County, Florida. This Notice of Filing is not intended to delay the resolution of this case or to provide additional arguments to this Court. Rather, it is provided solely to inform the Court and assist it in determining the issues before it.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 3rd day of May, 2019, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF System which will send a Notice of Electronic Filing to the following: Thomas Edwards, Jr., Esq., Edwards & Ragatz, PA, 1965 Beachway Rd.,

Building 1300, Jacksonville, FL 32207, tse@edwardsragatz.com, Counsel for Co-Defendant; D. Andrew Vloedman, III, Esq., Perry, Vloedman & Brady, The Meridien Center 2790 NW 43rd Street, Suite 200, Gainesville, FL 32606, Andy.vloedman@gmail.com., Co-Counsel for Co-Defendant; Bryan Gowdy, Esq. and Meredith Ross, Esq., Creed & Gowdy, P.A., 865 May St, Jacksonville, FL 32204 bgowdy@appellate-firm.com, mross@appellate-firm.com, filings@appellate-firm.com, Co-Counsel for Defendant; and Derek Angell, O'CONNOR & O'CONNOR, LLC 840 S. Denning Drive, Suite 200, DAngell@oconlaw.com Counsel for Plaintiff.

McCUMBER, DANIELS,
BUNTZ, HARTIG, PUIG & ROSS, P.A.

/s/ Derek M. Daniels

DEREK M. DANIELS
Florida Bar No. 060836
4401 W. Kennedy Blvd., Suite 200
Tampa, Florida 33609
(813) 287- 2822 Telephone
(813) 287- 2833 Facsimile
ddaniels@mccumberdaniels.com
adilday@mccumberdaniels.com
kmccann@mccumberdaniels.com
eservice@mccumberdaniels.com
Co-Counsel for Plaintiff

IN THE CIRCUIT COURT OF THE THIRTEENTH JUDICIAL CIRCUIT
IN AND FOR HILLSBOROUGH COUNTY, STATE OF FLORIDA
CIVIL DIVISION

LAWRENCE BRAWLEY,

Plaintiff,
v.

Case No. 17-CA-000119
Division: A

DONALD A. SMITH, M.D.,
UNIVERSITY OF SOUTH FLORIDA
BOARD OF TRUSTEES, and FLORIDA
HEALTH SCIENCES CENTER, INC.,
d/b/a TAMPA GENERAL HOSPITAL,

Defendants.
_____/

STATEMENT OF INTEREST OF THE UNITED STATES

It is in the interest of the United States that Patient Safety Work Product ("PSWP") is protected in this litigation, consistent with federal law, which requires that the Court analyze the purpose for which Tampa General Hospital ("TGH") created the documents that TGH seeks to protect as PSWP. The United States submits this statement of interest to address a matter of importance: reducing preventable medical errors by ensuring that PSWP created for the system of voluntary reporting established by the Patient Safety and Quality Improvement Act of 2005 ("Federal Act"), 42 U.S.C. 299b-21 *et seq*, will remain privileged and confidential. The privileged and confidential nature of PSWP lies at the heart of the system of reporting under which health care providers

voluntarily create PSWP to provide to Patient Safety Organizations (PSOs) with the aim of improving patient safety and the quality of care nationwide.

I. BACKGROUND

Federal Law

1. In 1999, the Institute of Medicine (IOM) issued a seminal report finding that preventable medical errors were responsible for tens of thousands of deaths each year, costing the country tens of billions of dollars annually, and proposing a "national agenda for reducing errors in health care." IOM, *To Err Is Human: Building a Safer Health System* (1999). One of the IOM's most important findings was that, although most medical errors are the result of human factors, most errors are systemic, meaning that they are due to breakdowns in the systems that deliver care. *Id.* at 51-53. To eliminate preventable medical errors and systemic breakdowns, the IOM endorsed voluntary reporting programs that encourage providers to share information about patient safety events so that those events can be analyzed. *Id.* at 9-10, 89-90. Further, because "fears about the legal discoverability of information" can discourage voluntary reporting, the IOM urged Congress to enact legislation protecting the confidentiality of information collected or shared "solely for purposes of improving safety and quality." *Id.* at 10.

2. In 2005, in response to the IOM's findings, Congress enacted the Federal Act, establishing a system under which health care providers can voluntarily report PSWP to PSOs with the aim of improving patient safety and the quality of care nationwide. *See* 42 U.S.C. §§ 299b-21 – § 299b-26.1; *see also* Patient Safety & Quality Improvement, 73 Fed. Reg. 70,732, 70,732 (Nov. 21, 2008). The PSOs aggregate and analyze PSWP and

provide feedback to health care providers with a goal to eliminate preventable medical errors. *See* H.R. Rep. No. 109-197 at 9. The providers receive broad privilege and confidentiality protections for PSWP, which alleviates concerns about PSWP being used against providers, such as in litigation. These broad protections are "intended to encourage the reporting and analysis of medical errors," H.R. Rep. No. 109-197 at 9, and are "required to encourage the reporting of errors and to create an environment in which errors became opportunities for learning and improvement," S. Rep. 108-196 at 3.

3. The Federal Act expressly provides that PSWP is both privileged and confidential "notwithstanding any other provision of Federal, State or local law." 42 U.S.C. §§ 299b-22(a), (b).

4. The Federal Act defines PSWP to mean "any data, reports, records, memoranda, 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). PSWP "does not include a patient's medical record, billing and discharge information, or any other original patient or provider record," 42 U.S.C. § 299b-21(7)(B)(i), or "information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system," 42 U.S.C. § 299b-21(7)(B)(ii).

5. The Federal Act defines "patient safety evaluation system" to mean "the collection, management, or analysis of information for reporting to or by a [PSO]. 42 U.S.C. § 299b-21(6).

6. "Information may become [PSWP] upon collection within a patient safety evaluation system. Such information may be voluntarily removed from a patient safety evaluation system if it has not been reported and would no longer be [PSWP]. As a result, providers need not maintain duplicate systems to separate information to be reported to a PSO from information that may be required to fulfill state reporting obligations. All of this information, collected in one patient safety evaluation system, is protected as [PSWP] unless the provider determines that certain information must be removed from the patient safety evaluation system for reporting to the state. Once removed from the patient safety evaluation system, this information is no longer [PSWP]." 73 Fed. Reg. 70732, 70,742 (Nov. 21, 2008).

7. PSWP is confidential and is not subject to discovery in any administrative or judicial proceeding. 42 U.S.C. 299b-22(a), (b), and (c).

Florida Law

8. In 2004, Florida voters passed Amendment 7 — the "Patients' Right to Know About Adverse Medical Incidents" provision — which added Article X, Section 25 to the Florida Constitution. Art. X, § 25, Fla. Const. Amendment 7 provides that "patients have a right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident." *Id.* Further, Amendment 7 establishes that "[t]he phrase 'have access to any records' means, in

addition to any other procedure for producing such records provided by general law, making the records available for inspection and copying upon formal or informal request by the patient or a representative of the patient . . . ." *Id.*

9. In *Charles v. Southern Baptist Hospital of Florida, Inc. (Charles II)*, the Florida Supreme Court held that the Federal Act did not preempt Amendment 7. 209 So.3d 1199, 1212 (Fla. 2017). Even where the Federal Act and Amendment 7 overlap, a "mandatory disclosure law in [the] state constitution is not preempted by a health care provider's choice to participate in the Federal Act, coupled with its choice to place documents into a patient safety evaluation system." *Id.* at 1214. Further, the Florida Supreme Court held that "adverse medical incident reports" are not PSWP "because Florida statutes and administrative rules require providers to create and maintain these records." *Id*. at 1216. Specifically, the Court ruled that the documents fell within the Federal Act's exception for information that is "collected, maintained, or developed separately, or exists separately," from a patient safety system because "Amendment 7 provides patients with a constitutional right to access these records." *Id.* at 1211.

The Brawley Litigation

10. Tampa General Hospital (TGH) filed a Motion for Protective Order (MPO) requesting that this Court grant a limited protective order related to Plaintiff's Adverse Medical Incident Request to produce documents during the pendency of the Declaratory Action pending in the United States District Court for the Middle District of Florida and only as to the documents subject to that action. In the federal action, TGH asserts that the 248 documents that have been submitted to the Patient Safety Organization of Florida

and are responsive to Plaintiff Brawley's request are privileged and confidential pursuant to the Federal Act. *Florida Health Sciences Center, Inc. v. Azar*, No. 8:18-cv-00238 (M.D. Fla.), Dkt. 17 at ¶ 22. TGH further asserts that the Florida Supreme Court ruled in *Charles II* that these types of documents are not protected and the Florida Constitution mandates disclosure. *See id.* at ¶¶ 24, 34.

11. This Court denied TGH's Motion for Protective Order and ordered TGH to produce the documents to Plaintiff Brawley.

II. DISCUSSION

In its Motion for Protective Order, TGH asserts that some documents responsive to Plaintiff's discovery request, specifically those that have been submitted to PSO Florida, are privileged and confidential pursuant to the Federal Act. Dkt. 48, ¶ 3. TGH further asserts that the Florida Supreme Court decision in *Charles II* mandates the disclosure of these types of documents. Id. at ¶ 4. The United States takes no position as to whether the 248 documents are, in fact, PSWP. The United States' interest is in ensuring proper application of the Federal Act. To the extent the Florida Supreme Court decision in *Charles II* requires the disclosure of PSWP, the decision would conflict with the Federal Act and would be preempted by it. Therefore, in determining whether any of the documents are PSWP and thus may be upheld from production, the Court should apply the Federal Act and determine the purpose for which the documents were assembled or developed to decide whether they are bona-fide PSWP.

A. The Federal Act Preempts the Florida Supreme Court Decision in *Charles II* Insofar As It Requires the Production of PSWP.

"The Supremacy Clause of Art. VI of the Constitution provides Congress with the power to preempt state law." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 368 (1986). "State action may be foreclosed by express language in a congressional enactment . . . ." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001) (citations omitted).

Here, the Federal Act states that: "[n]otwithstanding any other provision of Federal, State, or local law . . . [PSWP] shall be confidential and shall not be disclosed." 42 U.S.C. § 299b–22(b). This express preemption clause in the Federal Act demonstrates Congress's intent to supersede any state law requiring the production of documents that meet the definition of PSWP. *See* 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"). It is clear that the Court must apply the Federal Act to determine the confidentiality and privilege of the documents at issue.

In *Charles II*, the Florida Supreme Court concluded incorrectly that mandatory state disclosure laws were not preempted by the Federal Act. 209 So.3d 1199, 1212 (Fla. 2017). *Charles II* turns the Supremacy Clause on its head by allowing general Florida document disclosure laws to nullify the federal privilege and confidentiality protections for PSWP. States may not eliminate the privilege and confidentiality protections in the Federal Act—and gut the federal program designed to improve health outcomes through voluntary remediation of preventable errors—by foisting state disclosure requirements on providers. The potential programmatic impact is significant because *Charles II* has no

limiting principle. The scope of records covered by Amendment 7 is unbounded and could require the wholesale production of PSWP in litigation across Florida.

The Court should not automatically require the production of all documents that TGH turned over to the PSO, as such a categorical approach runs contrary to the Federal Act. Rather, the Court should conduct a review of the disputed documents to determine whether any PSWP exists among them, as well as ensure that any PSWP is protected consistent with federal law.

B. The Federal Act Sets the Standard for Reviewing TGH's Documents

The Federal Act is the standard for review of the documents subject to the Court's July 11, 2018 Order to determine whether they qualify as protected PSWP. In conducting its review, the Court must look to the broadly defined categories of material listed in the Federal Act: ". . . any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" which "could result in improved patient safety … quality, or … outcomes;" and are "assembled or developed" for the purpose of reporting to a PSO and in fact be reported to a PSO. 42 U.S.C. § 299b-21(7)(A). Application of any other standard may contravene Congress' intent to keep PSWP privileged and confidential.

1. The Court Should Determine the Purpose for Which the Documents Were Assembled or Developed.

The purpose for which the documents were assembled or developed must be known to determine with any accuracy whether the documents subject to the Court's July 11, 2018 Order qualify as PSWP.

The relevant portion of the definition of PSWP in the Federal Act states that PSWP is "data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" which "could result in improved patient safety … quality, or … outcomes" and are "assembled or developed by a provider for reporting to a [PSO] and are reported to a [PSO]." 42 U.S.C. § 299b-21(7)(A)(i). A common sense reading of this language is that it describes information that a provider assembles or develops for the purpose of reporting to a PSO—not information that must be created for some other purpose. As the Florida Supreme Court correctly stated, [PSWP] ''does not include a patient's medical record, billing and discharge information, or any other original patient or provider record." *Charles II*, 209 So.3d 1199, 1210 (Fla. 2017).

In May 2016, HHS issued guidance to "clarify what information that a provider creates or assembles can become [PSWP]." *HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations*, 81 Fed. Reg. 32655 (May 2016) ("HHS Guidance"). The guidance explains that "the reporting pathway is how providers generally create most of their PSWP." *Id*. at 32656. Accordingly, confidentiality and privilege determinations of PSWP are rooted in the purpose for which each document was assembled or developed and is a critical factor in determining whether information is bona-fide PSWP. Under the Federal Act, the Court must determine with specificity the purpose for which the documents were assembled or developed to determine with accuracy whether the documents are, indeed, PSWP.

The HHS guidance provides examples of determinations as to whether information is PSWP and makes clear that the answer depends squarely on the purpose

for which the information is assembled or developed. One example explains that "[a] list of provider staff who were present at the time a patient incident occurred" is not PSWP if prepared "[t]o ensure appropriate levels of clinician availability (e.g., routine personnel schedules), or for compliance purposes," but may be PSWP if "following the incident, the provider originally assembles the list for reporting to a PSO so the PSO can analyze the levels and types of staff involved in medication errors." *Id*. at 32656. Another example explains that "[w]ritten reports of witness accounts of what they observed at the time of a patient incident" is not PSWP if prepared "[f]or internal risk management (claims and liability purposes)," but may be PSWP if prepared "for reporting to a PSO so that the richness of the narrative can be mined for contributing factors." *Id*. These examples demonstrate the fact-specific nature of determining whether information is PSWP, as well as the fact that purpose is a key area of inquiry in making document-by-document privilege determinations.

2. *PSWP Does Not Include Information That is Separate From a Patient Safety Evaluation System.*

The Federal Act also excludes "information … collected, maintained, or developed separately, or [that] exists separately, from a patient safety evaluation system" from the definition of PSWP. 42 U.S.C. § 299b-21(7)(B)(ii). In *Charles II*, the Florida Supreme Court held that any document that may potentially be reported pursuant to state record keeping and reporting must exist separately from the patient safety evaluation system and therefore cannot be PSWP. This interpretation is incorrect; it contradicts the Federal Act, HHS regulations, and HHS clarifying guidance because it equates records "collected, maintained, or developed separately," with records "not created solely for the

purpose of submission to a patient safety evaluation system." In fact, "information … collected, maintained, or developed separately, or [that] exists separately, from a patient safety evaluation system" refers to where information is stored—either inside or outside the patient safety evaluation system. Further, this interpretation from *Charles II* runs contrary to the HHS' assurances that providers may place information into their patient safety evaluation system with the expectation of protection and may later remove the information if the provider later determines that it must be reported to the State. 73 Fed. Reg. at 70,732, 70,742 (Nov. 21, 2008). Privilege attaches to information created within the patient safety evaluation system immediately upon collection of the information and not at the time that the information is sent to a PSO. *Id*. at 70,741.

As indicated above, this overbroad interpretation subordinates the federal privilege and confidentiality provisions in the Federal Act to Florida law and fails to protect PSWP from state discovery laws. If the "exists separately" exception is read to cover information that "exists" in any part because of a state law requirement, it would defeat Congress's intent to preempt all state law requiring the production of documents that meet the definition of PSWP. The defeat of federal preemption would, in turn, defeat the main purpose of the Federal Act by gutting the incentive for health care providers to voluntarily report PSWP to PSOs and remediate preventable systemic medical errors.

The Court here should ask a straightforward and factual question to determine whether the documents qualify for this exception: Did TGH maintain the documents in its patient safety evaluation system for reporting to PSO Florida? If the answer to that

question is "yes," then the documents are not excluded from the definition of PSWP under the exception in 42 U.S.C. § 299b-21(7)(B)(ii).

III. CONCLUSION

The Court should apply the Federal Act in its review of the documents in a manner consistent with federal law as intended by Congress, and further explained in HHS guidance, to ensure that any PSWP that may be included in the disputed documents is protected from disclosure.

Respectfully submitted,

MARIA CHAPA LOPEZ
United States Attorney

By: */s/ Michael R. Kenneth*

MICHAEL R. KENNETH
Assistant United States Attorney
Florida Bar No. 44341
400 North Tampa Street, Suite 3200
Tampa, Florida 33602
Telephone: 813-274-6000
Facsimile: 813-274-6198
E-Mail: michael.kenneth@usdoj.gov

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing has been sent via E-mail on the 1st day of February 2019 to the following parties:

Chris M Limberopoulos
Kevin M Sparkman
Florida Law Group
407 N. Howard Avenue, Suite 100
Tampa, FL 33606
kevin@floridalawgroup.org

Derek M Daniels
Mason B Brinkley
McCumber, Daniels, Buntz, Hartig, Puig & Ross, P.A.
4401 West Kennedy Boulevard, Suite 200
Tampa, FL 33609
ddaniels@mccumberdaniels.com
mbinkley@mccumberdaniels.com

Derek B Alvarez
Genders Alvarez Diecidue
2307 West Cleveland Street
Tampa, FL 33609
GADeservice@gendersalvarez.com

Erin B Reynolds
Hughes Hamilton Rice
Bush Graziano Rice & Platter, P.A.
100 S. Ashley Drive, Suite 1400
Tampa, FL 33602
ereynolds@bgrplaw.com

Michael J Trentalage
Trentalange & Kelly, P.A.
218 N. Dale Mabry Highway
Tampa, FL 33609
mjt@tktampa.com

/s/ Michael R. Kenneth
Michael R. Kenneth
Assistant United States Attorney