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

CASE NO.: 16-2012-CA-002677
DIVISION: CV-H

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

Plaintiffs,

vs.

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

Defendants.

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

I. Background and Procedural Posture

This is a medical malpractice case. The Plaintiffs have alleged that Marie Charles suffered neurological injuries as the result of the negligence of the Defendants while she was a patient at Baptist Medical Center - South and Baptist Medical Center - Downtown. Specifically, the Plaintiffs allege that Marie Charles was subject to an unnecessary, and contra-indicated, surgery while under the care of the Defendants at Baptist Medical Center - South. They further

allege that, due to complicating medical factors known to the Defendants, Marie Charles suffered a stroke while undergoing this surgery. Finally, the Plaintiffs allege that the treatment given to Marie Charles at Baptist Medical Center - South and Baptist Medical Center - Downtown after suffering her stroke was untimely and negligent.

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

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

In addition, each request contained the following explanatory language:

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

(Emphasis added).

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

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

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

The parties have now reached an impasse. Baptist has produced Annual Reports, Code 15 Reports, and two incident reports relating to Marie Charles. It maintains its objection under the PSQIA to the production of any other documents. On June 24, 2014 the Plaintiffs brought this issue back before the Court. The Plaintiffs seek an order granting their motion to compel the production of all Amendment 7 Documents that were created or maintained by Baptist as required by state or federal law or regulation or credentialing entity requirements, or which were provided by Baptist to any state or federal agency or other credentialing entity pursuant to any obligation or requirement in any state or federal law, rule, regulation, or licensing or accreditation obligation. Baptist asks that the Court deny the Plaintiffs' motion to the extent it seeks documents not already produced.

II. Analysis

The Plaintiffs' Motion to Compel Production of Amendment 7 Documents deals with the

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

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

Since 2004, Amendment 7 has been the subject of extensive litigation. Florida appellate courts have ruled on issues relating to Amendment 7, turning back several common law and statutory challenges to the law. *See*: Cedars Healthcare Group v. Martinez, 39 Fla. L. Weekly, S60 (Fla. Jan. 30, 2014); Florida Hospital Waterman v. Buster, 984 So.2d 478 (Fla. 2008); West Florida Regional Medical Center v. Lynda See, et al., 70 So.3d 1 (Fla. 2012); Morton Plant Hospital Association, Inc. v. Shabhas, 960 So.2d 820 (Fla. 2nd DCA 2007); Columbia Hospital Corporation of South Broward v. Fain, 16 So.3d 236 (Fla. 4th DCA 2009); Baldwin v. Shands Teaching Hospital and Clinics, Inc., 45 So.3d 119 (Fla. 1st DCA 2010); Dania Acevedo v. Doctors Hospital, Inc., 68 So.3d 949 (Fla. 3rd DCA 2011); Lakeland Regional Medical Center v. Neely, 8 So.3d 1268 (Fla. 2nd 2009); Florida Eye Clinic v. Mary T. Gmash, 14 So.3d (Fla 5th DCA 2009).

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

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

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

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

> (B) CLARIFICATION
>
> (i) ...
>
> (ii) Information described in subparagraph (A) **does not** include information that is

collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

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

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

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

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

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

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

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

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

passage of the Patient Safety Act.

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

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

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

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

Id. at 70744 (Emphasis added).

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

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

Documents are not PSWP if those documents were collected or maintained for a purpose other than submission to a PSO or for a dual purposes. Any documents that are collected pursuant to a healthcare provider's obligation to comply with federal, state, or local laws, or accrediting or licensing requirements are not privileged under the PSQIA, and such documents do not gain privilege by being submitted to the PSO.

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

The language of the Plaintiffs' Third Request for Production is tailored to ask for only

those documents created or maintained pursuant to statutory, regulatory, licensing, or accreditation requirements. Since these documents are not PSWP, they are not privileged or protect from discovery under the PSQIA.

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

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

Accordingly, it is

ORDERED:

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

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

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

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

ORDER ENTERED

JUL 30 2014

/s/ WADDELL A. WALLACE

Waddell A. Wallace, III
Circuit Judge

Copies furnished to all counsel of record.