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CLIENT ADVISORY

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Florida Court Recognizes PSO Protections Preempt State Constitution, Acknowledge Congress' Intent to Enable Protected, Provider-Driven Patient Safety Activities

On October 28, 2015, Florida's First District Court of Appeals issued an opinion in *Southern Baptist Hospital of Florida, Inc. v. Charles*[1] that is of great importance to Patient Safety Organizations (PSOs) and healthcare providers who currently participate with, or are considering joining a PSO. In the opinion, the Court unanimously overruled a Florida circuit court's narrow interpretation of the federal Patient Safety and Quality Improvement Act (Patient Safety Act) and its implementing regulations, ruling that the federal law expressly and impliedly preempts overbroad discovery under Florida's Amendment 7, and that information properly delineated as Patient Safety Work Product (PSWP) under the federal law is not subject to discovery under the State's Amendment 7. The Court also acknowledged that providers have the authority to designate what documents constitute protected PSWP, and unless there is an allegation that the provider has failed to comply with state reporting or recordkeeping laws, courts should not be involved in the provider's participation under the Patient Safety Act.

Background

In the *Charles* case, the plaintiff alleged that neurological injury occurred due to the Hospital's negligence. In discovery, plaintiff filed broad requests pursuant to Amendment 7, a Florida Constitutional provision that gives individuals "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."[2] In response, the Hospital produced Code 15 Reports and Annual Reports required to be maintained by Florida Statutes §§ 395.0197(6)-(7), and two occurrence reports specific to plaintiff that had been extracted from the Hospital's Patient Safety Evaluation System (PSES) before they were reported to Florida PSO. The Hospital also disclosed that additional occurrence reports and other documents that were potentially responsive existed, but exerted these materials were privileged and confidential as PSWP under the Patient Safety Act. After all, the purpose of a PSO and its participating providers is to improve patient safety, and to be able to do so with an expectation of privilege and confidentiality.

Plaintiff moved the circuit court to compel production of the withheld documents, arguing that the Patient Safety Act only protects documents created solely for the purpose of submission to a PSO, and therefore documents may not constitute PSWP if collected or maintained for any other purpose, or for dual purposes, or if the information is in any way related to a provider's obligation to comply with federal, state, or local licensure or accrediting obligations. The circuit court agreed and granted plaintiff's motion to compel production, holding 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 Patient Safety Act]."[3]

Ruling

On appeal, the First District Court of Appeals overruled the circuit court by acknowledging the Patient Safety Act's protections applied to the withheld documents. By meeting the Act's "clear" and "unambiguous" definition of PSWP, the Court held the documents are protected. Specifically, (1) the Hospital placed the documents in its PSES, where they remained pending submission to Florida PSO; and also, (2) the documents did not meet the definition of what is *not* PSWP, meaning the documents were not original patient records and were not collected, maintained, or

[1] *Southern Baptist Hosp. of Fla., Inc. v. Charles*, 2015 Fla. App. LEXIS 16007 (Fla. Dist. Ct. App. 1st Dist. Oct. 28, 2015)
[2] Florida Constitution, Article X, Section 25.
[3] *Charles v. Southern Baptist Hosp. et al.*, Duval County, Case No. 2012□CA□002677 (July 30, 2014).

developed separately from the PSES, nor were they collected for a separate purpose. The Court opined that the lower court erred in holding that documents may not simultaneously be PSWP and also meet a state reporting requirement, because this would incorrectly impose additional terms on the definition of PSWP. Federal protection under the Patient Safety Act and state compliance need not be mutually exclusive.

The Court further acknowledged that the Patient Safety Act gives providers flexibility to collect and maintain its information as it chooses. The statutory definition of PSWP simply offers precautionary language that the PSES and designation of PSWP may not limit reporting or recordkeeping requirements under state or federal law. However, if providers fail to comply with state or federal reporting and recordkeeping laws, the consequences of noncompliance should be addressed by the corresponding licensing or accrediting agencies as would have occurred before passage of the Patient Safety Act. As first articulated in the dissent of *Tibbs v. Bunnell*, a Kentucky PSO case pending review with the United States Supreme Court, the proper remedy for noncompliance with reporting and recordkeeping laws is not for a trial court to "rummage through" the provider's PSES in search of documents that could possibly serve "dual purposes."[4] Notably, the Hospital in *Baptist* had already produced to plaintiff all Code 15 Reports and Annual Reports required to be reported under Florida law, therefore the Court of Appeal quashed plaintiff's motion to produce the additional occurrence reports that were potentially responsive to plaintiff's over-broad discovery request. The Court concluded this section of its analysis in stating,

> "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."[5]

The Court then provided a brief preemption analysis, ruling that the Patient Safety Act expressly preempts broad discovery requests under Amendment 7, clearly prohibiting discovery of any responsive documents that are designated by the provider as PSWP. The clear language of the Patient Safety Act, as well as Congress' imposition of civil monetary penalties for improper disclosures of PSWP make clear Congress' intent to expressly preempt state law including Amendment 7. The Court also ruled that Amendment 7 is impliedly preempted by the Act because compliance with both federal and state law would be impossible. Documents that meet the definition of PSWP are categorically protected and excluded from production, and to produce PSWP in response to an Amendment 7 discovery request would contradict the Patient Safety Act.

This ruling in *Charles* is a clear step forward as courts across the nation continue to struggle with applying the scope of the Patient Safety Act's privilege in the presence of conflicting state law. Although this ruling will set limited precedent in Florida and may be appealed to the Florida Supreme Court, the ruling offers a logical application of Congress' legislative intent to enable provider-driven patient safety activities without neglecting state and federal reporting or recordkeeping obligations. The Patient Safety Act faces continuing legal challenges across the country, and as of the date of this advisory, it is not yet clear whether the United States Supreme Court will choose to rule on the Kentucky Supreme Court's unfavorable ruling in *Tibbs v. Bunnell*. At this time, hospitals with more than 50 beds must implement a PSES for reporting to or by a PSO by January 1, 2017 in order to contract with Qualified Health Plans.[6]

If you have questions relating to recent PSO litigation, or any other aspects of PSO development, strategy, implementation, and policies, please contact Page Gravely (pgravely@hdjn.com), Molly Huffman (mhuffman@hdjn.com), or Andrew Schutte (aschutte@hdjn.com) by email or phone at (866) 967-9604. Additional information about Hancock, Daniel, Johnson & Nagle, P.C. is available on the firm's website at www.hdjn.com.

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[4] *Southern Baptist Hosp. of Fla., Inc. v. Charles*, 2015 Fla. App. LEXIS 16007 (Fla. Dist. Ct. App. 1st Dist. Oct. 28, 2015)
[5] *See Charles*, p. 18.
[6] Patient Protection and Affordable Care Act, Section 1311(h). *See also* 78 Fed. Reg. 72322 (Dec. 2, 2013).

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