

## **TALLAHASSEE MEMORIAL HEALTHCARE, INC. V. WILES: UPDATE ON THE CONFLICT BETWEEN THE FEDERAL PSQIA AND FLORIDA'S AMENDMENT 7**

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This Spring, the Florida Supreme Court will again review the intersection between the Patient Safety and Quality Improvement Act of 2005 (“PSQIA”) and Florida’s Amendment 7, the state constitutional provision requiring a right of access to certain records of healthcare providers. The opportunity comes after Florida’s First District Court of Appeal held that the PSQIA expressly preempts Amendment 7 to the extent that the state law would compel the disclosure of information considered confidential and privileged Patient Safety Work Product (“PSWP”) in *Tallahassee Memorial Healthcare, Inc. v. Wiles*. The *Wiles* case is the first chance for the Supreme Court of Florida to revisit the issue after a 2017 decision in *Southern Baptist Hospital of Florida, Inc. v. Charles*.<sup>1</sup>

### **BACKGROUND ON THE PSQIA**

Congress passed the PSQIA to establish a voluntary, confidential, and non-punitive system of data sharing of healthcare errors in order to improve patient safety and healthcare quality through the creation of Patient Safety Organizations (“PSOs”). Providers participating with PSOs have an opportunity to collect, analyze, and create confidential and privileged PSWP within a protected space that can then be shared with PSOs to further their quality improvement efforts. PSOs collect PSWP from participating providers and develop best practices, recommendations, and shared learnings.

Understanding that providers would be hesitant to share data about real or potential errors, and that the candor of the data is necessary to maximize improvement opportunities, PSWP is subject to mandatory protections under the federal statute, including that the information is not subject to discovery, court order, or subpoena, and is not admissible in evidence (among other protections). 42 U.S.C. § 299b-22(a). Importantly, the confidentiality and privilege requirements under the PSQIA are “notwithstanding any other provision of state or local law.” 42 U.S.C. § 299b-22(a)-(b).

Certain information cannot be PSWP under the statute, and a provider may not use its PSO participation to avoid external reporting obligations, such as required reporting to a state agency. A provider must work to ensure that its Patient Safety Evaluation System (PSES), where PSWP is collected for potential reporting to a PSO, is designed to ensure compliance with the federal statute.

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<sup>1</sup> Please see Hancock Daniel’s 2017 advisory on *Charles* here: <https://hancockdaniel.com/2017/02/florida-supreme-court-reverses-charles-decision-holding-psqia-protection-not-apply-documents-required-state-law/>.

## FLORIDA'S AMENDMENT 7 AND ADVERSE INCIDENT REPORTING REQUIREMENTS

A year before the enactment of the PSQIA, Florida's voters approved an amendment to the state's constitution providing a right of access to certain records of healthcare providers. Specifically, "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." [Fla. Const. Art. X, § 25\(a\)](#). An adverse medical incident is defined to mean:

[M]edical 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 death of a patient, including, but 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.

[Fla. Const. Art. X, § 25\(c\)\(3\)](#).

Amendment 7 is not a reporting statute, but rather a right of access. However, Florida statutes require reporting of certain adverse incidents. For example and specifically, [Fla. Stat. Ann. § 395.0197](#) mandates that healthcare facilities document and report certain information on "adverse incidents" to Florida's Agency for Health Care Administration ("AHCA"). An "adverse incident," which is defined more narrowly than an adverse incident under Amendment 7, means an event over which health care personnel could exercise control and that is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and that results in one of a number of specified injuries.

### TALLAHASSEE MEMORIAL HEALTHCARE, INC. V. WILES

The case in question, [Tallahassee Memorial Healthcare, Inc. v. Wiles](#), stemmed from a medical malpractice case during which the plaintiff requested the hospital disclose any "incident reports" related to the birth of their son, who experienced respiratory difficulties at birth and was later diagnosed with cerebral palsy. The Hospital identified a Safety Event Report, but declined to produce, claiming the report was confidential and privileged PSWP, protected by the PSQIA. Notably, this report was not required to be reported to Florida's AHCA or required to be collected and maintained under state law. Following a motion to compel, the Hospital argued that because the report was privileged under the PSQIA and because the PSQIA preempted any right of access under Amendment 7, the motion to compel should be denied. The trial court ruled that the report was not privileged and ordered its production. The matter was then appealed to the Florida First District Court of Appeal.

Before conducting its analysis, the Court compared the facts to those at issue in *Charles*. The Court noted that, in *Charles*, because the state high court had found the documents at issue were not PSWP because of their maintenance requirement under state law and also because they had not been reported to a PSO, the facts were distinguishable. In *Charles*, the Florida Supreme Court's discussion of preemption was essentially moot as the court had found the documents at issue were not PSWP.

In *Wiles*, the Court concluded that the Safety Event Report in question was entitled to privilege and confidentiality under the PSQIA for two reasons: (1) unlike the documents at issue in *Charles*, the report was submitted to the hospital's PSO; and (2) the document did not meet the definition of an "adverse incident" report under [Fla. Stat. Ann. § 395.0197](#), nor was it sent to a state regulatory entity or required to be filed under state law.

The Court also noted that regardless of whether the preemption language in *Charles* was dicta, the case was not controlling as *Charles* addressed preemption in the context of documents that were not PSWP. In contrast, the Safety Event Report in question in *Wiles* was PSWP. The Court further held that the PSQIA language expressly preempts Amendment 7 because of the plain language of the statute, and that the PSQIA also impliedly “preempts Amendment 7 because the two laws conflict in a way that it is impossible for Tallahassee Memorial to comply with both.” In sum, producing a document that meets the definition of PSWP in response to an Amendment 7 discovery request would contravene the PSQIA. Thus, the Court quashed the order of the circuit court requiring disclosure of the Safety Event Report. The Court also certified the following questions of great public importance to the Florida Supreme Court:

- 1) Whether Tallahassee Memorial's "Safety Event Report No. 67593" is privileged and confidential "patient safety work product" under the Federal Patient Safety Act of 2005?
- 2) If the report is privileged and confidential under the Federal Patient Safety Act of 2005, whether that federal law preempts the report's disclosure under Article X, section 25 of Florida's Constitution (Amendment 7)?

The appellate court denied a rehearing in this case on December 27, 2022, and the Florida Supreme Court docketed the case on January 25, 2023.

## CONCLUSION

While the Florida Supreme Court has yet to weigh in on the questions certified, the decision of the appellate court is positive for providers in Florida (and elsewhere) participating with a PSO. The opinion again highlights the importance of making sure any PSES is carefully designed to ensure providers simultaneously maintain compliance with the PSQIA and any applicable state laws.

If you have questions relating to recent PSO litigation in Florida or elsewhere, or other aspects of PSO development, strategy, implementation, and policies, please contact a member of Hancock Daniel's [Patient Safety and PSOs](#) Team.

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