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IN THE SUPREME COURT OF FLORIDA

TALLAHASSEE, FLORIDA

LENNOX WILES, a minor, by and through his parents and natural guardians, JADE WILES and JUSTIN WILES, and JADE WILES and JUSTIN WILES, individually,

Petitioners,

Case No. SC23-118

v.

TALLAHASSEE MEMORIAL HEALTHCARE, INC.,

Respondent.
___________________________/

INITIAL BRIEF OF PETITIONERS

On review from the District Court of Appeal, First District

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INTRODUCTION

The Wiles family sued Tallahassee Memorial Healthcare (TMH or the Hospital) for medical malpractice that resulted in their son Lennox developing cerebral palsy. They alleged that his injuries were due to negligent care during and after Lennox's delivery. In discovery, they requested that TMH produce any incident reports that it created concerning the circumstances of this treatment under section 395.0197(1)(e), Fla. Stat. In response, TMH identified a single incident report (the Wiles Report)—which it later admitted was created to comply with Florida law's reporting and recordkeeping requirements. But TMH objected to producing it based on an asserted privilege under the Patient Safety and Quality Improvement Act (PSQIA or the Act).

Based on TMH's concessions regarding the Wiles Report, the trial court ordered TMH to produce the Wiles Report, applying this Court's binding decision in *Charles v. Southern Baptist Hosp. of Fla., Inc.*, 209 So. 3d 1199 (Fla. 2017). In a split decision, the First District granted TMH's petition for writ of certiorari, holding instead that the Wiles Report was not an adverse incident report under Florida law, and that it was privileged under the PSQIA. It went further to hold

that the PSQIA preempts Article 10, section 25, of the Florida Constitution, commonly called Amendment 7.

The First District improperly granted certiorari relief. The trial court did not depart from clearly established law. To the contrary, the trial court was required to order the disclosure of the Wiles Report because Florida law required TMH to collect and maintain information regarding Lennox Wiles's transfer to the NICU, and Florida law expressly provides that such information is discoverable. *See* § 395.0197(4), Fla. Stat. ("The incident reports … are subject to discovery…"). The PSQIA expressly preserves such state-law obligations. *See Charles*, 209 So. 3d at 1211 (quoting 42 U.S.C. § 299b-21(7)(B)(ii)). There is no PSQIA privilege for information compiled under those state-law obligations. Because there is no privilege, the First District had no occasion to consider whether the PSQIA preempts Amendment 7.

STATEMENT OF THE CASE AND FACTS

The PSQIA itself is part of a framework of voluntary and mandatory incident reporting, consisting of the Act itself, regulations promulgated under the Act, as well as other statutes and regulations. Understanding why the First District erred requires a discussion of

that framework. Because a full understanding of applicable federal and state laws informs an understanding of which facts are material, this Brief discusses the legal backdrop first, and then the facts of this case.

A. Patient Safety and Quality Improvement Act (PSQIA).

Congress enacted the PSQIA in 2005, and it is codified at 42 U.S.C. §§ 299b-21 *et seq.* The Act provides for the creation and maintenance of a patient safety database of information reported to patient safety organizations (PSOs) by healthcare providers (including hospitals). *See* 42 U.S.C. § 299b-23. The Act does not require providers to report to PSOs; their decision to do so is voluntary. (R.944); *Charles*, 209 So. 3d at 1214; HHS, Patient Safety and Quality Improvement Act of 2005 Statute and Rule[1] ("The [PSQIA] establishes a voluntary reporting system…"). PSOs are certified entities, separate from providers, which collect, analyze, develop, disseminate, and use information to improve patient safety. *See* 42 U.S.C. §§ 299b-21(5), 299b-24. A related term of art is a patient safety evaluation system (PSES); it is defined as "the collection, management, or analysis of

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[1] Available at hhs.gov/hipaa/for-professionals/patient-safety/statute-and-rule/index.html (last visited Sept. 8, 2023).

information for reporting to or by a [PSO].” *Id.* § 299b-21(6). The Act makes privileged certain information reported to PSOs. *Id.* § 299b-22.

Under the Act, information recorded and reported by a hospital can fall into two categories, defined by subparagraphs (A) and (B) of paragraph (7) of 42 U.S.C. § 299b-21. The first category, “patient safety work product” (PSWP), is defined in subparagraph (A) and consists of “any data, reports, records, memorandum, analyses (such as root cause analyses), or written or oral statements” that satisfy any one of three alternative sub-categories. *Id.* § 299b-21(7)(A). One of these sub-categories, information developed by a PSO, is not at issue in this case. *See id.* § 299b-21(7)(A)(i)(II). The two other sub-categories that TMH has argued apply in this case are:

> (i) is “assembled or developed by a provider for reporting to a [PSO] and [is] reported to a [PSO]”; or
>
> (ii) “identif[ies] or constitute[s] the deliberations or analysis of, or identif[ies] the fact of reporting pursuant to, a [PSES].”

Id. § 299b021(7)(A)(i)(I) & (ii). Information fitting into one of these sub-categories is generally privileged PSWP, *see* 42 U.S.C. § 299b-22, but

subparagraph (B) limits the definition of PSWP and excludes certain compilations of information from that definition.

Subparagraph (B) is the second category of information: non-privileged information that is excluded from the PSQIA's definition of PSWP. This category is also broken down into sub-categories. *Id.* § 299b-21(7)(B)(i) & (ii). One sub-category consists of "a patient's medical record, billing and discharge information, or any other original patient or provider record." *Id.* § 299b-21(7)(B)(i). The Act does not define "original patient or provider record."

The other sub-category of non-privileged information, defined in clause (ii) of subparagraph (B) is called "separate information":

> (ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a [PSES]. *Such separate information or a copy thereof reported to a [PSO] shall not by reason of its reporting be considered [PSWP].*

Id. § 299b-21(7)(B)(ii).[2]

The final, third clause of subparagraph (B) preserves, rather than preempts, certain state-law reporting and recordkeeping

[2] All emphasis is added unless otherwise noted.

obligations. It states that "nothing in [the PSQIA] shall be construed to limit" the following:

> (I) the discovery of or admissibility of information described in this subparagraph [(B)] in a criminal, civil, or administrative proceeding;
>
> (II) *the reporting of information described in this subparagraph [(B)] to a Federal, State, or local governmental agency* for public health surveillance, investigation, or other public health purposes or health oversight purposes; or
>
> (III) *a provider's recordkeeping obligation* with respect to information described in this subparagraph [(B)] *under Federal, State, or local law.*

42 U.S.C. § 299b-21(7)(B)(iii).

The PSQIA also contains an anti-preemption provision, stating that nothing in the Act should be construed "as preempting or otherwise affecting any State law requiring a provider to report information that is not [PSWP]." 42 U.S.C. § 299b-22(g)(5).

Regarding subparagraph 299b-21(7)(B)(iii), "information described in this subparagraph" means non-privileged information described in *subparagraph (B)*, not privileged PSWP information described in *subparagraph (A)*.[3] In other words, a provider cannot use

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[3] *See Koons Buick Pontiac GMB, Inc. v. Nigh*, 543 U.S. 50, 60-61 (2004) (explaining that both the House and Senate legislative manuals

PSWP (defined by subparagraph (A)) instead of non-privileged information (defined by subparagraph (B)) to satisfy its state-law reporting and recordkeeping obligations; it must use non-privileged information (defined by subparagraph (B)).

B. Federal regulations and HHS's guidance on the PSQIA.

In 2008, pursuant to Congress's directive, the U.S. Department of Health and Human Services (HHS) adopted rules to implement the PSQIA. *See* Patient Safety and Quality Improvement Act, 73 Fed. Reg. 70732 (Nov. 21, 2008) (codified at 42 C.F.R. pt. 3). The public was given notice of the proposed rules and an opportunity to comment. *Id.* at 70733. HHS responded to the comments, modified the proposed rules, and provided guidance on how it would implement and interpret the PSQIA. *Id.* at 70733-93.

1. The PSQIA requires providers to use non-PSWP information to satisfy their external obligations.

HHS addressed public comments concerning how reporting information to PSOs would work in conjunction with reporting information to state authorities. It interpreted § 299-21(7) to mean that

designate paragraphs with Arabic numerals and subparagraphs with uppercase letters).

providers had to meet their obligations to oversight agencies with non-privileged information defined in subparagraph (B), not PSWP defined in subparagraph (A). *See* 73 Fed. Reg. at 70742 ("Even when laws or regulations require the reporting of the information regarding the type of events also reported to PSOs, the [PSQIA] does not shield providers from their obligation to comply with such requirements. These external obligations must be met with information that is not [PSWP]....").

Further, HHS stated that PSWP does *not* include information to which "oversight entities" had "*access prior to the passage of the [PSQIA]*" and directed that such entities "*continue[d] to have access to this original information in the same manner as such entities have had access* prior to the passage of the [PSQIA]." *Id.*

2. The no-duplication guidance.

In the same guidance, HHS interpreted the PSQIA to permit providers to collect information in a PSES without creating a duplicate system for state-law recordkeeping obligations. *Id.* at 70742. HHS provided its "no-duplication" guidance to provide "flexibility" to providers to protect "information as [PSWP] within their [PSES] while they consider whether the information is needed to meet external

reporting obligations." *Id.* But HHS warned that providers "should carefully consider the need for this information to meet their external reporting or health oversight obligations." *Id.*

3. State-mandated information is separate and not PSWP.

HHS clarified that state-mandated "information collection activities" remained "separate" and "distinct" from systems established by the PSQIA:

> The [PSQIA] establishes a protected space or system that is separate, distinct, and resides alongside but *does not replace other information collection activities mandated by laws, regulations, and accrediting and licensing requirements*[.]

Id. Critically, HHS stated: "Information is not [PSWP] if it is collected to comply with external obligations, such as: *state incident reporting requirements;* ... ; certification or licensing records for compliance with health oversight agency requirements; ...." *Id.* at 70742-43.

4. Information collected for a purpose other than reporting to a PSO does not become PSWP merely because a provider reports such information to a PSO.

HHS explained that, for information to be PSWP, it "must be collected or developed for the purpose of reporting to a [PSO]." *Id.* at 70739. HHS warned that information "collected for a purpose other than reporting to a PSO" was not PSWP:

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

Id. at 70744. As discussed below, *infra.* pp. 32-42, this principle compelled the trial court's conclusion that the Wiles Report was not privileged under the PSQIA.

In response to a comment that information collected for a PSO may be the same information that must be reported to a state agency, HHS said "that providers must comply with applicable regulatory requirements and that the protection of information as [PSWP] *does not relieve a provider of any obligation to maintain information separately.*" *Id.* at 70743. Also, HHS noted, the Act "does not preempt state laws that require providers to report information that is not [PSWP]," though states "may not require that [PSWP] be disclosed." *Id.* at 70743-44.

5. Hospitals cannot meet their external reporting and recordkeeping obligations by maintaining information in a PSES.

In 2016, the HHS issued new guidance in response to comments indicating that health care providers were storing information

in their PSES to fulfill state-law regulatory requirements while simultaneously claiming that it was all privileged PSWP. The guidance specifically criticized that practice, and rejected the notion that information could be PSWP when it was compiled for the dual purpose of satisfying state requirements and providing information to a PSO:

> [W]e are concerned about two ways that some providers may be attempting to misuse the Patient Safety Act protections to avoid their external obligations—in particular, to circumvent Federal or state regulatory obligations. First, some providers with recordkeeping or record maintenance requirements appear to be maintaining the required records only in their PSES and then refusing to disclose the records, asserting that the records in their PSES fulfill the applicable regulatory requirements while at the same time maintaining that the records are privileged and confidential PSWP.
>
> …
>
> The Patient Safety Act was not intended to give providers such methods to evade their regulatory obligations.

HHS Guidance Regarding Patient Safety Work Product and Providers External Obligations, 81 Fed. Reg. 32655, 32657 (codified at 42 CFR pt. 3).

The guidance continued to explain that this sort of system violates the PSQIA because the Act does not protect records that a hospital is required to maintain under existing law:

> HHS reiterates that any external reporting or recordkeeping obligations—whether they require a provider to report certain information, maintain specific records, or operate a separate system—cannot be met with PSWP. We also clarify that any information that is prepared to meet any Federal, state, or local health oversight agency requirements is not PSWP. As discussed above, the Patient Safety Act was intended to spur the development of additional information created through voluntary patient safety activities and to provide privilege and confidentiality protections for such new information. It was not intended to protect records generated or maintained as part of providers' existing mandatory information collection activities.

Id.

Unlike the 2008 rule, the 2016 guidance was not the result of public notice and comment. It was issued in connection with the United States Government's response to the Supreme Court's request for the Solicitor General's views concerning the PSQIA in a case in which it eventually denied certiorari. *See Tibbs v. Bunnell*, 448 S.W.3d 796 (Ky. 2014), *cert. denied*, 136 S. Ct. 2504 (2016). HHS's 2016 guidance was issued the same day as the Solicitor General's amicus brief. The purpose was to clarify any ambiguities left by HHS's prior guidance or the PSQIA itself. 81 Fed. Reg. 32655.

6. HHS's definition of "original provider record."

As noted above, in addition to state-mandated information not being PSWP, an "original patient or provider record" is excluded from

the definition of PSWP under 42 U.S.C. § 299b-21(7)(B)(i). The Act does not define that term, though. In its 2016 Guidance, HHS explained that documents generated pursuant to state regulatory requirements are not PSWP because they are original provider records within the meaning of that statutory provision:

> *HHS interprets "original provider records" to include:* (1) Original records (e.g., reports or documents) that are *required of a provider to meet any Federal, state, or local public health or health oversight requirement regardless of whether such records are maintained inside or outside of the provider's PSES*; and (2) copies of records residing within the provider's PSES that were prepared to satisfy a Federal, state, or local public health or health oversight record maintenance requirement, if while the provider is obligated to maintain such information, the information is only maintained by the provider within the PSES (e.g., if the records or documents that were being maintained outside the PSES to fulfill the external obligation were lost or destroyed).

81 Fed. Reg. at 32658 (footnote omitted).

C. Florida's recordkeeping and reporting laws.

The PSQIA refers to "separate information" that that is "collected, maintained, or developed" for reasons other than reporting to a PSO, and clearly says that it does not limit recordkeeping obligations under state law. *See* 42 U.S.C. § 299b-21(7)(B)(ii), (iii)(III). And, based on those provisions, PSWP does not include information to

which oversight agencies had access prior to the PSQIA's enactment. 73 Fed. Reg. at 70742.

Understanding what is excluded from the PSWP definition requires understanding what information Florida law mandates that hospitals collect and maintain, and what information an oversight agency may access. As discussed below, Florida statutes and regulations have consistently required hospitals to collect and maintain several categories of information, either for reporting directly to the Agency for Healthcare Administration (AHCA) or for recordkeeping and disclosure in the event AHCA wishes to access the information. None of these requirements has changed since before the PSQIA's enactment.

1. Florida statutes and regulations.

In contrast to the *voluntary* reporting of information authorized (but not mandated) by the PSQIA, Florida law *mandates* that hospitals create, collect, maintain, and develop certain patient safety information, including records of adverse incidents. *See, e.g.*, § 395.0197, Fla. Stat. (2014).

Under Florida law, incident reports are part of a hospital's mandatory internal risk-management program. *See generally id.* This

program must include "the investigation and analysis of the frequency and causes of ... adverse incidents to patients" and the "development of appropriate measures to minimize the risk of adverse incidents to patients." § 395.0197(1)(a) & (b), Fla. Stat. This program also "must include a system for informing a patient" that he or she "was the subject of an adverse incident." *Id.* § 395.0197(1)(d). Most notably, a risk-management program must include "an incident reporting system based upon the *affirmative duty* of all health care providers and all agents and employees of the [hospital] to report adverse incidents *to the risk manager*." *Id.* § 395.0197(1)(e).

Accordingly, a hospital's risk-management program, under Florida law, must collect, maintain, and develop three types of incident reports. First, all hospital providers and employees must report an adverse incident to the hospital's risk manager within three business days of the "occurrence"; these are called 3-day reports. *Id.* § 395.0197(1)(e). These reports are discoverable in civil litigation. *Id.* § 395.0197(4).

Second, a hospital must submit to the Agency for Health Care Administration (AHCA) its annual report, which summarizes the occurrence/3-day reports. *Id.* §§ 395.002(2), 395.0197(6)(a). Third, a

hospital must submit to AHCA reports of certain adverse incidents within fifteen days of the incident; these are called Code-15 reports. *Id.* § 395.0197(7).

While a hospital need not submit its 3-day reports to AHCA, it must give AHCA "access" to the reports. *See* Fla. Admin. Code R. 59A-10.0055(3)(b) (stating such reports "shall be made available for review to any authorized representative of [AHCA] upon request during normal working hours"); § 395.0197(13), Fla. Stat. (2014) ("[AHCA] shall have access to all licensed facility records necessary to carry out the provisions of this section."). The 3-day reports must contain specific information, including: a "clear and concise description of the incident"; a "statement of [the] physician's recommendations as to medical treatment"; and a "listing of all persons then known to be involved directly in the incident." Fla. Admin. Code R. 59A-10.0055(2).

2. Amendment 7.

Unlike the statutes and regulations, Amendment 7 does not mandate that hospitals or providers create, collect, or develop any particular information, reports, or records. *See* art. X, § 25, Fla. Const. But, if records of adverse medical incidents are created, collected, or developed, then Amendment 7 mandates that information

be maintained in a manner that allows requesting patients access to it. *See id.*

Under Amendment 7, 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.* § 25(a). An "adverse medical incident" includes "medical negligence" and "any other act, neglect, or default" of a hospital or provider "that caused or could have caused injury to or death of a patient." *Id.* § 25(b)(3). An "adverse medical incident" specifically includes "those incidents that are required by state or federal law to be reported to any governmental agency or body" or "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.* These records must be made available for inspection to a requesting patient. *See id.* § 25(a) & (c)(4).

D. TMH's federal PSES and state internal risk-management program.

TMH produced a corporate representative, Judy Davis (who is also TMH's risk manager), to testify regarding the hospital's compliance with section 395.0197, adverse-incident investigations,

training, AHCA reporting, and other reporting and investigation policies. (R.341-42, 353-54.) Ms. Davis's testimony is the only record evidence of how TMH manages its statutory and regulatory compliance, as well as how it handles reporting information to AHCA, to its PSO, and internally to its risk manager.

1) Florida law, specifically § 395.0197, requires two categories of incident reports to be recorded: Code 15 reports and "occurrence" or "3-day" reports (R.403-04);

2) Florida law requires that each Code 15 report must be reported to the state (AHCA) and included in an annual report, while the "occurrence" or "3-day" reports need only to be reported to the hospital's risk manager and made available to the state (AHCA) for inspection upon the agency's request (R.403, 410-11);

3) The state (AHCA) has created a form to be used by hospital personnel for preparing Code 15 reports, but Florida law requires each hospital to develop its own form for the "occurrence" or "3-day" reports, which must be in compliance with Florida Administrative Code Rule 59A-10.0055 (R.402-03);

4) In compliance with Florida Administrative Code Rule 59A-10.0055, TMH has created a form designated a "Safety Event Report," which requires the recording of information itemized in that regulation (R.402-03);

5) The Wiles Report is recorded on a "safety event report" form, not a Code 15 report form (R.374);

6) As required by Florida law, Davis personally reviews and investigates all safety event reports. (R.407-09, 454).

Ms. Davis testified specifically that the Wiles Report exists, at least in part, because of Florida's requirement to collect information for 3-day reports (R.489-90):

> Q. Okay. The Wiles incident report was created to comply with Florida law, the mandatory incident reporting system, right?
>
> MR. ANDREWS: Object to form.
>
> THE WITNESS: I know it was created. I'm not sure—I think she believed there was an unusual—the person must have believed there was an unusual event and created a report.
>
> BY MR. LEEDER:
> Q. You would agree with me that's to comply with the mandatory reporting requirements under Florida law, ma'am?
>
> A. It would be a requirement to report incidents within the facility, yes.
>
> Q. And that includes the Wiles incident report just so we're clear, right?
>
> A. Yes.

Ms. Davis also testified that if AHCA asked to see all Code 15 reports and 3-day reports, TMH would provide AHCA access to the Wiles Report (R.445-46):

> Q. If AHCA came to your hospital and wanted to see your patient safety events, Tallahassee Memorial Hospital

would be required to show them all the reports, including the Code 15 reports and the 3-day reports that we talked about?

MR. ANDREWS: Object to form. Calls for legal conclusion.

THE WITNESS: We provide de-identified documentation of events to AHCA when they come.

BY MR. LEEDER:

Q. Okay. And that would include the Wiles incident report, right?

A. Yes.

Every time a TMH employee fills out a Patient Safety Event Report, TMH considers it PSWP the moment it is generated. (R.428-29.) All reports are submitted to TMH's own database, and its PSO pulls the reports. (R.449.) TMH also shares those reports, internally, with several departments and employee managers. This practice is necessary to comply with Florida regulations. (R.569; *see also* Fla. Admin. Code R. 59A-10.002 (Definitions # 6, 7, 8, 9, & 14); *id.* R. 59A-10.0055 (Incident Reporting System).)

Finally, Ms. Davis explicitly conceded that the Wiles Report was generated for a "dual purpose" and not solely for submission to a PSO (R.426-27):

> Q. How does Tallahassee Memorial Hospital distinguish between Florida's mandatory reporting requirements and patient safety work product?
>
> A. I believe I just said that we consider all our safety events as patient safety work product.
>
> Q. So, it's fair to say that your reports are meant to comply with Florida law and that the same time you consider them patient safety work product?
>
> A. I do.
>
> …
>
> Q. … Is it fair to say that your patient safety work product is not created for the sole purpose of reporting to a patient safety organization if at the same time it is being created to comply with Florida's mandatory incident reporting requirements?
>
> MR. ANDREWS: Same objection.
>
> THE WITNESS: I believe it's a dual purpose, that it's created for both.
>
> Q. Okay. And I understand that. So it's fair to say then the patient safety work product is not created for the sole purpose of reporting to a PSO. That's a fair statement?
>
> A. Not for the sole purpose. It's a dual purpose.

Later (R.477-78):

> Q. Okay. Your Patient Safety Evaluation System you're saying is part of the PSO?
>
> A. The Patient Safety Evaluation System is forwarded to the PSO for protection. It's used for reporting to AHCA, it's

used for reporting to the PSO, and for other reporting requirements such as the annual report…

E. TMH's treatment of Lennox Wiles, this lawsuit, and procedural history.

On May 11, 2014, Lennox Wiles was delivered at TMH. (R.48.) There were signs of fetal distress during delivery. (R.48.) Although Lennox needed resuscitation and airway suctioning after delivery, he was sent to the recovery room instead of the NICU. (R.50.) After becoming unstable again, Lennox required another resuscitation, supplemental oxygen, and airway suctioning. TMH then transferred Lennox to the NICU. (R.50.)

On May 20, Lennox suffered an apneic event, which means an extended cessation of breathing, which is a sign of neurological injury. (R.51.) On May 23, a TMH employee created the Wiles Incident Report. Although the Wiles family has not seen the report, it evidently addresses a breathing issue. (R.791.)

The Wiles family sued TMH and other providers. Their complaint alleged, among other things, that TMH failed to timely perform a c-section when fetal distress was apparent, and it failed to ensure that Lennox's breathing and oxygen saturation were properly maintained to prevent hypoxia. (R.53-59.)

The Wiles family served several requests to produce documents. Among other documents, they requested all incident reports pertaining to Lennox's treatment. (R.206, 210.) TMH indicated that it had responsive materials, but objected to producing them by claiming they were PSWP under the PSQIA. (R.227, 234-35.)

The Wiles Family then sent another request seeking all incident reports under Florida Statutes § 395.0197(1)(e) (3-day reports, or occurrence reports). (R.674.) TMH responded by identifying the Wiles Report as the only responsive document, but raised the same privilege objection as before. (R.674.)

The trial court held a hearing on the Wiles family's motion to compel production of the Wiles Report. (R.782-822.) Throughout the hearing, the judge referred to this Court's opinion in *Charles* and expressed his conclusion that, under *Charles*, TMH's concession that the Wiles Report was created for a dual purpose was fatal to its position regarding the PSWP privilege. For example, Judge Smith addressed TMH's counsel early in the hearing (R.787):

> what I'm going to need you to focus on is how is it that the testimony of the corporate representative doesn't, in essence, give up the document. Because it looks like to me she was asked under oath and it [sic] replied it was not a single-purpose document that had been prepared and

> shared with, I think, what Mr. Leeder said, up to 16 people. That it had—it served both the state and the federal requirements.

Judge Smith also zeroed in on the material testimony from Ms. Davis (R.806-07):

> THE COURT: All right. So let's go to page 70 of the deposition ...
>
>> QUESTION: So it's fair to say that your reports are meant to comply with Florida law, and that—and that the same time you consider them patient safety work product.
>>
>> ANSWER: I do.
>
> THE COURT: Doesn't that kind of give up the ghost as far as this is Florida law required, as well as the federal requirement if it was simply the federal requirement. But then again, this is a divorce from right now, about whether it was an adverse event that you talked about.
>
> MR. ANDREWS: Right, so...
>
> THE COURT: I could go back and look, and I'll try to track that argument there, but. And I could go to other examples that Mr. Leeder [the Wiles family's counsel] just cited, but.
>
> MR. ANDREWS: Yeah. And my answer is going to be fairly similar in all those examples. All those examples is [sic] talking about the system, TMH's reporting system.

Following the hearing, the trial court issued an order granting the Wiles family's motion. (R.35.)

TMH filed a petition for writ of certiorari, which the First District granted. In its opinion, the district court noted this Court's decision in *Charles*, but held that it was not required to follow the result or reasoning of that decision for two reasons:

(1) The Wiles Incident Report "was submitted to the hospital's patient safety organization," and

(2) "the document is not an 'adverse incident' report, which state law defines and requires to be submitted to [AHCA]."

(R.952-53.)

The district court also articulated the standard for certiorari relief, but did not identify any clearly established law that the trial court failed to follow. Instead, the district court engaged in its own interpretation of the PSQIA and concluded that any information collected in a report that is not submitted to AHCA, and is submitted to a PSO, is by definition PSWP. The opinion did not quote, nor did it consider, the language in the PSQIA saying that "separate information … reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product."

Judge Makar dissented. (R.979-81.) He noted that regardless of whether the Wiles Incident Report was actually filed with AHCA, TMH was required to collect and maintain the information in the report.

That is because Florida law requires reporting by hospitals when a patient has a condition requiring transfer to a "more acute level of care" due to an event "associated in whole or in part with medical intervention." (R.981 (citing § 395.0197(5), (5)(a)(7), Fla. Stat.).)

The district court certified questions to this Court, and the Wiles family sought review here based on those questions, as well as conflict with *Charles*.

SUMMARY OF THE ARGUMENT

The decision of the First District should be reversed for three reasons. First, the decision represents a misuse of certiorari. Under this Court's decision in *State v. Garcia*, 350 So. 3d 322 (Fla. 2022), a district court should not decide new issues of law in a certiorari proceeding. A writ of certiorari is an extreme remedy, to be used only when a trial court fails to follow clearly established law that was binding upon it. Here, neither TMH nor the First District identified any clearly established law that the trial court failed to follow. To the contrary, the clearest binding pronouncement regarding application of the PSQIA was this Court's decision in *Charles*, which the trial court followed to the letter. There was no basis to grant a writ of certiorari.

Second, in addition to improperly making new law in a certiorari proceeding, the First District failed to follow *Charles*. The majority claimed not to be bound by *Charles* because of two purported factual distinctions: The Wiles Report was submitted to a PSO, whereas the reports in *Charles* were apparently not; and the Wiles Report was not required to be provided to AHCA as a Code 15 report. These distinctions did not justify a departure from *Charles*. Whether a report has been submitted to a PSO, or just stored in a PSES, makes no

difference to whether the information in the report is privileged. Instead, under the PSQIA, what matters is whether there was any obligation to collect and maintain the information under the law. Here, there was such an obligation. It also makes no difference that the Wiles Report was not a Code 15 report—neither were the reports in *Charles*. The Wiles Report, like the reports at issue in *Charles*, was created to report to TMH's risk manager as a 3-day report under section 395.0197(5). Such reports are discoverable under state law and are not privileged under the PSQIA's plain text.

Third and finally, an affirmance would require this Court to recede from *Charles*, which it should not do. Nothing about this Court's reasoning in *Charles* is "clearly erroneous," or even erroneous at all. *See State v. Poole*, 297 So. 3d 487, 507 (Fla. 2020). It is derived from a faithful reading of the PSQIA's plain text. What is more, the *Charles* decision is consistent with HHS guidance, to which this Court owes deference, as well as decisions from state and federal courts around the country.

For all these reasons, this Court should reverse the First District's grant of certiorari.

ARGUMENT

THE FIRST DISTRICT'S DECISION SHOULD BE REVERSED BECAUSE THE TRIAL COURT DID NOT DEPART FROM THE ESSENTIAL REQUIREMENTS OF THE LAW, AND THIS COURT SHOULD NOT RECEDE FROM *CHARLES V. SOUTHERN BAPTIST HOSPITAL OF FLORIDA*.

A. Preliminary matters.

1. Jurisdiction.

The Wiles family relies on its Brief on Jurisdiction filed February 6, 2023. Additionally, this Court has mandatory jurisdiction, as the First District's decision had the effect of "declaring invalid a … provision of the state constitution." *See* art. V, § 3(b)(1), Fla. Const.

2. Standard of review

The First District certified two questions to this Court:

1) Whether [TMH's] "Safety Event Report No. 67593" [the Wiles Report] is privileged and confidential "Patient Safety Work Product" under the [PSQIA]?
2) If the report is privileged and confidential under the [PSQIA], whether that federal law preempts the report's disclosure under [Amendment 7]?

As discussed in the Wiles Family's jurisdictional brief, these are not questions of great public importance. Furthermore, the question

misstates the standard for a writ of certiorari. The district court should not engage in its own fact finding to determine whether a party has met its burden of proof on an asserted privilege.

This Court recently dealt with a similar case in which a district court certified a question in a certiorari proceeding. *See Dodgen v. Grijalva*, 331 So. 3d 679 (Fla. 2021). This Court rephrased the question "[t]o more precisely express the dispositive issue presented in this case—a case involving certiorari review by the district court of a discovery order[.]" *Id.* at 681. Similarly, this Court should reframe the certified question in this case:

> Whether it is a departure from the essential requirements of law to permit discovery of an incident report where the trial court relied on binding precedent from the Florida Supreme Court, and no binding authority required the trial court to deny the discovery of the report?

As in *Dodgen*, this reframed question "more precisely" addresses the certiorari standard when reviewing a discovery order. That is because:

> For a district court to grant a writ of certiorari, the petitioner must demonstrate that the contested order constitutes (1) *a departure from the essential requirements of the law*, (2) resulting in material injury for the remainder of the case[,] (3) that cannot be corrected on postjudgment appeal.

State v. Garcia, 350 So. 3d 322, 325 (Fla. 2022) (quotation marks and citations omitted). A departure from the essential requirements of law occurs "*only when there has been a violation of a clearly established principle of law* resulting in a miscarriage of justice." *Id.* at 326 (emphasis in original).

Because the trial court did not violate a clearly established principle of law, this Court should answer the reframed question in the negative.

3. Burden of proof on a privilege.

TMH, as the party claiming a privilege, bears the burden of establishing that a privilege applies. *See S. Bell Tel. & Tel. Co. v. Deason*, 632 So. 2d 1377, 1383 (Fla. 1994) ("The burden of establishing the attorney-client privilege rests on the party claiming it."); *United States v. Zubaydah*, --- U.S. ---, 142 S. Ct. 959, 969 (2022) ("we agree … that the Government bears the burden of showing that the [state secrets] privilege should apply"). A statute granting a privilege must "be strictly construed so as to avoid a construction that would suppress otherwise competent evidence." *Baldrige v. Shapiro*, 455 U.S. 345, 360 (1982) (internal quotation marks omitted). This strict construction lies in the "fundamental maxim," grounded in the common law,

that the public "has a right to every man's evidence." *United States v. Bryan*, 339 U.S. 323, 331 (1950).

B. The district court improperly granted a writ of certiorari where the trial court followed clearly established law.

"It is extremely rare that erroneous interlocutory rulings can be corrected by resort to common law certiorari…. Because the most urgent interlocutory orders are appealable under Fla. R. App. P. 9.130, there will be very few cases in which common law certiorari will provide relief." *Garcia*, 350 So. 3d at 325 (cleaned up) (quoting Committee Notes to Fla. R. App. P. 9.130). "[T]he scope of certiorari review is more constrained than that of direct appellate review, for the writ was never intended to redress mere legal error." *Univ. of Fla. Bd. Of Trustees v. Carmody*, No. SC2022-0068, 2023 WL 4359498, at *4 (Fla. July 6, 2003) (internal quotation marks and alterations omitted).

Before the First District's decision in this case, there was no appellate decision holding that a report such as the Wiles Report would be PSWP under the PSQIA. Indeed, the only binding decisional law available to the trial court was to the contrary and directly on

point. The trial court followed *Charles*, and in fact there was no contrary precedent.

The district court did not identify any clearly established law that the trial court failed to follow. Instead, it summarily concluded that the Wiles Report did not describe an adverse incident, and therefore the trial court departed from the essential requirements of the law by ordering its disclosure.

This was a misapplication of the certiorari standard. It is not a departure from the essential requirements of the law for one court to decide that a report describes an adverse incident, even if another court believes it does not. *Cf. Carmody*, 2023 WL 4359498, at * 5 ("Whether the trial court erred in finding that the doctor was a qualified expert under the statute is an issue of mere legal error and does not amount to a violation of a clearly established principle of law resulting in a miscarriage of justice") (cleaned up). Instead, there must be "clearly established law, binding on trial court" that the court nevertheless failed to follow. *Garcia*, 350 So. 3d at 326. The trial court found that the Wiles Report *did* describe an adverse incident because the evidence regarding its creation required that conclusion.

First, TMH identified the Wiles Report as responsive to the Wiles family's discovery requests directed to adverse incident reports. (R.674.) Second, its corporate representative testified that a TMH employee created the Wiles Incident Report to comply with TMH's obligation to collect information for 3-day reports—those that must be provided to the hospital's risk manager within three days of the occurrence. *See* § 395.0197(1)(e), Fla. Stat.; (R.374, 445-46, 489-90). Third, and most importantly, the circumstances of Lennox Wiles's treatment demonstrate that TMH was required to collect and maintain this information under Florida's definition of "adverse incident."

As discussed *supra* pp. 15-16, section 395.0197 sets out two categories of adverse incidents. One category is required to be reported to AHCA as a "Code 15" report. There are eight kinds of such adverse incidents that must be reported to AHCA within 15 days. § 395.0197(7)(a)-(h), Fla. Stat. But there are also several other categories of adverse incidents which must be reported internally, and for which records must be *maintained* and *made available* to AHCA. Subsection (5) describes seven of them, of which one is relevant here:

> (5) For purposes of reporting to the agency pursuant to this section, the term "adverse incident" means an event over which health care personnel could exercise control and which is

associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which:

(a) Results in one of the following injuries:

…

7. *Any condition that required the transfer of the patient*, within or outside the facility, *to a unit providing a more acute level of care* due to the adverse incident, rather than the patient's condition prior to the adverse incident;

Id.

To illustrate how the Wiles Incident Report must consist of information collected and maintained in compliance with this statute:

Elements of an adverse incident under section 395.0197(5)	**Circumstances of Lennox Wiles's treatment**
"event over which health care personnel could exercise control"	TMH delivered Lennox, and its personnel actively treated Lennox and his mother at all times during and after labor and delivery.
"associated in whole or in part with medical intervention"	TMH personnel participated in resuscitating Lennox and suctioning his airways.
"Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident"	Lennox's condition required his transfer, within TMH, from the recovery room to the NICU, a more acute level of care, following multiple resuscitations.

Based on the evidence regarding how TMH prepared the Wiles Report, why it prepared the report, and the circumstances surrounding TMH's care of Lennox Wiles, the trial court had no alternative but to conclude that the Wiles Report contained information relating to an adverse incident under Florida law. The First District reached a contrary conclusion by erroneously considering only whether the Wiles Report described an adverse incident that had to be reported to AHCA as a Code 15 report. It ignored the other statutory definition of adverse incident. *See id.* § 395.0197(5).

Following the district court's recharacterization of the Wiles Report, it went on to hold that the report was PSWP because it was not directly reported to AHCA and it was submitted to the PSO. But nothing in *Charles*—nor any other binding or persuasive precedent—would have even hinted to the trial court that it should base its decision on those two distinctions.

To the contrary, in *Charles* this Court rejected the very same reasoning that the First District used in this case. Describing the First District's previous holding in *Charles*, this Court said:

> [T]he First District concluded that "[t]he plain language of the [PSQIA] is clear. A document is [PSWP] if it is placed into a [PSES] for reporting to a [PSO] and does not exist

> outside of the [PSES]. The documents here meet that definition and should be regarded as [PSWP], which is privileged, confidential, and not discoverable." *S. Baptist Hosp. of Fla., Inc. v. Charles*, 178 So. 3d 102, 110 (Fla. 1st DCA 2015). However, the First District's reading of the [PSQIA] was in error because it failed to consider the statute as a whole.

This Court also described Florida laws that "require a health care provider to create and maintain adverse incident reports" (even if they are not provided to AHCA), citing the same subsections of section 395.0197 discussed above.

The records at issue in *Charles* were not "Code 15" or annual reports; the hospital "ha[d] already produced the Code 15 Reports and Annual Reports that are required to be reported to the State under Florida law." *S. Baptist Hosp. of Fla., Inc. v. Charles*, 178 So. 3d 102, 109-10 (Fla. 1st DCA 2015). Instead, the hospital in *Charles* resisted producing 3-day reports, which it chose to store in its PSES. That is precisely the procedure that TMH uses: Its risk manager and corporate representative testified that all incident reports employees prepare for her are automatically stored in the PSES. TMH provides these reports to AHCA when asked, and does so by removing them from the PSES. (R.445-46). In the meantime, TMH uses the PSES to

store *all* 3-day reports. (R.428-29, 449.) The Wiles Report is the same kind of report that the hospital was required to produce in *Charles*.

In addition to *Charles*, the trial court was required to give deference to HHS's construction of the PSQIA. *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). *Chevron* is binding on state courts when interpreting federal statutes administered and interpreted by federal agencies. *See Smiley v. Citibank (S. Dakota), N.A.*, 517 U.S. 735, 737-39 (1996) (applying *Chevron* to resolve conflict among state courts construing federal legislation).

Under *Chevron*, courts must accept a federal agency's reasonable construction of an ambiguous statute[4] that is within the agency's jurisdiction. *E.g. Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980, 982 (2005). Under *Chevron*, courts must engage in a two-step process: first, ask whether the statute's plain terms "directly address the precise question at issue[,]" and if the statute is ambiguous, defer to the agency's interpretation "so long as

[4] To be clear, the Wiles Family's position is that the PSQIA's text is unambiguous, but addresses HHS guidance in the event this Court construes the Act to contain any ambiguity.

the construction is a reasonable policy choice for the agency to make." *Id.* (internal quotation marks omitted).

As discussed *supra* pp. 7-13, HHS has issued several interpretations that have a bearing on this case:

HHS interpretation	**Wiles Report**
PSWP does not include information to which "oversight entities" had "access prior to the passage of the [PSQIA]." 73 Fed. Reg. 70742.	Since before the PSQIA's enactment, section 395.0197 has given AHCA access to all 3-day reports upon request.
"Information is not [PSWP] if it is collected to comply with external obligations, such as: state incident reporting requirements." *Id.* at 70742-43.	The Wiles Incident Report consists of information collected for reporting to TMH's risk manager, who in turn must include it in TMH's annual report. § 395.0197(6)(a)
Information collected for a purpose other than reporting to a PSO is not PSWP even if it is ultimately reported to a PSO. *Id.* at 70744.	TMH conceded that the Wiles Incident Report consists of information collected for a "dual purpose." (R.426-27, 477-78.)
Hospitals may not satisfy their state-law recordkeeping obligations by storing collected information in a PSES and treating it as PSWP. *See* 81 Fed. Reg. 32655-01.	TMH collects information for the dual purpose of reporting to its risk manager and reporting to a PSO, then stores those 3-day reports in the PSES and treats them as confidential. (R.428-29, 449.)

All of these statements from HHS were the product of its obligation to issue regulations and guidance after receiving and considering public comment. They are also eminently reasonable interpretations of the PSQIA, because they are consistent with the statute's plain text: "separate information … reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product." 42 U.S.C. § 299b-21(7)(B)(ii).

Finally, although not binding on the trial court, several other courts have reached the same conclusion. In *Baptist Health Richmond, Inc. v. Clouse*, 497 S.W. 3d 759 (Ky. 2016), the Supreme Court of Kentucky said:

> Thus, reports that are required by the Commonwealth do not become privileged because the provider puts them in its patient safety evaluation system.
>
> ….
>
> In summary, a provider who participates in the Act may collect information within its patient safety evaluation system that complies with the Act and that also complies with state statutory and regulatory requirements. However, doing so does not relieve the provider from complying with those state requirements and, *to the extent information collected in the provider's internal patient safety evaluation system is needed to comply with those state requirements, it is not privileged.*

See also Penman v. Correct Care Solutions, LLC, 2020 WL 4253214 (W.D. Ky. 2020); *Hymas v. CVS Health Corp.*, 2019 WL 6727536 (N.D. Cal. 2019).

A United States District Court ordered disclosure of an incident report because it was created for the "dual purpose" of conducting quality improvement reviews for a contract with the state of Oregon and for reporting to a PSO. *Dence v. Wellpath, LLC, et al.*, 2022 WL 17261990, at *3 (D. Ore. Nov. 29, 2022). The report at issue was not actually provided to the state; it was reviewed only by a committee that the defendants themselves formed to comply with the contract. *Id.* Like the Wiles Incident Report, the report in *Dence* was reviewed internally and submitted only to a PSO. It was still discoverable, because the hospital had a contractual duty to the state to collect the information in the report, just as TMH had a statutory duty to do so.

The trial court's decision here followed this Court's precedent, the text of the PSQIA, the regulations and guidance promulgated by HHS, and decisions of other courts. Far from departing from clearly established law, the trial court followed uniform binding and persuasive authorities. There was no basis for the First District to grant a writ of certiorari.

The First District did not quash the trial court's order for failing to follow clearly established law; it quashed because the trial court did not follow the First District's decision in *Charles*, which this Court reversed. Indeed, there is no distinction between the First District's reasoning in this case and its reasoning in *Charles*. The trial court was bound to follow *this Court's* decision, not the First District's. Under these circumstances, the district court was required to deny TMH's petition.

C. The district court failed to follow this Court's decision in *Charles*.

Instead of correcting a departure from the essential requirements of the law, the First District made new law. This is inappropriate in a certiorari proceeding. "A writ of certiorari to correct a nonfinal order is indeed an extraordinary remedy." *Garcia*, 350 So. 3d at 325 (internal quotation marks and citation omitted). Because of its extraordinary nature, this writ should be issued sparingly. It exists to correct a trial court's failure to follow clearly established law; not to consider new questions and make new law.

This Court recognized as much in *Garcia*. There, the defendant was compelled to reveal the passcode to his cell phone. The district

court quashed that order and certified a question of great public importance to this Court regarding whether the revealing of a passcode was testimonial and therefore subject to the Fifth Amendment's privilege against self-incrimination. This Court declined to reach the question. It instead held that it was improper to grant certiorari, both because any effects of the compelled disclosure could be remedied in a plenary appeal, and because there was no clearly established law establishing whether the trial court's order violated the defendant's Fifth Amendment rights.

This Court noted that different courts had reached different conclusions regarding the Fifth Amendment issue, and determined that these conflicting decisions necessarily precluded the conclusion that there was any clearly established law on the subject. The reasoning in *Garcia* is clear: Certiorari exists only to remedy clear violations of the law by trial courts, not to resolve issues of first impression or to engage in new interpretations of statutes. The First District should not have used this original proceeding to interpret the PSQIA anew.

What is more, the district court contravened clear precedent binding upon it. Vertical stare decisis commands that lower courts

are "absolutely bound" by precedents of "higher courts within the same jurisdiction" as a "matter of owing obedience," and they "must adhere not just to the result but also to any reasoning necessary to that result." Bryan A. Garner et al., *The Law of Judicial Precedent* § 2, at 27 (2016). "The judges of all the inferior courts are bound to accept and follow [a state's highest court's] precedents completely, without regard to their own previous decision or their independent views of the law." *Id.* at 33.

The First District did not follow *Charles*, and concluded it was free to depart from its holding and reasoning based on two purported distinctions, one of which is immaterial and the other of which is not a distinction at all.

1. It does not matter that the Wiles Report was submitted to a PSO.

First, the district court said that, unlike the reports at issue in *Charles*, "the report here was submitted to the hospital's [PSO]." (R.951-52.) This is apparently a reference to the fact that, in *Charles*, the hospital had "placed" the reports into its PSES, "where they remained pending submission to a [PSO]." *Charles*, 209 So. 3d at 1206 (describing the First District's recitation of the record evidence).

There is nothing in the *Charles* opinion, though, that suggests this distinction makes any difference to the reasoning or result of that case, nor is there any such suggestion in the text of the PSQIA. Instead, it says:

> 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.

42 U.S.C. § 299b-21(7)(B)(ii).

Whether a document is privileged, then, has nothing to do with where it is "placed" or "reported"; it has everything to do with whether the hospital had a separate obligation to collect and maintain the *information* in the document. Describing the First District's error in *Charles*, this Court said:

> [T]he First District concluded that "[t]he plain language of the [Federal] Act is clear. A document is [patient safety work product] if it is placed into a [patient safety evaluation] system for reporting to a [patient safety organization] and does not exist outside of the [patient safety evaluation] system. The documents here meet that definition and should be regarded as [patient safety work product], which is privileged, confidential, and not discoverable." .... However, the First District's reading of the Federal Act was in error because it failed to consider the statute as a whole.

Id. at 1211 (alterations in original, citation omitted). Relying on the plain text of the PSQIA, this Court corrected the First District's misunderstanding:

> Simply put, adverse medical incident reports are not patient safety work product because Florida statutes and administrative rules require providers to create and maintain these records and Amendment 7 provides patients with a constitutional right to access these records. Thus, they fall within the exception of information "collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system." *See id.* § 299b–21(7)(B)(ii). In addition, their disclosure fits squarely within the providers' recordkeeping obligations under state law. *Id.* § 299b–21(7)(B)(iii).

Id.

The PSQIA's text also shows that whether information is actually reported to a PSO does not determine whether a document containing that information is privileged. A PSO is simply an entity "listed by the Secretary pursuant to section 299b-24(d)." 42 U.S.C. § 299b-21(4). That cross-referenced statute lists criteria for PSOs, including a provision that they must "collect[] patient safety work product from providers." 42 U.S.C. § 299b-24(b)(1)(F); *see also id.* § 299b-24(b)(1)(C) (requiring a PSO to have contracts with providers for "receiving and reviewing patient safety work product").

The patient safety evaluation system is the pathway through which information from a provider (TMH) is maintained and ultimately submitted to the PSO. The PSES is where information is collected, managed, or analyzed. *See id.* § 299b-21(6). This is precisely how TMH itself described its handling of reports: It stored them in its PSES, and the PSO then retrieved the reports itself; there is no step at which TMH delivers, either physically or electronically, a report directly to its PSO. (R.449-50.)

The distinction drawn by the First District is meaningless. Storing a report in a PSES for submission to a PSO is no different from submitting the document directly to a PSO. Whether the information is privileged or not does not turn on that fact; it turns on whether the information is (1) "separate information," (2) an "original patient or provider record," or (3) "a patient's medical record, billing and discharge information." 42 U.S.C. § 299b-21(B)(i)-(iii). This Court described those categories of information as "broad exceptions" that "Congress [had] carved out" to the definition of PSWP. *Charles*, 209 So. 3d at 1210.

The First District ignored this Court's reasoning in *Charles*, which rested on a provider's obligation to collect and maintain

information. Instead, it focused on an immaterial fact: whether the information was collected in a report that was submitted to a PSO. From there it held that because the Wiles Report was reported to a PSO, it must be privileged. Both the *Charles* opinion and the text of the PSQIA compelled the opposite result.

2. The Wiles Report is the same kind of adverse incident report as in *Charles*.

Second, the district court said that the Wiles Report "is not an 'adverse incident' report, which state law defines and requires to be submitted to the Agency for Health Care Administration." But the reports in *Charles* were not "require[d] to be submitted to" AHCA, either. This is how this Court explained the reports then:

> Consistent with the[] provisions of the [PSQIA], Florida has various statutes and rules … that require a health care provider to *create and maintain* adverse medical incident reports…. [H]ealth care providers are required by state law to *keep* adverse medical incident reports, and the right of patients to access those adverse medical incident reports is enshrined in Florida's Constitution.

Charles, 209 So. 3d at 1211. The reasoning in the *Charles* opinion was not based on state laws requiring hospitals to "submit" reports to AHCA; it was based on laws governing the collection and maintenance of information that is reported to hospital risk managers. That

reasoning was dictated by the text of the PSQIA, which says that PSWP "does not include information that is *collected, maintained, or developed* separately." 42 U.S.C. § 299b-21(7)(B)(ii).

As discussed above, *supra* pp. 34-35, the Wiles Report is the same kind of collection of information—a "3-day" report—that this Court held was not privileged in *Charles*. The distinction on which the district court relied is illusory.

D. *Charles* was correctly decided and this Court should not recede from its previous decision.

The First District acted contrary to this Court's precedent concerning both the availability of certiorari relief and the applicability of the PSQIA. Those are sufficient reasons to reverse its decision in this case. But even if this Court were to reexamine its decision in *Charles*, it should not recede from it.

That decision was true to this Court's adherence to the supremacy-of-the-text principle. *See Levy v. Levy*, 326 So. 3d 678, 681 (Fla. 2021 (quoting Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* (2012)). Not only did this Court apply this principle to the PSQIA, but it did so in a way that cannot leave this

Court with a firm conviction that its interpretation of the PSQIA was clearly erroneous.

1. Stare decisis.

A few years ago, the Court addressed stare decisis and receding from precedent. In *State v. Poole*, 297 So. 3d 487, 506 (Fla. 2020), the Court explained that adhering to precedent provides stability to the law, even though it does not command blind allegiance to precedent when there has been an error in legal analysis. The Court continued:

> It is no small matter for one Court to conclude that a predecessor Court has clearly erred. The later Court must approach precedent presuming that the earlier Court faithfully and competently carried out its duty. A conclusion that the earlier Court erred must be based on a searching inquiry, conducted with minds open to the possibility of reasonable differences of opinion. There is room for honest disagreement, even as we endeavor to find the correct answer.

Id. (cleaned up). After reassessing its precedent on stare decisis, the Court announced the standard for stare decisis it would apply going forward:

> We believe that the proper approach to stare decisis is much more straightforward. In a case where we are bound by a higher legal authority—whether it be a constitutional provision, a statute, or a decision of the Supreme Court—our job is to apply that law correctly to the case

> before us. When we are convinced that a precedent *clearly conflicts* with the law we are sworn to uphold, precedent normally must yield.

Id. at 507 (Fla. 2020); *see also id.* ("But once we have chosen to reassess a precedent and have come to the conclusion that it is *clearly erroneous*, the proper question becomes whether there is a valid reason *why not* to recede from that precedent." (second emphasis in original)).

There is no reason to believe that the *Charles* opinion is clearly erroneous. To the contrary, it is faithful to the text of the PSQIA and consistent with other courts' application and interpretation of the Act.

2. The *Charles* opinion correctly interpreted and applied the PSQIA because the Act expressly preserves state-law reporting and recordkeeping obligations, and it provides that information collected and maintained to comply with those obligations is not privileged.

The PSQIA does not preempt Florida's statutory requirements that hospitals must collect and maintain information regarding incidents such as Lennox Wiles's transfer to the NICU. Indeed, the Act expressly preserves such state-law requirements. 42 U.S.C. § 299b-21(7)(B)(iii)(II) & (III). Additionally, the PSQIA plainly states that the PSWP privilege does not apply to "information that is collected,

maintained, or developed separately, or exists separately, from a [PSES].” 42 U.S.C. § 299b-21(7)(B)(ii).

At oral argument in *Charles*, Justice Canady noted that the word “separately” does not refer to a place.[5] In other words, the question is not whether a report containing information exists in one place or another; the question is whether there is a reason for collecting, maintaining, or developing information that is separate from reporting it to a PSO. This is why the HHS has consistently interpreted the PSQIA as establishing systems that are “separate” and “distinct” from, but “do[] not replace,” the “other information collection activities mandated by [state] laws, regulations, and accrediting and licensing requirements.” 73 Fed. Reg. 70732, 70742-43. The PSQIA therefore does not “relieve a provider of any [state-law] obligations to maintain information separately.” *Id.* at 70743.

This Court should not recede from *Charles* because (a) providers like TMH have state-law obligations to collect, maintain, or develop information on this type of incident, (b) that state-mandated

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[5] Video of the oral argument is available at https://wfsu.org/gavel2gavel/viewcase.php?eid=2386 (last visited Sept. 8, 2023). This discussion occurs around the 30-minute mark.

information is non-privileged "separate information," not PSWP, (c) *Charles* is consistent with HHS guidance and uniform decisions of other courts, (d) state-mandated information is also an "original provider record," and (e) providers cannot transform state-mandated information into PSWP merely by storing it in a PSES for submission to a PSO.

All of these propositions are derived from the plain text of the PSQIA. Even if they were not, this Court would be required to defer to HHS's reasonable interpretations of the Act. But this Court should follow the same reasoning as it did in *Charles* by resort solely to the plain text, obviating the need to analyze whether there is any ambiguity and whether any deference is due. The only instance in which resort to HHS guidance is necessary concerns the definition of "original patient or provider record," a term that is undefined in the statute but for which the HHS has offered a reasonable interpretation.

a. Providers like TMH have state-law obligations to collect, maintain, and develop information regarding adverse medical incidents.

As discussed above, *supra* pp. 34-35, TMH was required to collect and maintain information regarding Lennox Wiles's transfer to the NICU within TMH's facility under section 395.0197(5), (5)(a)(7),

Florida Statutes. It was also required to give AHCA access to that information. *See* Fla. Admin. Code R. 59A-10.0055(3)(b); § 395.0197(13), Fla. Stat. Under these statutes and regulations, hospitals must collect, maintain, or develop this information "separately" from a privileged database. Or, stated differently, Florida law requires this information to "exist[] separately" from a PSES. *See* 42 U.S.C. § 299b-21(7)(B)(ii).

Nothing about these state-law obligations conflicts with the PSQIA. The First District was wrong to suggest that there is any conflict preemption. The PSQIA expressly preserves and incorporates these state-law obligations. 42 U.S.C. § 299b-21(7)(B)(iii)(II) & (III); *id.* § 299b-22(g)(5).

b. State-mandated information is non-privileged "separate information," not PSWP.

Clause (ii) of subparagraph (B) of § 299b-21(7) expressly says "information that is collected, maintained, or developed separately, or exists separately, from a [PSES]" is not privileged PSWP. Information that hospitals are required by state law to collect and maintain is, by definition, "separate information" under § 299b-21(7)(B)(ii). It cannot be PSWP.

The only way the Wiles Report could be privileged would be if it did not describe an adverse incident under Florida law. This is what TMH argued, and what the First District concluded. As discussed above, the circumstances of Lennox Wiles's treatment indicate that the information in the Wiles Report must relate to an adverse incident for purposes of reporting to TMH's risk manager. As was also discussed above, it makes no difference whether it was also an adverse incident for purposes of a Code 15 report, because the PSQIA draws no distinction between information that is *reported* to a state oversight agency and information that is *collected* and *maintained* and to which such an agency as *access.* Information of either sort is "separate information."

c. *Charles* is consistent with HHS guidance and uniform decisions of other courts.

The 2016 HHS guidance explicitly disapproves of the way in which TMH handles its collection of information. That guidance was addressed to providers doing exactly what TMH does:

> some providers with *recordkeeping or record maintenance* requirements appear to be maintaining the required records only in their PSES and then refusing to disclose the records, asserting that the record sin their PSES fulfill the applicable regulatory requirements while at the same time

maintaining that the records are privileged and confidential PSWP.

81 Fed. Reg. 32655, 32657. HHS went on to "reiterate[] that any external reporting or recordkeeping obligations … cannot be met with PSWP" and that "any information that is prepared to meet any Federal, state, or local health oversight agency requirements *is not PSWP*." *Id.*

Although not entitled to *Chevron* deference (because it was not the product of a notice-and-comment period), the 2016 guidance is entitled to deference under both *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), and *Auer v. Robbins*, 519 U.S. 415 (1997). *Skidmore* deference is due when an agency has "specialized experience" that advances "the value of uniformity … [that] a national law requires." *United States v. Mead Corp.*, 533 U.S. 218, 234-35 (2001). And under *Auer*, an agency's interpretation of its own regulation is "controlling" unless it is "plainly erroneous or inconsistent with the regulation." *Auer*, 519 U.S. at 461.

Both forms of non-*Chevron* deference apply to the 2016 guidance. HHS has specialized experience interpreting and implementing the PSQIA. Additionally, the 2016 guidance interprets and resolves a

potential ambiguity in HHS's own prior rule, in a way that is not "plainly erroneous or inconsistent[.]" It is based on, and explains the meaning of, the plain text of the PSQIA and HHS's 2008 rule.

This guidance squarely addresses how TMH handled the Wiles Report and concludes that such collections of information are not PSWP. And that is the same reasoning employed in *Charles*. Quoting the 2016 guidance, this Court rejected the notion that "medical providers would be free to determine for themselves what information was available in litigation through their own strategic use of the [PSQIA's] benefits … by placing all of their reports, regardless of any other state requirements, in the [PSES.]" 209 So. 3d at 1215.

In addition to being consistent with HHS guidance, *Charles* reaches the same result as several other courts. *See Clouse*, *supra* p. 40; *Penman*, *supra* p. 40; *Hymas*, *supra* p. 40; *Dence*, *supra* p. 41; *Tibbs v. Bunnell*, *Johnson v. Cook County*, No. 15-C-741, 2015 WL 5144365 (N.D. Ill. 2015) (information collected for jail's own quality improvement policy is not PSWP); *Estate of Hultman v. County of Ventura*, No. CV-21-06280, 2022 WL 2101723 (C.D. Cal. May 16, 2022) (report created "at least in part" for a purpose other than reporting to a PSO is not PSWP).

This Court should not recede from *Charles* for several reasons, one of which is that it is consistent with clear law across several jurisdictions, as well as with HHS's 2016 guidance. Under the reasoning of *any* of those authorities, the Wiles Report is not privileged.

d. State-mandated information is also an "original provider record."

A separate reason that the Wiles Incident Report is not entitled to the PSWP privilege is that the PSQIA specifically excludes any "original patient or provider record" from the definition of patient-safety work product. The absence of any definition of "original provider record" leaves a potential ambiguity in the statute, which this Court should resolve by deferring to the reasonable interpretation HHS has given to that term.

As discussed above, *supra* pp. 12-13, HHS

> interprets 'original provider records' to include: (1) Original records (e.g., reports or documents) that are required of a provider to meet any Federal, state, or local public health or health oversight requirement regardless of whether such records are maintained inside or outside of the provider's PSES;

81 Fed. Reg. at 32658. This interpretation is reasonable given the PSQIA's text, which makes clear that information required to be collected and maintained under state law is not PSWP.

The Wiles Report is a document that was required to be generated to meet state regulatory requirements and therefore is an "original provider record" specifically excluded from PSWP under 42 U.S.C. §299b-21(7)(B)(i). This is an independent reason to reverse the district court's decision.

e. Providers cannot transform state-mandated information into PSWP merely by storing it in a PSES for submission to a PSO.

Finally, "separate information" that is by definition not privileged cannot be made privileged merely by storing it in a PSES. The second sentence in section 299b-21(7)(B)(ii) makes this clear:

> 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.

TMH's approach to its recordkeeping obligations is to take all incidents that are reported to its risk manager and divide them into Code 15 reports and all others. Anything that is not a Code 15 report is stored in the PSES. From there, TMH pulls the report only if and when AHCA asks to access it. Until that time, TMH considers any 3-day reports privileged PSWP. This is precisely what the PSQIA does *not* allow.

The text of the PSQIA itself dictates the result in this case. The Wiles Report is the result of collecting and maintaining information under Florida state law, and it therefore consists of "separate information" under the Act. It is not PSWP, and could not become PSWP merely by TMH placing the Report in its PSES. The reasoning in *Charles* is the same as the reasoning required by the PSQIA's text: The Wiles Incident Report is not privileged.

3. This case is not an appropriate vehicle to consider preemption of Amendment 7.

Finally, some discussion of Amendment 7 is warranted, since the First District held that it was preempted and Judge Thomas devoted his concurring opinion to the subject. (R.957-79 (B.L. Thomas, J., concurring.) The First District reexamined whether the PSQIA preempts Amendment 7, concluding that this Court's discussion of preemption in *Charles* was *dicta.*

The district court's decision on preemption should be reversed because it was unnecessary to reach it. Amendment 7 address patients' rights to access reports of "any adverse medical incident" regardless of whether it is related to the requesting party's own care. *See* art. X, § 25(a), Fla. Const. Although the Wiles family did request

documents under Amendment 7, the Wiles Report itself was responsive not only to those requests, but to requests for incident reports regarding Lennox Wiles himself. They were entitled to the Report irrespective of Amendment 7.

Section 395.0197(4), Florida Statutes, provides that 3-day occurrence reports, like the Wiles Report, are "subject to discovery":

> The incident reports are part of the workpapers of the attorney defending the licensed facility in litigation relating to the licensed facility and are subject to discovery, but are not admissible as evidence in court.

Regardless of whether the *Charles* opinion's discussion of preemption was *dicta*, the First District should not have even considered this point. Unlike in *Charles*, the dispute in this case does not concern adverse incidents involving TMH generally, or the doctors or staff involved with Lennox's care. This case does not present a controversy involving Amendment 7 at all. Section 395.0197, the PSQIA, and the regulations promulgated under those statutes are dispositive of the issue of whether the Wiles Report is discoverable.

Furthermore, although the First District relied on both express and implied preemption, neither doctrine applies. As discussed above, there is no question that the PSQIA does *not* expressly

preempt Florida statutes or regulations. Quite the contrary, it *preserves* and incorporates those state-law obligations. *See* 42 U.S.C. § 299b-21(7)(B)(iii). And a law cannot implicitly preempt what it expressly preserves. *See Chamber of Commerce of U.S. v. Whiting*, 563 U.S. 582, 600-01 (2011) ("Given that Congress specifically preserved such authority for the States, it stands to reason that Congress did not intend to prevent States from using appropriate tools to exercise that authority.")

The district court even noted that the PSQIA creates a "voluntary" system. (R.944.) Nevertheless, it held that it implicitly preempted state law under conflict preemption because it is "impossible for a private party to comply with both state and federal requirements" and "the two law [the PSQIA and Amendment 7] conflict in a way that it is impossible for [TMH] to comply with both" (R.955, 956 (quoting *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013) (other citations omitted))). It based this conclusion on its own overruled decision in *Charles*, 178 So. 3d at 110.

At no point has either TMH or the district court identified any requirement in the PSQIA that TMH had to comply with, much less one that would conflict with Florida law. The First District articulated

the correct standard: Conflict preemption exists where a private actor cannot comply with both state-law requirements and federal-law requirements; the Supremacy Clause demands that state law give way to federal law in those circumstances. *See Bartlett*, 570 U.S. at 475. This concept has no place where, as here, federal law does not impose any requirements at all.

The district court should not have reached the issue of preemption. This Court should not consider that issue except to note that the district court's decision on that point does not have any precedential value, as it was not the subject of any dispute in this case.

CONCLUSION

For the foregoing reasons, the decision of the District Court of Appeal for the First District should be reversed, and this case should be remanded to the First District with instructions to vacate its writ of certiorari.

CERTIFICATE OF SERVICE

WE HEREBY CERTIFY a true copy of the foregoing was furnished to all counsel on the attached service list via the Florida Courts E-Filing Portal on September 8, 2023.

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CERTIFICATE OF COMPLIANCE

Pursuant to Florida Rules of Appellate Procedure 9.045(e) and 9.210(a)(2)(B), Petitioners hereby certifies that the type size and style of the Initial Brief of Petitioners is Bookman Old Style 14pt and that the word count is 12,385.

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