FIRST DISTRICT COURT OF APPEAL
STATE OF FLORIDA

No. 1D21-1503

TALLAHASSEE MEMORIAL HEALTHCARE, INC.,

Petitioner,

v.

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

Respondents.

Petition for Writ of Certiorari—Original Jurisdiction.

November 14, 2022

NORDBY, J.

Tallahassee Memorial Healthcare, a hospital, invokes this Court's certiorari jurisdiction to review an order compelling production of "Safety Event Report No. 67593." The report, which was created by a Tallahassee Memorial employee, is the focus of a discovery dispute in this medical malpractice case. We conclude that the report is privileged and confidential under the Federal

Patient Safety and Quality Improvement Act of 2005,[1] which preempts the report's compelled disclosure under Article X, section 25 of Florida's Constitution (commonly known as "Amendment 7"). We grant the petition and quash the trial court's order. We also certify these 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?
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> 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)?

I.

Thirty-nine weeks pregnant with her unborn son, Jade Wiles noticed decreased fetal movement and went to Tallahassee Memorial Healthcare. She was monitored for several hours, after which the baby was delivered via caesarean section. During delivery, meconium was discovered in the amniotic fluid. The newborn had respiratory difficulties; he required resuscitation and ventilation, which alleviated his breathing condition. But the infant remained on oxygen supplementation for several days before he was discharged.

Twelve days after the infant's delivery, a health care employee of Tallahassee Memorial created the Safety Event Report at issue. This report has been provided under seal to the circuit court and this court for *in camera* review.

Sadly, the Wiles' son was later diagnosed with cerebral palsy. The Wiles sued Tallahassee Memorial, a physician, and other

[1] 42 U.S.C. §§ 299b-21 to -26 (2005).

medical providers, asserting that the child's diagnosed condition resulted from a birth injury or medical negligence that occurred when the child was treated in the neonatal intensive care unit.

As the litigation unfolded, the Wiles requested that Tallahassee Memorial disclose any "incident reports." In response, the hospital objected to disclosing the report at issue, asserting that it was "patient safety work product" prepared "solely for submission to the patient safety organization" and, in fact, it was submitted to that organization. Thus, Tallahassee Memorial argued the report was privileged and not discoverable under the Federal Patient Safety Act. Tallahassee Memorial also argued that the Federal Patient Safety Act preempted Article X, section 25 of the Florida Constitution, known as "Amendment 7."

The trial court ruled that the Wiles could depose Tallahassee Memorial's corporate representative about the hospital's general policies, adverse medical incidents, and the hospital's system for collecting confidential reports under the Federal Patient Safety Act and Florida's statutory reporting requirements. But the court ruled that the Respondents could not depose Tallahassee Memorial about its quality assurance, peer-review and risk-management committees, analysis of incident reporting, system for recording and analyzing incident data, or the specific report at issue.

After the deposition and another hearing, the trial court ruled, without explanation, that the report was not privileged and ordered its production. This petition for writ of certiorari followed.

II.

Certiorari review is appropriate when a trial court order departs from the essential requirements of law, resulting in material harm that cannot be remedied on appeal. *SCI Funeral Servs. of Fla., Inc. v. Walthour*, 165 So. 3d 861, 863 (Fla. 1st DCA 2015). Because the trial court's order compels the disclosure of information over a claim of privilege, Tallahassee Memorial has established a sufficient threat of irreparable harm to invoke our jurisdiction. *Id.* ("Orders requiring disclosure of material not subject to discovery by reason of privilege are commonly reviewed by certiorari because the harm caused by wrongly compelling a

petitioner to disclose protected material is irreparable."). We now turn to the merits of the petition.

Tallahassee Memorial argues the specific report at issue is privileged from disclosure under the Federal Patient Safety Act, notwithstanding Florida's constitutional provision establishing a right of access to records "relating to any adverse medical incident." Art. X, § 25, Fla. Const. Because our decision turns on the interplay between these two laws, we provide some background.

A. The Federal Patient Safety and Quality Improvement Act of 2005 and Patient Safety Work Product

Through the Federal Patient Safety Act of 2005, Congress established a "voluntary, confidential, non-punitive system of data sharing of healthcare errors for the purpose of improving the quality of medical care and patient safety." *S. Baptist Hosp. of Fla., Inc. v. Charles* (*Charles I*), 178 So. 3d 102, 105 (Fla. 1st DCA 2015), *rev'd*, 209 So. 3d 1199 (Fla. 2017). Under the Act's framework, participating health care providers would establish a "patient safety evaluation system" to facilitate the collection, management, and analysis of relevant information. *See* 42 U.S.C. § 299b-21(6). "After the information is collected in the patient safety evaluation system, the provider would forward it to its patient safety organization (PSO), which serves to collect and analyze the data and provide feedback and recommendations to providers on ways to improve patient safety and quality of care." *Charles I*, 178 So. 3d at 105 (citing 42 U.S.C. § 299b–24; 73 Fed. Reg. at 70,733).

The Federal Patient Safety Act declared all "patient safety work product" to be privileged and confidential. 42 U.S.C. § 299b-22(a)–(b). This means that "[n]otwithstanding any other provision of Federal, State, or local law," if an item constitutes patient safety work product, then not only "shall [it] not be disclosed," *id.* § 299b-22(b), but it also "shall not be [] subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, [or] subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding." *Id.* § 299b-22(a)(1)–(2). Patient safety work product also may not be "admitted as evidence in any Federal, State, or local governmental

civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider." *Id.* § 299b-22(a)(4).

The definition of patient safety work product is broad and includes "any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements":

> (i) which--
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> > (I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or
> >
> > (II) are developed by a patient safety organization for the conduct of patient safety activities;
> >
> > and which could result in improved patient safety, health care quality, or health care outcomes; or
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> (ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

42 U.S.C. § 299b-21(7)(A). If *any* one of these criteria is met, the document is privileged and confidential.

Congress also specifically defined what patient safety work product is not. Patient safety work product "does not include a patient's medical record, billing and discharge information, or any other original patient or provider record." 42 U.S.C. § 299b-21(7)(B)(i). It also does not include "information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system." 42 U.S.C. § 299b-21(7)(B)(ii). "Patient safety evaluation system" means "the collection, management, or analysis of information for reporting to or by a patient safety organization." 42 U.S.C. § 299b-21(6). Thus, the "separate information" consists of data and records generated for reasons other than reporting to a patient safety organization and is not entitled to the privilege and confidentiality protections of the Federal Patient Safety Act.

Finally, the Federal Patient Safety Act made it clear that patient safety work product should not be construed to relieve a provider's duty to respond to federal, state, or local law obligations with information that is *not* privileged or confidential:

> (iii) Nothing in this part shall be construed to limit—
>
> > (I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;
> >
> > (II) the reporting of information described in this subparagraph to a Federal, State, or local 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 under Federal, State, or local law.

42 U.S.C. § 299b-21(7)(B)(iii).

Under this framework, if federal, state, or local law *requires* a provider to document and report certain information, then that information falls outside the definition of patient safety work product and no privilege attaches. If, however, the information does meet the definition, then, under federal law, it is confidential, the privilege attaches, and "[n]otwithstanding any other provision of Federal, State, or local law," it "shall not" be disclosed, it "shall not" be subject to subpoena or order, it "shall not" be subject to discovery, and it "shall not" be admitted as evidence in any proceeding against a provider.[2]

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[2] Of course, the Act contains some express exceptions from this privilege and confidentiality, but none of them apply here. *See, e.g.*, 42 U.S.C. § 299b-22(c)(1)(A) (providing exception for use in criminal proceedings "but only after a court makes an *in camera* determination that such patient safety work product contains evidence of a criminal act and that such patient safety work product is material to the proceeding and not reasonably available

B. "Amendment 7" and Florida's Adverse Incident Reporting Requirements

A year before enactment of the Federal Patient Safety Act, Florida voters approved a citizen initiative to amend the state's constitution. Known as Amendment 7, the provision recognizes "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." Art. X, § 25(a), Fla. Const. An "adverse medical incident" is defined broadly to include "medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient[.]" Art. X, § 25(c)(3), Fla. Const.

Also pre-dating the Federal Act are various Florida statutes and rules that require health care facilities to document and report "adverse incidents" to Florida's Agency for Health Care Administration. An adverse incident is "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 results in one of several enumerated injuries. § 395.0197(5), Fla. Stat. (2014).

Under this regulatory scheme, each licensed facility must establish an internal risk management program to investigate and analyze "the frequency and causes of general categories and specific types of adverse incidents to patients"; develop "appropriate measures to minimize the risk of adverse incidents to patients"; analyze "patient grievances that relate to patient care and the quality of medical services"; include a system for informing

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from any other source"); *id.* § 299b-22(c)(1)(C) (authorizing disclosure "if authorized by each provider identified in such work product"); *id.* § 299b-22(c)(2)(D) (allowing voluntary disclosure by a provider "to the Food and Drug Administration with respect to a product or activity regulated by the Food and Drug Administration").

patients when they are "the subject of an adverse incident"; and develop and implement an "incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the licensed health care facility to report adverse incidents to the risk manager . . . within 3 business days after their occurrence." § 395.0197(1), Fla. Stat.; *see also* Fla. Admin. Code R. 59A-10.0055(1)–(3) (addressing requirements for risk management system to report adverse incidents to Florida's Agency for Health Care Administration).

In turn, a facility's risk manager shall "be responsible for the regular and systematic reviewing of all incident reports including 15-day incident reports for the purpose of identifying trends or patterns as to time, place or persons." Fla. Admin. Code R. 59A-10.0055(1)–(3). "Evidence of the incidents reporting and analysis system and copies of summary reports, incident reports filed within the facility, and evidence of recommended and accomplished corrective actions shall be made available for review to any authorized representative of the Agency [for Health Care Administration] upon request during normal working hours." Fla. Admin. Code R. 59A-10.0055(3).

We note that the definition of "adverse medical incident" under Amendment 7 is broader than the definition of "adverse incident" under section 395.0197. So Amendment 7 can apply even if section 395.0197 does not.

III.

Our task is to figure out where Tallahassee Memorial's safety report fits within this mosaic of federal and state laws. Also informing our analysis is the Florida Supreme Court's decision in *Charles v. Southern Baptist Hosp. of Florida, Inc.* (*Charles II*), 209 So. 3d 1199 (Fla. 2017), which reversed *Charles I*, 178 So. 3d at 102, a decision of this Court.

A. Charles I *and* Charles II

In *Charles I*, Southern Baptist Hospital provided the plaintiffs in a medical malpractice action with several reports, including reports it had removed from its patient safety evaluation system. It declined to provide other "occurrence reports" that were

considered patient safety work product. *Charles I,* 178 So. 3d at 106. The plaintiffs then filed a demand for those documents in the circuit court arguing that because those documents were not "solely" prepared for submission to a patient safety organization, they were not privileged and confidential under the Federal Patient Safety Act. *Id.* at 106–07.

The circuit court agreed, ruling that the undisclosed occurrence reports were subject to discovery, "even if the information was collected in a [patient safety evaluation] system for submission to a [patient safety organization]." *Id.* at 107. The circuit court ruled 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 Act.]" *Id.* (alteration in original). In its petition for certiorari in this Court, the hospital asserted that the circuit court order "contradict[ed] the plain language of federal law and undermine[d] the important federal policies that Congress intended to advance." *Id.*

This Court held that the occurrence reports prepared by the workers at Southern Baptist were privileged and confidential patient safety work product because they were placed into the hospital's patient safety evaluation system, "where they remained *pending submission* to a [patient safety organization]." *Charles I*, 178 So. 3d at 108 (emphasis in original). We noted that the "documents at issue also do not meet the [Federal Patient Safety] Act's definition of what is *not* [patient safety work product]." *Id.* (emphasis added). We concluded that the documents were "not original patient records and were not collected, maintained, or developed separately from the [Patient Safety Evaluation] system. *See* 42 U.S.C. § 299-21(7)(B)(i)–(ii)." *Id.* Thus, "because they meet the definition of [patient safety work product] the documents are entitled to the federal protection under the Act." *Id.* at 108–09.

This Court also held that the Federal Patient Safety Act "expressly preempts any broad discovery right under Amendment 7 to documents meeting the definition of [patient safety work product]." *Id.* at 110. Besides finding express preemption, this Court also found an implied preemption of Amendment 7:

> because compliance with both federal and state law would be impossible. That is, documents that meet the definition of [patient safety work product] under the Act are categorically protected and excluded from production. To produce [patient safety work product] in response to an Amendment 7 discovery request would be in contravention to the Act.

Charles I, 178 So. 3d at 110.

The Florida Supreme Court saw the case differently and reversed this Court in *Charles II*. Reviewing our decision under its mandatory appellate jurisdiction,[3] the Supreme Court found that the documents were "adverse incident reports" that the hospital had to create and maintain under Florida law:

> 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)

Charles II, 209 So. 3d at 1211.

The adverse incident reports, which were never submitted to a patient safety organization, "were not created solely for the

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[3] The Supreme Court explained that the case arose under its "mandatory jurisdiction of appeals from a decision of a district court of appeal 'declaring invalid a state statute or a provision of the state constitution.'" *Charles II*, 209 So. 3d at 1203 (citing Art. V, § 3(b)(1), Fla. Const.).

purpose of submission to a patient safety organization." *Id.* at 1216 (citing § 395.0197(4)–(7), Fla. Stat. (2015); Fla. Admin. Code R. 59A-10.0055). Because the documents were created for a "dual purpose"—as both patient safety work product under the federal law and for other purposes under state law—the hospital lost the protection of the federal privilege and confidentiality. *Charles II*, 209 So. 3d at 1216.

The Supreme Court, however, acknowledged that the Federal Patient Safety Act created "a tightly crafted federal privilege for 'patient safety work product' actually reported to a 'patient safety organization.'" *Id.* at 1207 (quoting *Lee Med., Inc. v. Beecher*, 312 S.W.3d 515, 535 (Tenn. 2010)). And "[s]uch information is not subject to discovery in legal proceedings." *Id.* (quoting *Rasor v. Nw. Hosp., LLC*, 373 P.3d 563, 573 (Ariz. Ct. App. 2016)). Because Southern Baptist's documents fell outside the definition of patient safety work product, the aegis of the Federal Act's "tightly crafted" privilege did not shield them from discovery.

The Supreme Court then addressed whether the Federal Act preempted Amendment 7. It did so even though it had concluded the adverse incident reports at issue did not fall under the Act's definition of patient safety work product.

As to express preemption, the Court reasoned that the Federal Act did not expressly preempt Amendment 7 because "the documents to which citizens have a right to access pursuant to Amendment 7 are not patient safety work product under the Federal Act's definition." *Id.* at 1213. The Court then explained that there was no implied preemption, as "a review of the plain meaning of the Federal Act, coupled with the statements of Congress and the Department of Health and Human Services, which is in charge of implementing the Federal Act, in light of Florida's Amendment 7, shows that the two systems can coexist harmoniously." *Id.* at 1215.

B. The Document in This Case

We conclude that Tallahassee Memorial's "Safety Event Report No. 67593" qualifies as patient safety work product and is entitled to confidentiality under the Federal Patient Safety Act for two reasons. First, unlike the documents at issue in *Charles II*, the

report here *was* submitted to the hospital's patient safety organization. Second, the document is not an "adverse incident" report, which state law defines and requires to be submitted to the Agency for Health Care Administration. The circuit court made no such finding that the document was an adverse incident report and, based on our *in camera* review, it does not document an "adverse incident" under section 395.0197(5), Florida Statutes. Tallahassee Memorial did not send this report to the Agency for Health Care Administration or any relevant state regulatory entity, *nor was it required to file the report* under state law. Given this, the document retains its privileged status as patient safety work product under the Federal Patient Safety Act. The trial court departed from the essential requirements of the law in concluding otherwise.

Section 395.0197, Florida Statutes, requires the creation of internal incident reports related to statutorily defined "adverse incidents." An adverse incident is "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 results in death, brain, or spinal damage, and other severe injuries, as well as other occurrences not relevant here. *See* § 395.0197(5)–(7), Fla. Stat. (2014). These reports are required to be reported to Florida's Agency for Health Care Administration within fifteen days. § 395.0197(7), Fla. Stat.; § 395.002(2), Fla. Stat. (defining "Agency" as the Agency for Health Care Administration).

The report at issue was not an original provider record related to the medical treatment of the Wiles' son. The infant had respiratory difficulties at birth, after an initial observation of decreased fetal movement before birth. This respiratory condition required resuscitation and ventilation, which alleviated his breathing condition. Still, the infant remained on oxygen supplementation for several days before he was discharged. He was not diagnosed with any specified brain or spinal injury (either at the time of his birth or when the report was created), which would have required Tallahassee Memorial to file an adverse-incident report under section 395.0197, Florida Statutes. The report does not document an event "associated in whole or in part with medical intervention" that resulted in one of the specified

injuries referenced in this statute. Because the report did not document an "adverse incident," it was not required to be reported to the agency, nor was it reported.

The Wiles argue that because Tallahassee Memorial's corporate representative testified that the document was created as part of the hospital's record-keeping responsibilities, this constituted an admission that the document was not "solely" created as patient safety work product under *Charles II*. But again, the Wiles do not and cannot argue that the document was provided to any state entity. And an answer in a deposition does not dictate how this Court considers the document: if the document was created for the patient safety evaluation system, and if the document was provided to a patient safety organization (as it was here), then it is privileged and confidential as mandated by the Federal Patient Safety Act. Thus, the document remains privileged under federal law, regardless of the representative's ambiguous testimony, which merely acknowledged that the patient safety evaluation system contained patient safety work product *and* reports mandated by state law for record-keeping purposes and state review.

IV.

Having concluded that the report is privileged and confidential patient safety work product under the Federal Patient Safety and Quality Improvement Act, we now address preemption. Tallahassee Memorial argues that the Federal Patient Safety Act preempts the report's compelled disclosure under Amendment 7. We agree. But first, a word about *Charles II*.

Although the Florida Supreme Court in *Charles II* sought to address "whether Amendment 7 and other Florida statutes are preempted by the Federal [Patient Safety] Act," 209 So. 3d at 1212, it did not resolve the issue before us today. The Court's preemption analysis immediately followed its conclusion that the documents at issue were not patient safety work product under the Federal Act. *Id.* Without the federal law's confidentiality and privilege provisions at play, there was no need to reach the matter of preemption. Because the Court did not need to address preemption to reach the ultimate disposition in the case, its discussion on the subject could be dicta. *See Pedroza v. State*, 291 So. 3d 541, 547

(Fla. 2020) ("Any statement of law in a judicial opinion that is not a holding is dictum. . . 'A holding consists of those propositions along the chosen decisional path or paths of reasoning that (1) are actually decided, (2) are based upon the facts of the case, and (3) lead to the judgment.'") ((quoting *State v. Yule*, 905 So. 2d 251, 259 n.10 (Fla. 2d DCA 2005) (Canady, J., specially concurring)). That said, we are reluctant to conclude that the Supreme Court's express statements on preemption in *Charles II* constitute mere dicta, so our analysis does not assume such.

Yet whether the preemption language in *Charles II* is dicta or not, because that case is distinguishable, it does not control here. *Charles II* addressed preemption in the context of documents that were not patient safety work product (and thus not subject to the privilege protections under federal law). Given our conclusion that Tallahassee Memorial's report is patient safety work product, *Charles II* is not dispositive.

Now for the question at hand. Preemption is grounded in the Supremacy Clause of the United States Constitution, which provides that a federal law is "supreme" over any conflicting state law. Art. VI, cl. 2, U.S. Const. (stating that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding"); *see Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992) ("[U]nder the Supremacy Clause, from which our pre-emption doctrine is derived, any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield" (internal quotation marks omitted)).

Three types of preemption exist—express, conflict, and field. *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1480 (2018). Although bearing different names, each "work[s] in the same way: Congress enacts a law that imposes restrictions or confers rights on private actors; a state law confers rights or imposes restrictions that conflict with the federal law; and therefore the federal law takes precedence and the state law is preempted." *Id.*

Express preemption exists when a federal statute includes "explicit pre-emptive language." *Gade*, 505 U.S. at 98. Absent such language, a state law may be impliedly pre-empted through

conflict with a federal law if it is "impossible for a private party to comply with both state and federal requirements." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013) (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990); *see also Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963) ("A holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility . . . ."). And field preemption exists when "the scheme of federal regulation is 'so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it[.]'" *Gade*, 505 U.S. at 98 (quoting *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982)).

We hold that the Federal Patient Safety Act expressly preempts Amendment 7 to the extent that the state law would compel the disclosure of Tallahassee Memorial's document. Pointedly, the federal law contains an express preemption clause, which makes "patient safety work product" privileged regardless of state law to the contrary. *See* 42 U.S.C. § 299b-22(a)(1)–(2). "[W]hen Congress has made its intent known through explicit statutory language, the courts' task is an easy one." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). The Act makes clear that *"[n]otwithstanding any other provision of Federal, State, or local law*," if an item constitutes patient safety work product, then not only "shall [it] not be disclosed," *id.* § 299b-22(b), but it also "shall not be [] subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, [or] subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding." *Id.* § 299b-22(a)(1)–(2). Patient safety work product also may not be "admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider." *Id.* § 299b-22(a)(4). Because Congress has included explicit language of preemption in the Federal Patient Safety Act, Amendment 7 cannot compel disclosure of Tallahassee Memorial's report. *See Fla. Health Scis. Ctr., Inc. v. Azar*, 420 F. Supp. 3d 1300, 1306 (M.D. Fla. 2019), *vacated on other grounds and remanded sub nom. Fla. Health Scis. Ctr., Inc. v. Sec'y, U.S. Dep't of Health & Hum. Servs.*, 844 F. App'x

217 (11th Cir. 2021) ("Here, it is undisputed that the documents at issue in the state court action are patient safety work product. Accordingly, the Court concludes that the Patient Safety Act preempts Amendment 7 with respect to these documents."); *Daley v. Teruel*, 107 N.E.3d 1028, 1045–46 (Ill. App. Ct. 1st Dist. 2018) ("[T]he express preemption clause in the Patient Safety Act demonstrates Congress's intent to supersede any court order requiring the production of documents that meet the definition of patient safety work product."); *Quimbey v. Cmty. Health Sys. Prof'l Servs. Corp.*, 222 F. Supp. 3d 1038, 1043 (D.N.M. 2016) (finding that "the express language of the [the Federal Patient Safety Act] demonstrates Congressional intent to preempt" any state laws providing for less protection of documents that constitute patient safety work product); *see also* Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,774 (Nov. 21, 2008) (stating that the Federal Patient Safety Act "generally preempt[s] State or other laws that would permit or require disclosure of information contained within patient safety work product").

The Federal Act also preempts Amendment 7 because the two laws conflict in a way that it is impossible for Tallahassee Memorial to comply with both. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013). "That is, documents that meet the definition of [patient safety work product] under the Act are categorically protected and excluded from production. To produce [patient safety work product] in response to an Amendment 7 discovery request would be in contravention to the Act." *Charles I*, 178 So. 3d at 110.

We are mindful that federal preemption of any state law is "strong medicine, not casually to be dispensed." *Grant's Dairy--Maine, LLC v. Comm'r of Maine Dep't of Agric., Food & Rural Res.*, 232 F.3d 8, 18 (1st Cir. 2000). But, as prescribed by the Supremacy Clause, because Amendment 7 conflicts with federal law, the former must yield to the latter.

We GRANT the Petition and quash the order of the circuit court requiring disclosure of Tallahassee Memorial's Safety Event Report; QUESTIONS CERTIFIED.

B.L. THOMAS, J., concurs with opinion; MAKAR, J., dissents with opinion.

Not final until disposition of any timely and authorized motion under Fla. R. App. P. 9.330 or 9.331.

B.L. THOMAS, J., concurring.

I fully concur in the majority opinion. I also concur in the certified questions.

I agree with the majority opinion that the discussion in *Charles II* rejecting our prior decision's holding on preemption could be dicta, and I also agree that the decision in *Charles II* is distinguishable from this case.

I write to provide an additional perspective regarding the interplay between Amendment 7 and the Federal Patient Safety Act. I also write to discuss the judicial interpretations of Amendment 7 which have greatly expanded the legal reach of that constitutional provision far beyond the limits provided by the amendment's proponents in the ballot title, summary, and text of Amendment 7.

The Federal Patient Safety Act was precisely intended to protect these types of reports, prepared by health care workers to identify and recommend improvements to patient safety under the protection of confidentiality. Forced disclosure in violation of the federal law would destroy the overarching purpose of the Act which is to assure that health care workers can safely create candid and beneficial recommendations to save patients' lives without concern for disclosure in adverse litigation. The circuit court's order of disclosure was a departure from the essential requirement of law that would result in irreparable harm to Petitioner, which would be forced to disclose its patient safety work product in violation of federal law. And Petitioner's health care workers would lack any incentive to produce patient safety work product to enhance patient safety, when they know that such reports will be disclosed in litigation.

The Joint Commission on the Accreditation of Health Care Organizations, the nation's oldest and largest standards-setting and accrediting body in the health care field, filed an amicus brief in this Court in *Charles I* describing its advocacy to promote patient safety organizations and support the confidentiality and privilege of patient safety work product.[*] Brief of the Joint Commission in Support of Petitioner, *Charles I*, 178 So. 3d 102 (No. 1D15-109), 2015 WL 10734108. The Joint Commission explained that when it began its quest in 1997, calling for congressional action to establish defensive barriers to prevent patient injury, the term "patient safety" was not yet widely used in healthcare. *Id.* at *8. The Joint Commission recalled that at that time, few in the health-care field appreciated that many of the reasons for patient safety events were due to the failure of organizations and practitioners to systematically identify, analyze, and take appropriate action against preventable risks, and serious adverse events or risks thereof were not routinely reported or shared among providers for fear of reprisal, shame, or litigation. *Id.*

The Senate Committee Report on the Federal Patient Safety Act noted that "society's long-standing reliance *on the threat of malpractice litigation discourages health care professionals* and organizations from disclosing, sharing and discussing information about medical errors." S. Rep. No. 108-196, at 2 (2003) (emphasis added). The report stated, "[t]he bill also provides broad confidentiality protections, which are necessary to engender the trust and cooperation of the health care providers. *Without participation of health care providers the system cannot be effective in collecting information*." *Id.* at 3 (emphasis added).

To create a culture of safety, Congress created certain protections:

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[*] This Court may take judicial notice of our own records. § 90.202(6), Fla. Stat. (stating a court may take judicial notice of "[r]ecords of any court of this state or of any court of record of the United States or of any state, territory, or jurisdiction of the United States.").

> The Patient Safety Act focuses on creating a voluntary program through which health care providers can share information relating to patient safety events with [patient safety organizations], with the aim of improving patient safety and the quality of care nationwide. The statute attaches privilege and confidentiality protections to this information, termed 'patient safety work product,' to encourage providers to share this information without fear of liability and creates [patient safety organizations] to receive this protected information and analyze patient safety events. These protections will enable all health care providers, including multi-facility health care systems, to share data within a protected legal environment, both within and across states, without the threat that the information will be used against the subject providers.

Patient Safety and Quality Improvement, 73 Fed. Reg. 70732-01, (Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3).

I note that the decision in *Charles II* stated that the Federal Patient Safety Act's "Rules of Construction" provided that the Act did not preempt "*any State law requiring a provider to report information that is not patient safety work product*." *Charles v. S. Baptist Hosp. of Fla., Inc. (Charles II)*, 209 So. 3d 1199, 1210 (Fla. 2017). The supreme court then stated that Congress "carved out broad exceptions to the Federal Patient Safety Act's definition of patient safety work product." *Id.* But in fact Congress created a *broad privilege* of confidentiality which was the foundation of the patient safety work product. S. Rep. 108-196, at 3. Without this protection, the federally enacted patient safety work product would be meaningless, because no health care worker would candidly create the report knowing that any statements will be subject to forced disclosure and used against the health care worker or their employer in litigation.

The History of Amendment 7 and Judicial Expansion of the Reach of That Amendment.

To better understand the reason the document more fully at issue is confidential under the Federal Patient Safety Act and not subject to discovery disclosure, it is helpful to review the

interpretation of Amendment 7 rendered in *Charles II* and related decisions.

The history of the expansion of Amendment 7 begins with the supreme court's 2004 advisory opinion. The supreme court held that the ballot summary and text of Amendment 7 did not violate the single-subject state constitutional requirement of article XI, section 3 of the Florida Constitution. The court also held the initiative petition did not violate section 101.161, Florida Statutes, which requires the ballot summary to accurately inform the electorate of the true intention and likely future impact of Amendment 7. *See In re Advisory Op. to the Att'y Gen. re Patients' Right to Know About Adverse Med. Incidents*, 880 So. 2d 617 (Fla. 2004) ("Patients' Right to Know"). This interpretation and its aftermath which led to the rationale of the decision in *Charles II,* have adversely affected the effort of the United States Congress to improve patient safety in Florida by providing a system for health care workers to confidentially report recommendations and observations to protect future patients from medical errors. *See S. Baptist Hosp. of Fla., Inc. v. Charles (Charles I)*, 178 So. 3d 102, 105 (Fla. 1st DCA 2015), *rev'd* 209 So. 3d 1199 (Fla. 2017), ("IOM estimated that at least 44,000 people and potentially as many as 98,000 people die in United States Hospitals each year as a result of *preventable* medical errors." (citing *To Err is Human: Building a Safer Health System*, Institute of Medicine (1999))).

In its review of the ballot title and summary of Amendment 7, the supreme court included the following language from the "Statement and Purpose" of the initiative text:

> The Legislature has enacted provisions relating to a patients' bill of rights and responsibilities, including provisions relating to information about practitioners' qualifications, treatment and financial aspects of patient care. The Legislature *has*, however, *restricted public access* to information concerning a particular health care provider's or facility's investigations, incidents or history of *acts, neglects, or defaults* that have injured patients or had the potential to injure *patients*. This information may be important to a *patient*. The purpose of this amendment is to create a constitutional right for a *patient or potential*

> *patient* to know and have access to records of a health care facility's or provider's adverse medical incidents, including medical malpractice and other *acts* which have caused or have the potential to cause injury or death.

Patients' Right to Know, 880 So. 2d at 618 (emphasis added).

The initiative text then provided the title "*Patients'* Right to Know About Adverse Medical Incidents" and states that "[i]n addition to any other similar rights provided herein or by general law, *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.* (emphasis added).

The phrase "adverse medical incident" is defined as:

> [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.*

Id. (emphasis added).

The supreme court then provided the ballot summary of Amendment 7:

> Current Florida law *restricts information* available to patients related to investigations of adverse medical incidents, such as medical malpractice. This amendment would give *patients* the right *to review, upon request,* records of health care facility's or providers' adverse medical incidents, including those which *could* cause injury or death[.]

Id. (emphasis added).

Nowhere in the ballot title, summary, or text did the proponents inform the electorate that the purpose of Amendment 7 was to transform medical malpractice litigation by untethering such lawsuits from the rules of civil procedure, by allowing one party's counsel to obtain medical records or reports irrelevant to the alleged negligence asserted. *See Morton Plant Hosp. Ass'n, Inc. v. Shahbas ex rel. Shahbas*, 960 So. 2d 820, 824, 826–27 (Fla. 2d DCA 2007) (stating that "[t]here is no requirement that the records discoverable under Amendment 7 be relevant to any pending litigation . . . . Whether the request is overly burdensome is not a relevant consideration under Amendment 7"); *Columbia Hosp. Corp. of S. Broward v. Fain*, 16 So. 3d 236, 240 (Fla. 4th DCA 2009) ("A request for Amendment 7 materials is not an ordinary discovery request which can be subjected to overbreadth, irrelevance, or burdensomeness objections. Pursuant to the amendment, a 'patient' has the *absolute right* to discover records relating to *any* adverse medical incident and that right is not conditioned on the discovery being relevant to a pending claim." (emphasis added)).

Similarly, the ballot title, summary, and text do not include words or phrases such as "lawyer," "lawsuit," "attorney," "counsel," "discovery," "privilege," "client," "litigation," "absolute right," or any other indication that the amendment was meant to greatly benefit one party in medical malpractice litigation, rather than simply help inform patients to choose a health care provider more knowledgeably. Nor did the Amendment 7 proponents inform the electorate that it would require courts to admit evidence that would be otherwise *inadmissible* under the Florida Evidence Code, including irrelevant and purported bad acts, and essentially "subsequent remedial measures" of hospitals. *See* § 90.402, .404, .407, Fla. Stat.

Thus, the putative intent of Amendment 7, based on its ballot title, summary, and text was not to punish health care workers by forcing them to disclose in adverse litigation what they thought was confidential information created to enhance patient safety. *See Patients' Right to Know,* 880 So. 2d at 621 (rejecting challenge to amendment by Florida Dental Association and characterizing Association's prescient predictions that amendment would eviscerate work-product privilege as "speculation"). Rather, the

stated purpose of the amendment was to promote a patient's "right to know" to allow patients to wisely choose a health care provider by having access to more information about a provider's adverse medical incidents.

A more accurate ballot title and summary would have informed the electorate that the amendment would strip health care workers of any evidentiary protections, including work-product and attorney-client privileges, by forcing health care workers to disclose reports that they assumed were confidential. And the dissenting opinion in *Edwards v. Thomas* correctly noted that nothing in *Patients' Right to Know* acknowledged this legal transformation that results from the elimination of all limits on what plaintiffs' counsel can obtain and use against health care workers, *regardless of relevancy, privilege, or its inflammatory effect on a jury*. *Edwards v. Thomas*, 229 So. 3d 277, 295 (Fla. 2017) (Canady, J., dissenting). Furthermore, the decision in *Patients' Right to Know* did not acknowledge the massive legal changes that subsequent legal decisions have approved.

The Resulting Legal Transformation.

Many state court decisions, and the supreme court, now describe the power of counsel under Amendment 7 to force health care workers to disclose memoranda designed to enhance patient safety, as an *absolute right* that trumps all legal protections previously applicable:

> Since *Buster*, courts across the State have reiterated the statements contained therein, and have commented on a patient's right to access these Amendment 7 adverse medical incident reports. *See Baldwin v. Shands Teaching Hosp. & Clinics, Inc.*, 45 So. 3d 118, 123 (Fla. 1st DCA 2010) ("The Florida Supreme Court has recognized that this popularly adopted amendment affects, or even abrogates, statutes that previously exempted records of investigations, proceedings, and records of peer review panels from discovery in civil or administrative actions."); *Lakeland Reg'l Med. Ctr. v. Neely ex rel. Neely*, 8 So. 3d 1268, 1270 (Fla. 2d DCA 2009) ("As broadly construed by the court in *Buster*, Amendment 7 'remove[s] *any barrier* to a patient's

discovery of adverse medical incident information, including the peer review protections provided by the statute.' " (alteration in original) (emphasis added)); *Columbia Hosp. Corp. of S. Broward v. Fain*, 16 So. 3d 236, 240 (Fla. 4th DCA 2009) ("The purpose of Amendment 7 was to lift the shroud of secrecy from records of adverse medical incidents and make them widely available . . . . A request for Amendment 7 materials is not an ordinary discovery request which can be subjected to overbreadth, irrelevance, or burdensomeness objections. Pursuant to the amendment, a 'patient' has the *absolute right* to discover records relating to *any* adverse medical incident and that right is not conditioned on the discovery being relevant to a pending claim." (emphasis added)); *See*, 79 So. 3d at 15 ("[Limiting disclosure of adverse medical incidents] conflicts with Amendment 7's definition of adverse medical incidents, which does not place a boundary on matters to be disclosed to patients."); *Gmach*, 14 So. 3d at 1050 ("In approving Amendment 7, the citizens of Florida have demonstrated their conclusion that a patient's right to obtain records made in the course of business by a health care provider is a more important consideration than the chilling effect created by the potential public disclosure of those records."); *see also See*, 79 So. 3d at 14 ("[The Hospital's] argument that pursuant to [section 381.028(7)(b)1., Florida Statutes,] it must provide only certain reports . . . is expressly contrary to the amendment. The amendment provides that it is '*not limited to'* incidents that already must be reported under law." (emphasis in original) (quoting *Fain*, 16 So. 3d at 241)); *Buster*, 984 So. 2d at 489 ("Indeed, in our opinion approving placement of the amendment of [sic] the ballot we concluded that it 'creates a broader right to know about adverse medical incidents than currently exists.' "). While some courts have continued to reiterate the Amendment's purpose as abrogating pre-existing statutory limitations on adverse medical incident discovery, others have referred to the constitutional right created by Amendment 7 as an "*absolute right*," *Fain*, 16 So. 3d at 240 (emphasis added), aimed at eliminating

> "*any* legal barrier to obtaining this information," *Buster*, 984 So. 2d at 489 (emphasis added).

Edwards, 229 So. 3d at 286–87.

Thus, under state law, there now appears to be no limitation on the ability of legal counsel in litigation to demand of health care workers any confidential reports prepared to enhance patient safety.

This is so notwithstanding any attempt to assert formerly held legal rights of evidentiary privileges or protections otherwise provided by state law:

> Tellingly, "[t]he Florida Legislature enacted these peer review statutes in an effort to control the escalating cost of health care by encouraging self-regulation by the medical profession through peer review and evaluation." *Cruger v. Love*, 599 So. 2d 111, 113 (Fla. 1992). These statutes, however, are the floor, rather than the ceiling for health care facilities' self-regulation. *See* § 395.0197(3), Fla. Stat. (2017) ("In addition to the programs mandated by this section, other innovative approaches intended to reduce the frequency and severity of medical malpractice and patient injury claims shall be encouraged and their implementation and operation facilitated."). In addition to those required by statute, health care facilities can participate in and seek out additional voluntary committees and programs that provide additional resources on how to improve the quality of care rendered to patients. *Id.; see generally Charles*, 209 So. 3d 1199 (discussing the Federal Patient Safety and Quality Improvement Act and how it relates to patients' rights under Amendment 7). These additional programs and reviews cannot logically be excluded from Amendment 7's application simply because they are in addition to the base-level, statutorily-required risk management committees. Such a result would be directly contrary to the intent and express words of Florida voters to have greater access to adverse medical incident records than they did before the passage of Amendment 7. Moreover, the result asserted by Bartow would provide a

> trap door through which hospitals could totally avoid their *discovery* obligations by outsourcing their adverse medical incident reporting to external, voluntary risk management committees separate from those required by the Florida statutory scheme.
>
> Therefore, we hold that, based on the express language and the principles of constitutional analysis, the external peer review committee at issue in this case does qualify as a "similar committee" under Amendment 7.

Edwards, 229 So. 3d at 289–90 (emphasis added). Again, *nothing* in the ballot title, summary, or text refers to discovery. And yet the courts have held that many discovery limitations do *not* apply to Amendment 7.

Other decisions such as *Columbia Hospital Corporation of South Broward v. Fain*, have also rendered interpretations of Amendment 7 that have eviscerated former rights of health care workers to engage in previously confidential communications designed to enhance and protect patient safety:

> Prior to the passage of Amendment 7, a hospital's incident reports have generally been considered protected as fact work product and discoverable only upon a showing of need and undue hardship. *N. Broward Hosp. Dist. v. Button,* 592 So. 2d 367, 368 (Fla. 4th DCA 1992); *Mount Sinai Med. Ctr. v. Schulte,* 546 So. 2d 37 (Fla. 3d DCA 1989); *Bay Med. Ctr. v. Sapp,* 535 So. 2d 308, 312 (Fla. 1st DCA 1988); *Humana of Fla., Inc. v. Evans,* 519 So. 2d 1022 (Fla. 5th DCA 1987).
>
> . . . .
>
> A request for Amendment 7 materials *is not an ordinary discovery request* which can be subjected to overbreadth, irrelevance, or burdensomeness objections. Pursuant to the amendment, a "patient" has the absolute right to discover records relating to any adverse medical incident and that right is not conditioned on the discovery being relevant to a pending claim. A litigant in a medical

> malpractice case clearly qualifies as a "patient" under the amendment and is entitled to discover the information. *It is illogical to conclude that the estate could discover information regarding adverse medical incidents outside the context of this litigation but cannot discover the same information as part of its discovery in this case.*
>
> . . . .
>
> . . . In *Buster*, the Florida Supreme Court made clear that the limited *discovery protections previously afforded by Florida's statutes were effectively abolished* by the passage of Amendment 7 as far as adverse medical incidents are concerned. 984 So. 2d at 488–89. These discovery protections were not mandated by the federal Health Care Quality Improvement Act of 1986, *and while they may have contributed to effective peer review in Florida,* the people of the State of Florida are not preempted from abolishing these statutory protections by constitutional amendment.

Columbia Hosp. Corp. of S. Broward v. Fain, 16 So. 3d 236, 239–41, 243 (Fla. 4th DCA 2009) (emphasis added).

It is not "illogical," however, to interpret Amendment 7 to exclude the forced disclosure in a litigation of previously privileged information created by health care providers to *protect patients*. But as noted, nothing in the amendment's text, ballot title, or summary makes a single reference to discovery, litigation, or the elimination of peer-review confidentiality designed to promote patient safety. The amendment's "Statement of Purpose" refers only to legislative "restrictions" of certain information, with no explanation that the Legislature had a valid rationale to limit access to communications to improve future patients' safety and well-being through confidential peer review and other confidential work product. Nor does the amendment's public description inform voters of the danger to patient safety that logically flows from such disclosures, which was precisely the reason Congress enacted the Patient Safety Act one year after Amendment 7 was approved in 2004.

Florida courts' interpretations of Amendment 7 have all but completely eliminated health care workers' confidentiality in Florida. The dissent's discussion in *Florida Hospital Waterman, Inc. v. Buster* of the purpose of the invalidated statutes is relevant to this case and the purpose of the Federal Patient Safety Act, as it demonstrates how Amendment 7 conflicts with the Federal Patient Safety Act. *Fla. Hosp. Waterman, Inc. v. Buster*, 984 So. 2d 478 (Fla. 2008) (Wells, J., partial dissent). Pre-*Charles II* decisions, *Charles II*, and post-*Charles II* decisions eliminate the confidentiality previously recognized in law for health care workers to engage in a confidential communication necessary to promote patient safety, without the fear of such discussions being used by adverse parties in litigation against hospitals and health-care workers:

> The majority states at page 490: "Importantly, the statutes in question do not actually create a statutory privilege. The statutes do not deem relevant materials confidential or privileged." *This statement is in direct conflict with what this Court held in Cruger v. Love,* 599 So. 2d 111 (Fla. 1992)) *in dealing with these precise statutory sections* where the Court said:
>
> > We have previously held that "[t]he discovery privilege . . . was clearly designed to provide that degree of confidentiality necessary for the full, frank medical peer evaluation which the legislature sought to encourage." *Holly v. Auld,* 450 So. 2d at 220. Without the privilege, information necessary to the peer review process could not be obtained. *Feldman v. Glucroft,* 522 So. 2d 798, 801 (Fla. 1988). While we recognized in *Holly* that the discovery privilege would impinge upon the rights of litigants to obtain information helpful or even essential to their cases, we assumed that the legislature balanced that against the benefits offered by effective self-policing by the medical community. *Holly,* 450 So. 2d at 220.

We hold that the privilege provided by sections 766.101(5) and 395.011(9), Florida Statutes, protects any document considered by the committee or board as part of its decision-making process. The policy of encouraging full candor in peer review proceedings is advanced only if all documents considered by the committee or board during the peer review or credentialing process are protected. Committee members and those providing information to the committee must be able to operate without fear of reprisal. Similarly, it is essential that doctors seeking hospital privileges disclose all pertinent information to the committee. Physicians who fear that information provided in an application might someday be used against them by a third party will be reluctant to fully detail matters that the committee should consider. Accordingly, we find that a physician's application for staff privileges is a record of the committee or board for purposes of the statutory privilege.

. . . .

The policy behind the confidentiality privilege mandates this interpretation. *See Byrd v. Richardson–Greenshields Sec., Inc.,* 552 So. 2d 1099, 1102 (Fla. 1989) (a court's obligation is to honor the obvious legislative intent and policy behind an enactment, even where that intent requires an interpretation that exceeds the literal language of the statute). The privilege afforded to peer review committees is intended to prohibit the chilling effect of the potential public disclosure of statements made to or information prepared for and used by the committee in carrying out its peer review function. *See Dworkin v. St. Francis Hosp., Inc.,* 517 A.2d 302, 307 (Del. Super. Ct. 1986). This

chilling effect is attributable to several factors. As one commentator has noted:

> [D]octors seem to be reluctant to engage in strict peer review due to a number of apprehensions: loss of referrals, respect, and friends, possible retaliations, vulnerability to torts, and fear of malpractice actions in which the records of the peer review proceedings might be used. It is this ambivalence that lawmakers seek to avert and eliminate by shielding peer review deliberations from legal attacks.

Gregory G. Gosfield, *Medical Peer Review Protection in the Health Care Industry,* 52 Temp. L.Q. 552, 558 (1979) (footnote omitted). These fears are alleviated only by interpreting the statute as we do today.

> A different interpretation of this provision would completely eviscerate the protection the legislature sought to provide. Ultimately, all peer review committee records would be discoverable. What would not be discoverable in one action because of the nature of the lawsuit would be discoverable in another action. The confidential nature of the peer review proceedings would be obliterated. *See Sanderson v. Frank S. Bryan, M.D., Ltd.,* 361 Pa. Super. 491, 522 A.2d 1138, 1141 (1987) (interpreting the confidentiality provision of Pennsylvania's Peer Review Protection Act), *appeal denied,* 517 Pa. 624, 538 A.2d 877 (1988).

Cruger, 599 So. 2d at 113–15. Thus, pursuant to this Court's express opinion in *Cruger* and as acknowledged in *Brandon Regional Hospital*, 957 So. 2d at 594, the statutes in question do actually create a statutory privilege. The majority here is plainly in error.

Buster, 984 So. 2d at 500–01 (Wells, J., concurring in part and dissenting in part) (emphasis added) (footnote omitted).

Footnote 7 of Justice Wells' partial concurrence, to which Justices Cantero and Bell concurred, acknowledged the history of legislative efforts to provide confidentiality to health care professionals who seek to promote patient safety by providing candid assessments of errors and potential errors:

> In order to fully appreciate the effect of this decision as to retroactivity, it is important to first review the law which made these records confidential until the constitutional revision. Prior to Amendment 7, in order to secure quality medical services to the public, the Florida Legislature enacted an in-depth system with a state-mandated peer review process. In 1973, the Legislature first created the peer review evidentiary privilege in an effort to encourage hospitals to use and promulgate programs establishing committees for the purpose of reviewing standards of care, utilization, and expense in the rendering of health services in an effort to deter the rising costs of health care. *See* ch. 73–50, § 1, Laws of Fla. In 1982, the Legislature passed a comprehensive act regulating the licensure of hospitals with a state-mandated peer review process in order to improve medical care for the public by fostering and enhancing peer review. The act, which among numerous other provisions, provided that the proceedings and records of committees and governing bodies of any licensed facility relating to disciplinary actions against persons with staff privileges were not subject to inspection under chapter 119, and any meetings were not required to be open to the public. *See* ch. 82–182, § 26, at 655, Laws of Fla. *These provisions were amended over the years and included an explicit requirement for licensed facilities to provide for peer review of the physicians who deliver health care services at the facility and guaranteeing that the proceedings or records of such proceedings would not be subject to discovery or introduction into evidence in any civil or administrative action against a provider of professional health care services arising out of matters*

> *which were the subject of evaluation and review*. The fundamental premise of the act was the peer review process would be enhanced if health care providers knew that the records of the review *would not be used against them in medical malpractice or libel civil actions*. *Holly v. Auld,* 450 So. 2d 217 (Fla. 1984). The sections protecting records and statements in peer review are sections 395.0191(8), 395.0193(8), 766.101(5), 766.1016(2), and 395.0197(6)(c), (7), (8), (13) of the Florida Statutes (2002).

Id. at 495 n.7 (emphasis added).

Thus, state-court decisions interpreting Amendment 7 have invalidated legislation which was designed to promote patient safety, by protecting the confidentiality of "persons providing information or participating in any peer review panel, medical review committee, hospital committee or other hospital board," from forced disclosure and litigation abuse. *See id.* at 483 n.3, (citing § 381.028(6), Fla. Stat.). In *Buster*, the court's 4–3 decision held this elimination of health-care workers' evidentiary privileges and confidentiality rights was retroactive over the vigorous dissent of three justices noting that health-care providers' vested rights were thereby nullified, without any reference to retroactivity in the ballot title, summary, or text of Amendment 7. *Id.* at 498.

The Consequences of Amendment 7 Were Accurately Predicted, but Rejected

It is not idle speculation to wonder that if the proponents had informed the electorate of these consequences—that Amendment 7 would take away the protection of the rules of evidence, work-product and attorney-client privileges from health care workers, all in service of one party in medical malpractice litigation—whether the electorate would have approved the amendment. It is certainly not idle speculation to consider that the voters *should* have been informed of these consequences. *See Armstrong v. Harris*, 773 So. 2d 7, 12, 16–18 (Fla. 2000) (stating that proposed state constitutional amendments cannot "fly under *false colors*" or "*hide the ball*," otherwise the amendment "would be a nullity" under article XI, section 5 of the Florida Constitution and section 101.161, Florida Statutes) (emphasis added) (footnote omitted).

All of this is precisely what the Florida Dental Association predicted would occur in 2004, but their assessment was unanimously rejected by the supreme court:

> Opponent also argues that the amendment would affect Florida Rule of Civil Procedure 1.280(c), which restricts the discovery of work product, including incident reports generated by health care providers and facilities. . . . [T]he amendment does not expressly affect either rule 1.280(c) or the attorney-client privilege, *and there is no evidence of any intent to do so.* Any effect on the rule or the privilege is *purely speculative;* and, even if true, any such effect would not rise to the level of "substantially" altering or performing a function of the judiciary.

Patients' Right to Know, 880 So. 2d at 621 (emphasis added). In retrospect, it is hard to imagine an initiative amendment that has had *more* effect on the judiciary, and it has certainly "substantially" altered the landscape of medical malpractice actions. The instant case is a prime example: the trial court, without explanation or analysis, ordered this health-care worker's memorandum—which was submitted to *promote patient safety*, confidential under federal law, and not required to be reported to any state agency—to be turned over to the Respondents.

In 2009, *Florida Eye Clinic v. Gmach* also brushed aside any "chilling effect" that Amendment 7 would have on health-care workers who are now required to disclose patient safety work product to adverse attorneys. But interestingly, that court held, in error as it turned out, that Amendment 7 had no such chilling effect on *lawyers*:

> In approving Amendment 7, the citizens of Florida have demonstrated their conclusion that a patient's right to obtain records made in the course of business by a health care provider *is a more important consideration than the chilling effect created by the potential public disclosure of those records. See Amisub N. Ridge Hosp., Inc. v. Sonaglia*, 995 So. 2d 999 (Fla. 4th DCA 2008). On the other hand, nothing in the passage of Amendment 7 indicates an intent amongst the voters to create the same chilling effect *within the legal profession* by mandating

> the disclosure of any adverse medical incident reports containing the mental impressions, conclusions, theories, or opinions of an attorney (i.e., opinion work product).

Fla. Eye Clinic v. Gmach, 14 So. 3d 1044, 1050 (Fla. 5th DCA 2009) (emphasis added) (citation omitted).

But in 2017, the supreme court in *Edwards* explained:

> Thus, while in our opinion in *Buster* we explained one of the chief purposes of Amendment 7 as being aimed at eliminating prior statutory restrictions on adverse medical incident discovery, we did not do so in a way that limited the right created by the amendment. The prior statutory protections served only as an explanation for Amendment 7's genesis, rather than a limitation on the amendment's broad application. Moreover, in the cases since *Buster*, *many courts have expanded upon Buster's explanation by interpreting the amendment's right as an absolute right to review adverse medical incident reports.* Therefore, as the plain language of the amendment mandates, we hold that Amendment 7 was aimed at eliminating *all* discovery restrictions on "*any* records . . . relating to *any* adverse medical incident." Art. X, § 25(a), Fla. Const. (emphasis added).

Edwards, 229 So. 3d at 287 (emphasis added). But again, nothing in the plain language of Amendment 7 addressed discovery or litigation in any manner whatsoever.

And despite its previous statements in *Patients' Right to Know*, characterizing these predicted consequences as "speculation," the court in *Edwards* stated that this legal transformation of medical malpractice litigation *was apparent from the beginning*: "we knew *from the outset* that attempts would be made to *whittle away* at Amendment 7's broad scope, thus attempting to deprive the citizens of Florida of the rights they *specifically voted* to include in their state constitution." *Id*. at 282. This statement describing health care workers assertion of formerly bedrock legal rights was further elaborated in footnote 3, approvingly quoting an article in the Florida Bar Journal, in which the author stated that "the two most significant challenges to

Amendment 7 will remain 1) *attempts by health care providers and facilities to limit* through assertions of the *attorney-client privilege*, or *work product* doctrine, the operation of the amendment in response to discovery requests; and 2) *charges* of federal preemption." *Id.* at 282–83 n.3 (emphasis added).

The *Edwards* court further stated:

> As we explained in *Buster*:
>
> > [T]he chief purpose of Amendment 7 was to do away with the legislative restrictions on a Florida patient's access to a medical provider's "history of acts, neglects, or defaults" because such history "may be important to a patient." In other words, while this history was not previously accessible, it became accessible when the electorate approved a constitutional override of the prior statutory restrictions. The central focus of the amendment was to provide access to records that existed but were not accessible due to statutory restrictions. The language of the amendment could hardly have been more specific or articulate in expressing the intent that what was not accessible before would be accessible with the passage of the amendment.
>
> Similarly, the ballot summary for the amendment reflects that the amendment's clear purpose was to do away with existing restrictions on a patient's right to access a medical provider's history of adverse medical incidents and to provide a clear path to access those records.
>
> . . . .
>
> The ballot summary, like the text of the amendment itself, clearly expressed an intent to do away with then current Florida law restricting access to this information and would lead voters to the conclusion that *all records*,

> including existing records, would henceforth be subject to patient review. The summary indicates that, with the passage of the amendment, there would no longer be *any legal barrier* to obtaining this information and that a patient, the day after this amendment passed, would have access to this important information of a provider's past record.

Buster, 984 So. 2d at 488–89 (emphasis added) (citations omitted).

> In addition, in *Buster*, we specifically noted that the statutory restrictions constituted only *one barrier* at issue with regard to production of this information and the constitutional provision resulted in removing that obstacle to access. *Id*. at 489. Thus, our explanation in *Buster* that the passage of Amendment 7 was a related result of the pre-existing statutory protections on the discoverability of adverse medical incident reports is not the be all and end all in this analysis; rather, it was one of the most apparent and significant obstacles to adverse medical incident discovery in place at the time. *It does not necessarily follow, however, that Amendment 7's scope was thus limited only to discovery of adverse medical incident reports previously protected by statute.*

Id. at 285–86 (emphasis added). Again Amendment 7 made no reference to "litigant," "lawsuit," "discovery," or "litigation." And yet, the amendment has been interpreted to drastically transform medical malpractice litigation in a manner that was apparently present in 2004, when the supreme court reviewed the petition initiative.

The dissenting opinion in *Edwards* characterized the majority opinion as eliminating the work-product privilege under Amendment 7:

> Work product prepared in anticipation of litigation is the antithesis of the "records made or received in the course of business" that fall within Amendment 7's ambit. *See Progressive Am. Ins. Co. v. Lanier*, 800 So. 2d 689, 691

(Fla. 1st DCA 2001) (explaining that the work-product doctrine protects documents prepared "in anticipation of litigation, rather than in the ordinary course of . . . business"); *see also* § 381.028(3)(j), Fla. Stat. (2010) (defining "records" for purposes of legislation implementing Amendment 7 to exclude "documents or portions thereof which constitute, contain, or reflect any attorney-client communications or any attorney-client work product").

To reach the opposite conclusion—that the expert reports the hospital, through its counsel, obtained in anticipation of litigation in this case "are the type that are 'made or received in the course of business by a health care facility or provider,' " majority op. at 293 (quoting art. X, § 25(a), Fla. Const.)—the majority reasons that hospitals generally keep records of adverse medical incidents, so the reports at issue must have been prepared and received in the course of the hospital's business. From there, the majority concludes that, even if the reports contain work product, they are nevertheless subject to disclosure under Amendment 7. The *majority's circular reasoning*, however, ignores the plain language of Amendment 7's "course of business" requirement, which is not satisfied on the facts of this case.

As the Second District explained below, the hospital's legal "counsel requested the reports at issue for purposes of litigation" from a company called M.D. Review that "does not perform the routine function of reviewing incidents for the [h]ospital when medical negligence or other events occur as specified in Amendment 7," but rather "provides an expert opinion on the standard of care on sporadic occasions when litigation is imminent." *Bartow HMA, LLC v. Edwards*, 175 So. 3d 820, 824–26 (Fla. 2d DCA 2015). There is no evidence that the hospital sought these expert opinions—which were not "part of [its] regular peer review process"—in an attempt to avoid the disclosure requirements of Amendment 7. *Id.* at 826. Rather, "[t]he [h]ospital has already satisfied [Amendment 7's] requirements by

providing access to numerous documents pertaining to internal adverse incident reporting and peer review" and, in contrast, relied upon M.D. Review's reports for "an expert opinion on the standard of care" to prepare for "litigation [that was] imminent." *Id.* at 825–26. Accordingly, as the Second District correctly held, the reports at issue, which were "created by an expert retained for purposes of litigation[,] are not kept in the course of regularly conducted business activity" and therefore "were not 'made or received in the course of business' under Amendment 7." *Id.* at 825.

Moreover, while proper application of Amendment 7's "course of business" requirement is sufficient to end the inquiry*, see Fla. League of Cities v. Smith*, 607 So. 2d 397, 400 (Fla. 1992) ("[W]hen constitutional language is precise, its exact letter must be enforced . . . ."), Amendment 7's history underscores that it was not intended to destroy the work-product doctrine or the attorney-client privilege. Specifically, in approving Amendment 7 for placement on the ballot, this Court rejected the argument that Amendment 7 "would affect Florida Rule of Civil Procedure 1.280(c), which restricts the discovery of work product, including incident reports generated by health care providers and facilities . . . [and] infringes on the statutes and rules delineating the attorney-client privilege." *Advisory Op. to Atty. Gen. re Patients' Right to Know About Adverse Med. Incidents*, 880 So. 2d 617, 621 (Fla. 2004). In so doing, this Court held that "the amendment does not expressly affect either rule 1.280(c) or the attorney-client privilege, and there is no evidence of any intent to do so." *Id.*

Applying Amendment 7's plain language consistently with this Court's holding regarding its intent, like the Second District, I would conclude that the expert reports at issue—prepared at the request of the hospital's counsel, outside of the ordinary peer review process, in anticipation of imminent litigation—are not "records made or received in the course of business" subject to disclosure pursuant to Amendment 7. The

> majority's contrary holding improperly reads the "course of business" language as superfluous and recasts the constitutional provision, without it, as providing for discovery of any records relating to adverse medical incidents with "no limitation[.]" Majority op. at 284. Therefore, I dissent.

Id. at 294–95 (Lawson, J., dissenting) (emphasis added). Thus, the evolution of judicial interpretations of Amendment 7 has resulted in a complete restructuring of medical malpractice litigation despite the complete absence of any textual support for such a result in the language of the initiative.

The evolution of the decisions in Florida greatly expanding the reach of Amendment 7 merits reconsideration, given that the voters were never asked to enact a state constitutional amendment that radically transformed medical malpractice litigation in Florida. This entire body of law deserves a more rigorous review, as it has developed far beyond the limits of the ballot title, summary, and text of Amendment 7, to eliminate work-product privileges of confidentiality, relevancy, and overbreadth limits of discovery rules, all to the detriment of patient safety and the ability of already-stressed health care workers to identify actual and potential medical errors to prevent future errors and save patients' lives. If the document here is not protected from forced disclosure under these interpretations of Amendment 7, then the Federal Patient Safety Act, which was designed to eliminate the "culture of blame" and punishment, and thereby encourage a culture of patient safety based on the confidentiality of patient safety work product, has been rendered a nullity in Florida.

MAKAR, J., dissenting on merits but concurring in certified questions.

At issue is the trial court's order, which found that an incident report prepared by Tallahassee Memorial Hospital was not privileged under the Federal Patient Safety and Quality Improvement Act (PSQIA) and is thereby discoverable.

Affirmance is in order because the factual record, construed in favor of the trial court's ruling, reflects that the incident report

at issue was not prepared solely for submission to a patient safety organization (PSO) and that the hospital's internal system—which simply "offloaded" *all* such reports into a confidential status for *potential* submission to a PSO—was of the type that the federal law frowns upon as a superficial means of feigning federal compliance. The Department of Health and Human Services issued a statement on this point, making it clear that offloading of this type is an improper means of claiming immunity when actual compliance with federal standards is lacking, as our supreme court has noted. *See Charles v. S. Baptist Hosp. of Fla., Inc.*, 209 So. 3d 1199, 1216 (Fla. 2017) (noting that "some providers with recordkeeping or record maintenance requirements appear to be maintaining the required records only in their [patient safety evaluation system] and then refusing to disclose the records, asserting that the records in their [patient safety evaluation system] fulfill the applicable regulatory requirements while at the same time maintaining that the records are privileged and confidential [patient safety work product].") (citing 81 Fed. Reg. 32,655–01, 32,657–58). As such, the incident report is not protected under the voluntary federal standards, which require a system used for submission of reports *solely* to a PSO. 81 Fed. Reg. 32655-01 (noting that "information prepared for purposes other than reporting to a PSO is not [patient safety work product] under the reporting pathway").

Plus, the hospital's director of safety specifically testified under oath that the hospital defined patient safety work product as "anything that is reported to us within the patient safety system," adding "we consider all our safety events as patient safety work product." In other words, rather than carefully sequester potential PSQIA incident reports into their own category solely for reporting to a PSO, all reports were lumped together. She testified that the report at issue was prepared under Florida law and not just for potential compliance with the PSQIA. In addition, the hospital's written policy and procedures predated the adoption of the PSQIA in 2005 and were not revised to comply with the act. Rather, the safety policy and procedures were implemented to comply with Florida Statutes. When asked if it was fair to say that the reports were meant to comply with Florida law and at the same time were considered patient safety work product, she replied, "I do." She specifically testified that the patient safety work product

was not created for the sole purpose of reporting to a PSO, adding "*It's a dual purpose*." (Emphasis added). The hospital tried to pull back her testimony, but the trial judge was entitled to rely upon and give it credence. Because patient safety work product "cannot be used to fulfill external obligations," the preparation of the report for a "dual purpose" negates the hospital's claim of privilege.

Finally, the hospital claims that the incident report does not relate to an adverse incident under 395.0197(5), Florida Statutes; and further alleges that the report is not necessitated under state law and is solely information to be reported to a PSO. But the newborn's transfer an hour after birth to the neo-natal intensive care unit made it an adverse incident as a transfer within a facility to a unit providing a more acute level of care. § 395.0197(5)(a)7., Fla. Stat. (2022) (defining an adverse incident as meaning "an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention," which results in "[a]ny 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"). That the hospital didn't report the incident as an adverse incident, and potentially didn't follow the applicable legal standard, doesn't mean the incident was not an adverse one; it was.

In conclusion, the trial court's thorough order, which reflected a full understanding and accurate application of this complicated area of the law to the factual record, should be affirmed; the incident report should not be shielded from disclosure. As to the certified questions set forth in the majority opinion, I concur.

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