SIXTH DISTRICT COURT OF APPEAL STATE OF FLORIDA

Case No. 6D2023-1069 Lower Tribunal No. 2019-CA-2848

PHILIP REGALA, M.D., PHILIP REGALA, M.D. P.L., f/k/a PHILIP REGALA, M.D., P.A., and Physicians Day Surgery Center, LLC,

Petitioners,

v.

MICHAEL MCDONALD,

Respondent.

Petition for Writ of Certiorari to the Circuit Court for Collier County. Hugh D. Hayes, Judge.

September 6, 2024

WOZNIAK, J.

Petitioners Philip Regala, M.D., Philip Regala, M.D., P.L. (collectively "Dr. Regala"), and Physicians Day Surgery Center, LLC ("PDSC"), defendants below,

¹ The parties' filings indicate that the trial court's order concerning documents that Dr. Regala must produce are not at issue in this petition; however, Dr. Regala joins the petition because the documents PDSC must produce pursuant to the trial court's order include Dr. Regala's personal health information.

seek a writ of certiorari quashing the trial court's order requiring that they produce documents to Respondent Michael McDonald contained in Dr. Regala's credentialing file in the underlying medical malpractice/negligent credentialing suit.² PDSC seeks an order quashing the trial court's order, which was based on the court's conclusion that documents contained in the credentialing file were discoverable pursuant to article X, section 25 of the Florida Constitution ("Amendment 7"). For the reasons expressed below, we grant the petition to the extent the trial court ordered discovery of documents that were considered by the hospital in its process of deciding to credential Dr. Regala but were not, themselves, reflective of an act taken by PDSC that related to an established and proven adverse medical incident.³

BACKGROUND

In 2019, McDonald brought suit against Dr. Regala, an orthopedic physician, and PDSC, the ambulatory surgical facility where Dr. Regala held staff privileges,

² This case was transferred from the Second District Court of Appeal to this Court on January 1, 2023.

³ A claim of negligent credentialing necessitates evidence that the hospital has breached its "independent duty to select and retain competent independent physicians seeking staff privileges"; the hospital will be "responsible for the negligence of an independent physician when it has failed to exercise due care in the selection and retention of that physician on its staff." *Insinga v. LaBella*, 543 So. 2d 209, 214 (Fla. 1989); *see generally* Benjamin J. Vernia, Annotation, *Tort Claim for Negligent Credentialing of Physician*, 98 A.L.R.5th 533 (2002) (gathering authorities).

alleging that PDSC's negligent credentialing of Dr. Regala and Dr. Regala's negligent care resulted in the amputation of his leg.⁴ Pretrial discovery issues necessitating this Court's resolution have arisen twice. In the first certiorari proceeding, this Court granted certiorari in part, finding that Amendment 7 did not apply to the interrogatories propounded by McDonald and further finding that some of the information requested was statutorily immune from discovery pursuant to Florida's peer review statutes. *See Regala v. McDonald*, 374 So. 3d 855 (Fla. 6th DCA 2023) ("*Regala I*"). Before us now is the second certiorari petition stemming from the same trial court proceeding.

At issue here is McDonald's request for production Number 13 directed to PDSC, which essentially seeks PDSC's entire credentialing file relative to Dr. Regala, and PDSC's objections to the request:

13. All materials, submissions, applications, references, correspondence and investigative material, if any, considered by Physicians Day Surgery Center when deciding whether to grant REGALA privileges.

RESPONSE: Objection - The [request] as phrased is overbroad, unduly burdensome, irrelevant, immaterial, not properly limited in time, scope, or duration, and harassing; and therefore, not considered reasonably calculated to lead to the discovery of relevant/admissible evidence. PDSC further objects to the Plaintiff's request on the grounds that it seeks privileged and non-discoverable information pursuant to

⁴ Count I of McDonald's complaint alleges Dr. Regala's negligence; Count II alleges the vicarious liability of Philip Regala, M.D., P.L.; Count III alleges the negligent selection, credentialing, retention, granting of privileges, and oversight of Dr. Regala by PDSC; and Count IV alleges the vicarious medical negligence of PDSC.

section 395.091(8), Florida Statutes and section 766.101(5), Florida Statutes. See e.g. Columbia/JFK Medical Center Limited Partnership d/b/a JFK Medical Center v. Sanguonchitte, 920 So. 2d 711 (Fla. 4th DCA 2006).

McDonald sought to compel discovery, and PDSC filed a motion for a protective order on the ground that the information sought was privileged and not discoverable.

Upon McDonald's request, the trial court ordered PDSC to produce a privilege log and conducted a live, in camera inspection of documents, summarizing the pertinent query as whether each document was related to an adverse medical incident under Amendment 7 and stating that any of the documents regarding Dr. Regala himself "are in play for this particular lawsuit." During the hearing, the trial court stated that a document becomes discoverable under Amendment 7 as a document relating to an adverse medical incident "when the lawsuit is filed." Consequently, the court broadly held that if documents were related to the credentialing of Dr. Regala at PDSC's facility and bore on PDSC's credentialing decision, they were discoverable. The court found that items relating to Dr. Regala's education and training were discoverable because they related to the adverse medical incident involving McDonald. Thereafter, the court's rulings were condensed to "same ruling" or words to that effect for all other documents. It is from this order that PDSC seeks certiorari relief.

ANALYSIS

I. <u>Irreparable Harm</u>

As we explained in *Regala I*,

[t]o be entitled to certiorari relief, Petitioners must establish "1) a departure from the essential requirements of the law; 2) resulting in material injury for the rest of the trial; 3) that cannot be remedied on post-judgment appeal." Walt Disney Parks & Resorts U.S., Inc. v. Alesi, 351 So. 3d 642, 644 (Fla. 5th DCA 2022). Because the second and third elements, which are jointly referenced as "irreparable harm," are jurisdictional, they must be established before the first element, i.e., the merits, may be addressed. DecisionHR USA, Inc. v. Mills, 341 So. 3d 448, 452 (Fla. 2d DCA 2022) (quoting Tanner v. Hart, 313 So. 3d 805, 807 (Fla. 2d DCA 2021)); see also Miami Dade Coll. v. Allen, 271 So. 3d 1194, 1196 (Fla. 3d DCA 2019) ("A party seeking certiorari review of a non-final order must first demonstrate that the order under review would result in a material injury that cannot be corrected on appeal (often referred to as 'irreparable harm')."). Should Petitioners be required to disclose information that is otherwise privileged and immune from discovery, irreparable harm would result; accordingly, we find that the threshold requirement of showing irreparable harm is met. See Tarpon Springs Hosp. Found. Inc. v. White, 286 So. 3d 879, 881-82 (Fla. 2d DCA 2019) ("An order requiring the production of documents privileged under section 395.0191 that do not relate to an adverse medical incident satisfies the 'threshold showing of irreparable harm necessary to invoke this court's certiorari jurisdiction." (quoting Bartow HMA, LLC v. Kirkland, 126 So. 3d 1247, 1252 (Fla. 2d DCA 2013) (concluding that because the requests for production may require the disclosure of privileged documents, petitioner met the threshold showing of irreparable harm))).

374 So. 3d at 858. We find that PDSC has met the irreparable harm threshold requirement because, if the trial court's order requires PDSC to produce otherwise privileged information, irreparable harm will result. Accordingly, we turn to the merits of PDSC's petition.

II. Departure from the Essential Requirements of Law

The issue before us is whether Amendment 7, titled "Patients' right to know about adverse medical incidents," authorized the discovery of otherwise privileged documents in PDSC's credentialing file that were sought by McDonald in support of his negligent credentialing claim. We begin by acknowledging that the credentialing committee's file contains documents that it considered in its decisionmaking process and thus would largely be protected by sections 395.0191(8), 395.0193(8), and 766.101(5), Florida Statutes (2022) (collectively the "Peer Review Statutes"), if not for the possible impact of Amendment 7. PDSC contends that all of the trial court's rulings were based on the court's erroneous belief that simply asserting a negligent credentialing claim meets Amendment 7's definition of "adverse medical incident" and eliminates all statutory protections contained in the Peer Review Statutes. PDSC claims that the requested documents are simply "general credentialing documents" for Dr. Regala and thus do not pertain to a specific adverse medical incident, as required by Amendment 7.

A. Florida's Peer Review Statutes and Amendment 7

Florida's Peer Review Statutes, as relevant here, provide that "the investigations, proceedings, and records of a peer review committee are not subject to discovery or introduction into evidence in any civil action against a provider of professional health services arising out of matters that are the subject of evaluation and review." *Brandon Reg'l Hosp. v. Murray*, 957 So. 2d 590, 591 (Fla. 2007) (citing

§§ 395.0191(8), 766.101(5), Fla. Stat. (2001)).⁵ The privilege "provide[s] that degree of confidentiality necessary for the full, frank medical peer evaluation which the legislature sought to encourage." *Cruger v. Love*, 599 So. 2d 111, 113-14 (Fla. 1992) (quoting *Holly v. Auld*, 450 So. 2d 217, 220 (Fla. 1984)).

This privilege extends not only to documents created by the board, but to "any document considered by the committee or board as part of its decision-making process." *Id.* at 114. However, documents "otherwise available from original sources are not to be construed as immune from discovery . . . merely because they were presented during proceedings of such board." § 395.0191(8). In other words, a document that "a party secures from the original source is not privileged merely because it was during presented peer review committee or board proceedings." Cruger, 599 So. 2d at 114 (citing Feldman v. Glucroft, 522 So. 2d 798, 801 (Fla. 1988)); see also Columbia/JFK Med. Ctr. Ltd. P'ship v. Sanguonchitte, 920 So. 2d 711, 712 (Fla. 4th DCA 2006) (same).

Tarpon Springs Hosp. Found. Inc. v. White, 286 So. 3d 879, 882 (Fla. 2d DCA 2019).

When the Peer Review Statutes were the sole consideration, the analysis was fairly straightforward. However, in 2004, the Florida Constitution was amended to add Amendment 7, which provides in full:

(a) In 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.

⁵ Although *Brandon* addressed the scope of only two of the three Peer Review Statutes, this language is applicable to all three as all three provide substantially identical immunity from discovery, as we observed in *Regala I. See Regala I*, 374 So. 3d at 860, 861.

- (b) In providing such access, the identity of patients involved in the incidents shall not be disclosed, and any privacy restrictions imposed by federal law shall be maintained.
- (c) For purposes of this section, the following terms have the following meanings:
- (1) The phrases "health care facility" and "health care provider" have the meaning given in general law related to a patient's rights and responsibilities.
- (2) The term "patient" means an individual who has sought, is seeking, is undergoing, or has undergone care or treatment in a health care facility or by a health care provider.
- (3) The phrase "adverse medical incident" means 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, 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.
- (4) The phrase "have access to any records" means, in addition to any other procedure for producing such records provided by general law, making the records available for inspection and copying upon formal or informal request by the patient or a representative of the patient, provided that current records which have been made publicly available by publication or on the Internet may be "provided" by reference to the location at which the records are publicly available.

Art. X, § 25, Fla. Const. (emphasis added).⁶ Amendment 7 creates a constitutional right to obtain records considered or created by a hospital board that may otherwise

⁶ The ballot summary states that the purpose of the amendment is to "give patients the right to review, upon request, records of health care facilities' or providers' adverse medical incidents, including those which could cause injury or

be protected by the Peer Review Statutes, provided the records concern adverse medical incidents; general credentialing information unrelated to an adverse medical incident is not included in Amendment 7. *Bartow HMA, LLC v. Kirkland*, 126 So. 3d at 1253; *West Fla. Reg'l Med. Ctr., Inc. v. See*, 18 So. 3d 676, 690 (Fla. 1st DCA 2009) ("See I") (quashing trial court's order requiring production of doctors' training documents when no established adverse medical incident existed). Notably, under subsection (c)(3), an "adverse medical incident" is an act of a health care facility or provider that *caused or could have caused* a patient's injury or death, written in the past tense.

The Second District addressed a similar scenario in *Tarpon Springs*. There, the plaintiff sued for medical malpractice and sought production of every record that "identifies each and every time [the doctor] became board eligible by the American Board of Internal Medicine" *Tarpon Springs*, 286 So. 3d at 881. The Second District quashed the trial court's order requiring such production as "overbroad because it require[d] disclosure of privileged documents considered by the hospital board in its hiring and credentialing of' the doctor. *Id.* at 883. The Second District rejected the plaintiff's argument that the hospital's negligence in the credentialing

death." Advisory Op. to the Att'y Gen. re Patients' Right to Know About Adverse Med. Incidents, 880 So. 2d 617, 619 (Fla. 2004) (quoting Amendment 7's ballot summary).

process⁷ led to the doctor being allowed to treat the plaintiff's husband, resulting in the "medical incident" that led to his death:

[T]he doctors' training records [in See I] did not relate to an adverse medical incident within the meaning of Amendment 7. [See I, 18 So. 3d] at 690. Rather, a document relates to an "adverse medical incident" when it relates to a "specific incident involving a specific patient that caused or could have caused injury to or the death of that patient." Id. Similarly, because "there is no established adverse medical incident to which the documents of [Dr. Cappiello's] training relate, the trial court departed from the essential requirements of the law in ordering the production of those documents." Id. See also Shahbas ex rel. Shahbas, 960 So. 2d at 827 ("Because [appellees] are entitled under Amendment 7 only to those documents which contain information about an adverse medical incident, the trial court departed from the essential requirements of law in ordering a blanket disclosure of privileged documents on the basis of Amendment 7.").

Id.

In so holding, the Second District relied on the First District's reasoning in *See I*. There, the First District considered the plaintiffs' request to produce issued to a hospital based on the plaintiffs' claim that the hospital was both vicariously liable for two doctors' negligent performance and directly liable for its own negligent grant of staff privileges to those doctors. Citing Amendment 7, the plaintiffs asked the hospital to produce all adverse incident reports and the entire credentialing files for the two doctors, including evidence of their training to perform the surgery at issue,

⁷ The Second District's opinion states that the claim at issue was medical malpractice, but the plaintiff made arguments about negligent credentialing in support of its quest for documents under Amendment 7. 286 So. 3d at 883. Here, Regala's claims were for both medical malpractice and negligent credentialing; both remain pending and unproven at this juncture.

and further sought the hospital's blank application for medical staff privileges. *See I*, 18 So. 3d at 681. The court parsed Amendment 7's definition of "adverse medical incident" and wrote:

This definition is quite broad, but it does contain some limiting language. First, the word "incident" itself indicates an isolated event. Additionally, an event may constitute an "adverse medical incident" only if it is shown that the event "caused or could have caused injury to or death of a patient." Thus, we interpret the phrase "adverse medical incident" as a specific incident involving a specific patient that caused or could have caused injury to or the death of that patient. *Accord Shahbas*, 960 So. 2d at 827 (quashing an order that required the production of credentialing documents that did not "contain information about particular adverse medical incidents"). An adverse medical incident may be a negligent act or omission, as the definition indicates, but the act or omission must be connected with a patient and must be the cause or near-cause of an injury or death.

Id. at 690. After concluding that the negligent act must be connected with a patient and be the cause or near cause of that patient's injury or death, the First District found that there was "no identifiable adverse medical incident to which the records of the doctors' training [to perform the surgery at issue] relate." *Id.*

The First District did not completely exclude the possibility that a claim of negligent credentialing could come within the definition of adverse medical incident, but held that such a claim must be established and not simply alleged:

Even if we were to accept that negligent credentialing could fall under the definition of an adverse medical incident, the negligent credentialing alleged in the instant case could not serve as the relevant incident because it has not yet been established, as it is one of the ultimate issues in this non-final case. The same logic applies to any contention that the performance of the Roux-en-y hepaticojejunostomy was the relevant adverse medical incident. As Petitioner has aptly observed, Amendment 7 does not envision that a party may establish an adverse medical incident for the purposes of discovery simply by asserting a particular cause of action; causes of action do not determine the scope of the amendment. If the amendment were intended to be interpreted so broadly, it would not have been limited to records relating to adverse medical incidents; instead, it would provide access to all records relevant to any causes of action asserted against health care providers.

If we were to accept Respondents' interpretation of Amendment 7, there would be no limit to what could be discovered in civil litigation under the amendment, and we would be in conflict with both the Third and Fourth Districts, which have found limits to the amendment. Both courts have concluded that an order requiring the production of an entire credentialing file on a particular physician was beyond the scope of Amendment 7. See Shahbas, 960 So. 2d at 827; Baptist Hosp. of Miami, Inc. v. Garcia, 994 So. 2d 390, 393 (Fla. 3d DCA 2008). If Amendment 7 required the production of any documents relating to a cause of action for medical malpractice or negligent credentialing, then the limits recognized by Shahbas and Garcia would be improper. As we have explained, we agree with the courts in Shahbas and Garcia that Amendment 7 is not limitless.

Because, in this case, there is no established adverse medical incident to which the documents of the doctors' training relate, the trial court departed from the essential requirements of the law in ordering the production of those documents. Accordingly, we quash this portion of the trial court's order.

Id. According to the First District and the cases cited therein, a mere alleged claim of negligent credentialing cannot support Amendment 7 discovery. Rather, there must be an established adverse medical incident before Amendment 7 is triggered.

We are persuaded by our sister courts' reasoning in *Tarpon Springs* and *See I* and therefore hold that asserting a cause of action—where allegations are made but have not been established or proven through trial or pretrial adjudication such as

summary judgment—does not constitute an adverse medical incident under Amendment 7. Therefore, a party cannot use Amendment 7 to obtain otherwise privileged discovery of the acts underlying either the medical malpractice cause of action or the negligent credentialing cause of action if an independent adverse medical incident has not first been established. Here, McDonald relies solely on his allegations of negligent credentialing and medical malpractice in the underlying case to argue Amendment 7 requires the credentialing file to be produced. Allegations do not establish an adverse medical incident under Amendment 7, and documents otherwise protected under the Peer Review Statutes cannot be produced.

B. See II

We respectfully recognize the Florida Supreme Court's decision in *West Florida Regional Medical Center, Inc. v. See*, 79 So. 3d 1 (Fla. 2012) ("See II"), which, like the negligent credentialing claim in the instant case, arose from a cause of action for the negligent grant of medical staff privileges. In *See II*, the supreme court held that a *blank* application for hospital staff privileges and, more particularly, the types of questions asked by the credentialing committee on that blank application, did not fall under the purview of the Peer Review Statutes. After this holding, the court further reasoned:

Even if a blank application were considered to be within the parameters of sections 766.101(5) and 395.0191(8), we conclude that Amendment 7 nonetheless mandates its disclosure because, in See's action for negligent grant of medical staff privileges, the blank application is a record of an adverse medical incident. It is the blank form upon which

the information was placed to generate the record of the medical staff application process and procedure that led to the alleged negligent grant of medical staff privileges to Dr. Benson and Dr. Rees, which led to the injury inflicted on See.

Id. at 11. The supreme court observed that its holding was

consistent with the plain language of Amendment 7, which requires that patients have access to "adverse medical incidents." Amendment 7's definition of "adverse medical incidents" includes "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 or death of a patient." (Emphasis added.) Part of the conduct, or act by West Florida Hospital, that led to the alleged negligent grant of staff privileges to Dr. Benson and Dr. Rees are the questions that the hospital posed on its application for medical staff privileges. More specifically, if the questions asked by West Florida Hospital on its application for medical staff privileges failed to lead to a proper inquiry into the qualifications of Dr. Benson and Dr. Rees, which in turn led to the grant of privileges to these possibly unqualified physicians, that application is a record of, and evidence pertaining to, West Florida Hospital's potential negligent conduct, or act, of granting those staff privileges, which purportedly resulted in the injury to See.

Id. at 13.

Because the supreme court held that the blank application was not protected by the Peer Review Statutes, we respectfully believe the court's discussion of Amendment 7's application is dicta because it was not necessary to the court's holding. As the supreme court has recognized,

[a]ny statement of law in a judicial opinion that is not a holding is dictum. *State v. Yule*, 905 So. 2d 251, 259 n.10 (Fla. 2d DCA 2005) (Canady, J., specially concurring) (quoting Michael Abramowicz & Maxwell Stearns, *Defining Dicta*, 57 Stan. L. Rev. 953, 1065 (2005)). "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." *Id*.

Pedroza v. State, 291 So. 3d 541, 547 (Fla. 2020). We are not bound by dicta. Churchill v. DBI Servs., LLC, 361 So. 3d 896, 904 (Fla. 1st DCA 2023) (citation omitted).

The same question raised in the instant case was presented and resolved in *See I. See I*, 18 So. 3d at 690 (identifying issue as "whether the records of the doctors' training to perform the procedure in question constitute records 'relating to any adverse medical incident,' within the meaning of Amendment 7" and holding that because "there is no established adverse medical incident to which the documents of the doctors' training relate, the trial court departed from the essential requirements of the law in ordering the production of those documents"). Only *See I*'s holding that the trial court correctly ordered the disclosure of the blank application was approved by the supreme court in *See II*; the remainder of *See I*'s holding was not addressed by the supreme court in approving the First District's decision. Thus, we cannot read *See II* as approving or disapproving, even implicitly, any other portion of *See I*, and we are persuaded by *See I*'s reasoning.

Because we are not bound by the dicta of *See II* pertaining to Amendment 7, and we conclude that merely asserting a cause of action does not establish the existence of an adverse medical incident for purposes of invoking Amendment 7, we hold that documents otherwise protected under the Peer Review Statutes do not

become discoverable under Amendment 7 until the existence of an adverse medical incident has actually been established.

Accordingly, because no adverse medical incident has yet been established in this case, the only requested documents or records that are discoverable are those that are not protected under the Peer Review Statutes. The documents considered by PDSC in the credentialing process that are not related to an established adverse medical incident remain protected by the Peer Review Statutes. We therefore grant the petition and quash the order requiring discovery of, essentially, the entire credentialing file based on Amendment 7.

We sua sponte certify to the Florida Supreme Court, pursuant to Florida Rule of Appellate Procedure 9.030(a)(2)(A)(v), the following question as one of great public importance:

DOES WEST FLORIDA REGIONAL MEDICAL CENTER, INC. v. SEE, 79 SO. 3D 1 (FLA. 2012), REQUIRE A HEALTH CARE FACILITY TO PRODUCE ALL DOCUMENTS CONTAINED IN ITS CREDENTIALING FILE AND/OR CONSIDERED BY THE CREDENTIALING COMMITTEE WHEN SOUGHT BY A PATIENT ALLEGING CAUSES OF ACTION FOR NEGLIGENT CREDENTIALING AND MEDICAL MALPRACTICE?

PETITION GRANTED; ORDER QUASHED; QUESTION CERTIFIED.

MIZE and BROWNLEE, JJ., concur.

Jason M. Azzarone, Louis J. La Cava, Amanda M. Smith, and Mark R. Messerschmidt, of La Cava Jacobson & Goodis, P.A., Tampa, for Petitioners.

George A. Vaka, of Vaka Law Group, P.L., Tampa, for Respondent.

NOT FINAL UNTIL TIME EXPIRES TO FILE MOTION FOR REHEARING AND DISPOSITION THEREOF IF TIMELY FILED