IN THE SUPREME COURT OF FLORIDA

CASE NO. SC09-1997
L.T. CONSOLIDATED CASE NOS. 1D09-1055 and 1D09-1144

WEST FLORIDA REGIONAL
MEDICAL CENTER, INC. d/b/a WEST
FLORIDA HOSPITAL,

Petitioner/Defendant,

vs.

LYNDA S. SEE and RODNEY C. SEE,

Respondents/Plaintiffs. /

PETITIONER'S
INITIAL BRIEF ON THE MERITS

On Discretionary Review from a
Decision of the First District Court of Appeal

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INTRODUCTION

Petitioner/Defendant, West Florida Regional Medical Center, Inc., d/b/a West Florida Hospital (the "Hospital"), appeals from two non-final Orders compelling it to disclose privileged and confidential documents pursuant to Article X, section 25, of the Florida Constitution (commonly known as "Amendment 7"). Amendment 7 provides that a patient may access records relating to any adverse medical incident of a health care facility. See Art. X, § 25, Fla. Const.

The Hospital filed separate petitions for writ of certiorari with the First District, challenging each Order and the appellate matters were consolidated. The First District granted in part and denied in part the Hospital's petitions and this Court granted review.

STATEMENT OF THE CASE AND FACTS

Plaintiffs, Lynda and Rodney See, allege that Mrs. See's physicians improperly performed surgeries that resulted in the severing of her bile duct and damage to her liver. (App. 30).[1] Plaintiffs sued West Florida Regional Medical Center, asserting claims of vicarious liability for her physicians' negligence and

[1] Pursuant to Florida Rule of Appellate Procedure 9.220, documents referenced in this brief are included in Petitioner's Appendix To Petitioner's Initial Brief on the Merits and will be referenced as (App. Tab No.:Page No. or Paragraph No. or Exhibit No.).

direct liability for the Hospital's grant of clinical privileges to the physicians who performed her surgeries. (App. 30).

During discovery, Plaintiffs requested, pursuant to Amendment 7, that the Hospital produce all adverse incident reports as to Mrs. See and the two physicians, pertaining to the two surgical procedures. (App. 29:¶22). Plaintiffs also sought the entire credentialing file of the two physicians. (App. 23; 29:¶17). Thereafter, Plaintiffs served a subpoena duces tecum directed at the Chief Executive Officer of the Hospital, seeking production of a blank application for medical staff privileges, among other requested documents. (App. 26).

The Hospital objected to these discovery requests and moved for protective orders. (App. 21; 22; 27; 28). The Hospital asserted, among other objections, that the requests sought documents related to the credentialing process that were confidential and statutorily protected and beyond the scope of "adverse medical incidents" discoverable under Amendment 7, citing sections 395.0191, 395.0193, 766.101, Florida Statutes, Tenet Healthsystem Hospitals, Inc. v. Taitel, 855 So. 2d 1257 (Fla. 4th DCA 2003), and Morton Plant Hospital Association v. Shahbas, 960 So. 2d 820 (Fla. 2d DCA 2007). (App. 21:5, 23-24; 25:6-8; 27:2-3; 28:5-8; see also (App. 14:14-15).

The Hospital also submitted various materials in support of its motions for protective order. (App. 24). These materials included the Medical Staff Bylaws of the Hospital (the "Bylaws"). (App. 24:Exh. C).

The Bylaws were adopted by the Hospital's governing board and medical staff, pursuant to Florida law, to set forth the procedures and criteria for physicians to apply for appointment and reappointment to the medical staff. (App. 25:Exh. C. at Article 2.2.5, 13.1). Chapter 395, Florida Statutes, provides the authority, requirements and criteria for application, review, and appointment or reappointment to the medical staff and for clinical privileges at licensed facilities. The Hospital's governing board must "set standards and procedures to be applied by the licensed facility and its medical staff in considering and acting upon applications for staff membership or clinical privileges." § 395.0191(5), Fla. Stat.

The statute provides that approval of medical staff membership and privileges should be based on a provider's "background, experience, health, training, and demonstrated competency; the applicant's adherence to applicable professional ethics; the applicant's reputation; and the applicant's ability to work with others and by such other elements as determined by the governing board, consistent with this part." § 395.0191(4), Fla. Stat.

The Bylaws likewise define this "credentialing" process as the "series of activities designed to collect relevant data that will serve as a basis for decisions

regarding appointments and reappointments to the Medical Staff, as well as delineation of clinical privileges." (App. 24:Exh. C at Article 10.1.3). Under the Bylaws, the application for medical staff membership is used to determine eligibility for membership on the medical staff, as well as clinical privileges. (App. 24:Exh. C at Article 3.1, 3.7.2-3.7.3). The application and supporting documentation are given to the Credentials Committee, which prepares a written report and recommendation. (App. 24:Exh. C at Article 3.7.5.2). These documents are then reviewed by the Medical Executive Committee, which gives its recommendation to the Board of Trustees, which in turn makes the ultimate decision regarding privileges. (App. 24:Exh. C at Article 3.7.5.3, 3.7.5.5.5).

The Bylaws generally identify certain types of information that the completed application shall include. (App. 24:Exh. C at Article 3.7.3.1-3.7.3.22). The Bylaws also describe steps that should be taken to verify the information in the completed application, application processing, ongoing verification of credentials, performance profiling including measurement, monitoring, analysis and improvement of the quality and appropriateness of services provided by the individual Medical Staff members and other individuals with clinical privileges, as well as provisional status and proctoring. (App. 24:Exh. C at Article 3.7.1).

These standards and procedures in the Bylaws are required to be available for public inspection. See § 395.0191(5), Fla. Stat. By contrast, the application to

the medical staff is part of the credentialing and recredentialing committee's process and is subject to the Hospital's records confidentiality policy. (App. 24:Exh. C at Article 12.1-12.2). Access to even the blank application form is limited. A physician is not provided with a blank application for medical staff membership until after that physician demonstrates eligibility for membership. (App. 24:Exh. C at Article 3.7.1). The Bylaws require that prior to providing an application to a prospective candidate, the Medical Staff Office must screen the prospective candidate, including requiring documentation of eligibility to apply for privileges. (App. 24:Exh. C at Article 3.7.1).

In support of its objections, the Hospital also submitted the affidavit of Sharon Smith, the Hospital's Risk Manager, attesting to the burdensome nature of the requests for production, and the fact that complying with such a request would interfere both with the operations of the hospital and the ability to perform her risk management functions that are required by state law. (App. 20:Exh. 1, ¶¶38-39).

The Hospital also argued that pursuant to section 381.028(7)(b)1, Florida Statutes, which was left intact by this Court's decision in Florida Hospital Waterman, Inc. v. Buster, 984 So. 2d 478, 493-94 (Fla. 2008), it should be allowed to identify "adverse medical incidents" using the process set forth in section 395.0197, Florida Statutes. (App. 21:4-5, 23; 28:2). Section 395.0197 provides

the framework for the risk management program that is required in all Florida hospitals. (App. 21:5, 23; see also App. 14:7, 16-19).

Finally, the Hospital argued that Amendment 7 is unconstitutional because it conflicts with and is impliedly preempted by the Health Care Quality Improvement Act of 1986 ("HCQIA"), 42 U.S.C. §§ 11101, et seq. (App. 21:3, 10-14; 28:3, 17-25; see also App. 14:9, 46-50, 52-63).[2]

In response, Plaintiffs filed memoranda, arguing the requested information was discoverable under Amendment 7. (App. 15; 17; 19). Plaintiffs contended that the blank application for medical staff privileges was discoverable under Amendment 7. (App. 19:16, 60-61). As to the Hospital's argument that pursuant to section 381.028, it should be allowed to identify "adverse medical incidents" using the process set forth in section 395.0197, Plaintiffs argued that section 381.028 does not apply to discovery requests made in civil lawsuits. (App. 19:53-57; see also App. 14:71-72). Lastly, Plaintiffs argued Amendment 7 was constitutional and not preempted. (App. 19:17-37; see also App. 14:65-67).

At the hearing, the parties made arguments consistent with those made in their motions and responses. (App. 14).

[2] While the Hospital raised various other objections to the requested discovery, those are not at issue in this appeal. (App. 14; 22; 23; 26; 28; 29).

On February 6, 2009, the trial court issued its Order granting, in part, and denying, in part, the Hospital's Amended Motion for Protective Order. (App. 13). The trial court rejected the Hospital's constitutional challenges to Amendment 7 and denied the motion as to "documents relating to adverse medical incidents," as defined in Amendment 7, of the two physicians for two years preceding the date of the first surgery performed on Mrs. See. (App. 13). The motion was otherwise granted. (App. 13:4). The Order is silent as to the Hospital's arguments regarding section 381.028(7)(b)1. (App. 13).

On February 9, 2009, the trial court issued its Order on the Hospital's Amended Motion to Quash and for Protective Order. (App. 12). In this Order, the trial court denied the motion for protective order as to the blank application for medical staff privileges and as to the two physicians' training specific to the surgical procedures performed on Mrs. See. (App. 12:2). The court otherwise granted the motion, including as to the two physicians' credentialing files to the extent they did not contain records of adverse medical incidents. (App. 12:3).

The Hospital filed separate petitions for writ of certiorari, challenging each Order and the appellate matters were consolidated. (App. 1; 7; 10). The Hospital argued that the trial court departed from the essential requirements of law by: (1) denying the Hospital's motion to quash with respect to a copy of the blank application for medical staff privileges; (2) denying the Hospital its statutory rights

under section 381.028, Florida Statutes, including denial of costs prior to production and denial of the Hospital's right to use the method set forth in section 395.0197, Florida Statutes, to identify records of adverse medical incidents; and, (3) finding that Amendment 7 is not preempted and does not violate the United States Constitution. (App. 1; 7; 10).[3] While the First District granted in part, and denied in part, the petitions, the First District rejected the Hospital's arguments on these issues. See W. Fla. Reg'l Med. Ctr., Inc. v. See, 18 So. 3d 676 (Fla. 1st DCA 2009); (App. 1).

As to the blank application for medical staff privileges, the First District did not adopt Plaintiffs' argument that Amendment 7 permitted its discovery. Id. at 690-91. Instead, the First District disagreed with the Fourth District's decision in Taitel, 855 So. 2d at 1258, that the Cruger v. Love, 599 So. 2d 111 (Fla. 1992), standard requires its protection, stating that "although the trial court did depart from the essential requirements of the law in failing to follow Taitel, which was the only district court decision on point at the time, the departure was harmless." Id.

With regard to section 381.028(7)(b)1, the First District stated that it declined to limit the scope of Amendment 7 by adopting the Hospital's interpretation of the statute and held that to the extent the statute requires less of

[3] While the Hospital raised other issues in its petition for writ of certiorari, those are not at issue here. (App. 14; 21; 22; 25; 27; 28).

hospitals, it conflicts with Amendment 7. See 18 So. 3d at 683-84. The First District also rejected the Hospital's argument that Amendment 7 violates the Supremacy Clause of the U.S. Constitution because it is impliedly preempted by HCQIA. Id. at 684-87.

The Hospital's Motion for Clarification, Rehearing and/or Rehearing En Banc, and for Certification of Questions to the Florida Supreme Court was denied, though the court withdrew and substituted its original decision. Id.; (App. 1; 3; 4).[4]

The Hospital's jurisdictional brief to this Court argued conflict with the Fourth District's decision in Taitel, 855 So. 2d 1257, as to the blank application for medical staff privileges. It further argued this Court has jurisdiction, because the First District expressly construed Amendment 7, a provision of the Florida Constitution, as well as the Supremacy Clause of the United States Constitution.

[4] The original decision included a footnote that stated, "Parenthetically, we note that we do not interpret the trial court's order as denying Petitioner the right to require prepayment of costs. The trial court's order simply does not address this issue, and Petitioner never made an affirmative request for a ruling on it. Instead, Petitioner merely noted its entitlement to the statutory right to require the prepayment of costs." (App. 4:7-8, n.2). That footnote was not included in the court's substituted opinion. See 18 So. 3d 676.

SUMMARY OF ARGUMENT

The trial court erred in ordering production of a blank application for medical staff privileges, because the application is privileged and confidential pursuant to sections 395.0191(8) and 766.101(5), Florida Statutes. These statutes protect the privilege and confidentiality of credentialing committee records and investigations, including the blank application here. See Tenet Healthsystem Hospitals, Inc. v. Taitel, 855 So. 2d 1257 (Fla. 4th DCA 2003). Moreover, these confidentiality provisions are still in effect to the extent that they do not prohibit the production of records relating to adverse medical incidents under Amendment 7. Because the blank application form for medical staff privileges is not related to any adverse medical incident, it is not subject to production under Amendment 7.

The trial court further erred in failing to order that production under Amendment 7 be performed pursuant to section 381.028(7)(b)(1), Florida Statutes, which this Court declined to find unconstitutional in Florida Hospital Waterman, Inc. v. Buster, 984 So. 2d 478, 493-94 (Fla. 2008). This subsection provides that a Hospital shall use the risk management program in section 395.0197 to identify records as records of adverse medical incidents.

Lastly, the trial court erroneously ordered production under Amendment 7, which is impliedly preempted by the Health Care Quality Improvement Act of

1986 ("HCQIA"), because Amendment 7 will eviscerate effective peer review and frustrate HCQIA's purpose in that regard.

Accordingly, the trial court's Orders should be quashed to the extent they require production of the blank application for medical staff privileges and to the extent that they require production of privileged and confidential records protected by sections 395.0191, 395.0193 and 766.101, on the basis that Amendment 7 is preempted. Should this Court determine that Amendment 7 is not preempted, then the trial court should be instructed to permit the Hospital to use the process set forth in section 381.028(7)(b)1 to identify records of adverse medical incidents, under Amendment 7. The First District's decision should be reversed to the extent it is inconsistent with the relief sought herein.

ARGUMENT

I. THE TRIAL COURT ERRED IN ORDERING PRODUCTION OF THE BLANK APPLICATION FOR MEDICAL STAFF PRIVILEGES

A. Standard of Review: De Novo

The trial court's interpretations of the statutory provisions providing for the confidentiality of a blank application for medical staff privileges and of Amendment 7 is reviewed de novo. See Cruger v. Love, 599 So. 2d 111 (Fla. 1992) (reviewing de novo the construction of statutory provisions providing for the confidentiality of peer review and credentialing process); Benjamin v. Tandem Healthcare, Inc., 998 So. 2d 566, 570 (Fla. 2008) (reviewing construction of Amendment 7 de novo).

B. An Application For Medical Staff Privileges Is Statutorily Protected And Not Subject To Production

The trial court erred in ordering production of the blank application for medical staff privileges, because the application is privileged and confidential pursuant to chapters 395 and 766, Florida Statutes. All documents and information pertaining to the work of credentialing and medical review committees were protected from discovery in civil cases prior to the enactment of Amendment 7. See §§ 395.0191(8), 395.0193(8), 395.0197, 766.101(5), Fla. Stat. Because Amendment 7 does not apply to the application, it remains privileged and confidential, not subject to production.

1. The application for medical staff privileges is not subject to production under Amendment 7

Amendment 7 did not altogether eliminate the privilege and confidentiality afforded under chapters 395 and 766, Florida Statutes. Rather, Amendment 7 provides that a patient may access "any records made or received in the course of business by a health care facility or provider **relating to any adverse medical incident**." Article X, § 25(a), Fla. Const. (emphasis added). Indeed, the First District, Second District and Third District have each held that the confidentiality provisions in chapters 395 and 766, Florida Statutes, are still in effect to the extent that they do not prohibit the production of records relating to adverse medical incidents under Amendment 7. See W. Fla. Reg'l Med. Ctr. v. See, 18 So. 3d 676, 688-89 (Fla. 1st DCA 2009); Baptist Hosp. of Miami, Inc. v. Garcia, 994 So. 2d 390, 393 (Fla. 3d DCA 2008); Morton Plant Hosp. Ass'n v. Shahbas, 960 So. 2d 820, 827 (Fla. 2d DCA 2007). The blank application form for medical staff privileges is not related to any adverse medical incident. As such, it is not subject to production under Amendment 7.

Notably, here, the First District rejected Plaintiffs' argument that the blank application was subject to production under Amendment 7. Instead, the First District determined that a blank application for medical staff privileges was not statutorily protected. In this regard, the First District erred.

2. Consistent with Taitel, a blank application for medical staff privileges is confidential and not subject to production

Chapters 395 and 766, Florida Statutes, broadly protect the investigations, proceedings and records of committees involved in credentialing. Section 395.0191(8), Florida Statutes, provides:

> The investigations, proceedings, and records of the board [involved in determining staff membership or clinical privileges], or agent thereof . . . shall not be subject to discovery . . . against a provider of professional health services arising out of matters which are the subject of evaluation and review by such board. . .

Similarly, section 766.101(5), Florida Statutes, provides:

> The investigations, proceedings, and records of a [medical review committee] shall not be subject to discovery . . . in any civil or administrative action against a provider of professional health services arising out of the matters which are the subject of evaluation and review by such committee.

These statutes protect the privilege and confidentiality of credentialing committee records and investigations. Indeed, this Court in Cruger v. Love, 599 So. 2d 111, 113 (Fla. 1992), held that the privileges provided by sections 395.0191 and 766.101, "protect[] any document considered by the [credentialing or peer review] committee or board as part of its decision-making process." See also Brandon Reg'l Hosp. v. Murray, 957 So. 2d 590, 592 (Fla. 2007) (affirming prohibition in sections 766.101 and 395.0191 of discovery in civil litigation of investigations, proceedings and records of Hospital committees involved in

credentialing). This Court explained the necessity of encouraging candor within the credentialing process, explaining, "it is essential that doctors seeking hospital privileges disclose all pertinent information to the committee." Cruger, 599 So. 2d at 113.

This Court ultimately found in Cruger that a physician's application for medical staff membership or clinical privileges was privileged and confidential under the above statutes. This Court also held that documents that originated from sources outside the Board or committee proceedings were also privileged and could not be accessed from the Hospital committee's records. Id. at 114 ("We reject the interpretation . . . [that] documents, information, or records in the possession of the committee are not protected if they originated from sources outside the board or committee proceedings.").

While Cruger held that an application to the medical staff was privileged, the Fourth District in Tenet Healthsystem Hospitals, Inc. v. Taitel, 855 So. 2d 1257 (Fla. 4th DCA 2003), explained that even a blank version of a form created by a credentialing committee to evaluate hospital employees is statutorily privileged as a credentialing record. In that case, the plaintiff wanted the forms to determine the criteria that committees deemed important in reviewing nurse competency. Relying on the importance of "effective self-policing by the medical community,"

the Fourth District held that a blank document used by a committee for evaluating nurses was statutorily privileged. Id. at 1258.

The First District's decision in this case that a blank application for medical staff privileges is not protected, See, 18 So. 3d at 691, expressly and directly conflicts with the Fourth District's decision in Taitel, 855 So. 2d at 1258, and is contrary to this Court's decision in Cruger, 599 So. 2d 111. Indeed, the First District acknowledged conflict with Taitel by stating that it did not agree with the Taitel court "that the Cruger, standard requires the protection of blank forms." Id. Additionally, the First District held that "although the trial court did depart from the essential requirements of the law in failing to follow Taitel, which was the only district court decision on point at the time, the departure was harmless." Id.

In so holding, the First District erred and departed from this Court's holding in Cruger, 599 So. 2d at 114, that the privilege provided by sections 766.101(5) and 395.011(9),[5] "protects any document considered by the committee or board as part of its decision-making process."

The undisputed evidence before the trial court, which included the Bylaws, demonstrates the blank application for privileges is considered by the Hospital's Credentials Committee, Medical Review Committee and Board of Trustees as part

[5] Section 395.011(9) is an earlier version of section 395.0191(8), Florida Statutes.

of its decision-making process, and as such, constitutes an investigation, proceeding or record of the committee. (App. 24:Exh. C at Article 3.1.1-.10, 3.7.2-.3, 3.7.5.2-.5, 10.1.3). The application form assists the committees in obtaining and evaluating the qualifications of particular physicians applying for appointment to the medical staff and is used to determine what privileges will be granted. (App. 24:Exh. C at Article 3.1.1-.10, 3.7.2-.3, 3.7.5.2-.5, 10.1.3).

First, the application form is considered by the Credentialing Committee, the Medical Executive Committee and the Board. Each of these bodies reviews the application and either makes recommendations, in the case of the Committees, or decides to grant or deny privileges. (App. 24:Exh. C at Article 3.7.5). As these bodies can only consider the responses to the application in the context of the questions posed to the candidate, the application form itself is considered by the Committees and the Board and thus constitutes a record of those bodies.

Moreover, the blank application for privileges also constitutes part of the Committees' and Board's investigation of the candidate. There is no practical difference between questions asked orally by the Committees and the Board as part of their investigation of a candidate and questions asked in writing in the application for privileges. As the questions posed to a candidate during a committee or Board meeting would be subject to the privileges found in sections

395.0191(8) and 766.101(5), those questions posed in writing share the same privilege.

Finally, the Hospital itself treats the blank application for privileges as privileged and confidential. The application to the medical staff is subject to the Hospital's records confidentiality policy. (App. 24:Exh. C at Article 3.7.2, 12.1-12.2). Access to this application form is limited. A physician who wishes to apply for privileges is not provided with a blank application until after that physician demonstrates initial eligibility. (App. 24:Exh. C at Article 3.7.1). The Bylaws require that prior to providing an application to a prospective candidate, the Medical Staff Office must screen the candidate, including requiring documentation of eligibility to apply for privileges. (App. 24:Exh. C at Article 3.7.1).

As this Court observed in Cruger, in enacting the statutory framework providing for confidentiality, the legislature made a policy decision and balanced the need to obtain information against the benefits offered by effective self-policing by the medical community. 599 So. 2d at 114. In balancing those needs, the legislature determined that as provided in section 395.0191(5), the standards and procedures that apply when the medical staff considers and acts upon applications for staff membership or clinical privileges shall be available to the

public, but ensured that the investigations, proceedings and records of those bodies would be confidential under sections 395.0191(8) and 766.101(5).

The evidence in this case demonstrates that the Hospital complied with section 395.0191(5). The Bylaws identify standards and procedures to be applied in making credentialing decisions. (App. 24:Exh. C at Article 13.1). Specifically, the Bylaws identify information that the completed application shall include. (App. 24:Exh. C at Article 3.7.3.1-3.7.3.22). Consequently, while Plaintiffs may not have access to the blank application form that reflects the process by which candidates are evaluated and the questions asked of candidates, Plaintiffs do have the Bylaws which identify the type of information that an applicant should disclose. (App. 24:Exh. C at Article 3.7.3.1-.22). As such, on balance and consistent with the legislative policy considerations in enacting the statutes and this Court's decision in Cruger, the blank application form is confidential and should be protected. See Cruger, 599 So. 2d at 113 (court bound to look to legislative intent and policy behind these statutes to determine extent of privilege) (citing White v. Pepsico, Inc., 568 So. 2d 886, 889 (Fla. 1990); Devin v. City of Hollywood, 351 So. 2d 1022, 1023 (Fla. 4th DCA 1976)).

Accordingly, consistent with Taitel, 855 So. 2d 1257, the trial court erred as a matter of law in ordering production of the blank application form for medical staff privileges.

II. THE TRIAL COURT ERRED IN IGNORING THE PROCESS BY WHICH THE HOSPITAL MUST IDENTIFY RECORDS UNDER SECTION 381.028, FLORIDA STATUTES

A. Standard of Review: De Novo

The trial court's interpretation of Amendment 7 and section 381.028, Florida Statutes, is reviewed de novo. See Benjamin, 998 So. 2d at 570 (reviewing construction of Amendment 7 de novo); Cruger, 599 So. 2d 111 (reviewing de novo the construction of statutory provisions providing for the confidentiality of peer review and credentialing process).

B. The Trial Court Failed To Address/Enforce Section 381.028(7)(b)1

Plaintiffs' discovery requests were made pursuant to Amendment 7. Section 381.028, Florida Statutes, was expressly enacted to implement Amendment 7. While this Court, in Buster, 984 So. 2d at 494, found that certain subsections of section 381.028 were unconstitutional, this Court severed those unconstitutional subsections from the statute and allowed the remainder to stand. In allowing the remainder of the statute to stand, this Court determined these subsections of "the statute may be given a fair construction that is consistent with the federal and state constitutions as well as with the legislative intent." Sunset Harbour Condo. Ass'n v. Robbins, 914 So. 2d 925, 929 (Fla. 2005); see also State v. Kolacia, 558 So. 2d 190, 191 (Fla. 4th DCA 1990). Among the subsections of the statute that this Court declined to find unconstitutional was section 381.028(7)(b)(1).

In ordering the discovery produced in this case, however, the trial court, refused to enforce subsection (7)(b)(1). In this regard, the trial court erred as a matter of law, warranting reversal.

Under section 381.028(7)(b)(1), hospitals are responsible for identifying records of adverse medical incidents under the Amendment. The Legislature provided that to identify records under Amendment 7, hospitals must use the process found within an existing system, the hospitals' internal risk management program, which is statutorily required in licensed health care facilities in Florida. See § 395.0197, Fla. Stat. Subsection (7)(b)(1) provides specifically that "[u]sing the process provided in s. 395.0197, the health care facility shall be responsible for identifying records as records of an adverse medical incident, as defined in s. 25, Art. X of the State Constitution." The plain language of this subsection provides that a Hospital may use the risk management program in section 395.0197 to identify records as records of adverse medical incidents.

Thus, the Hospital need not look at every single record in its possession to locate responsive records. Such a search would not only be extremely costly, but according to the Hospital's risk manager, would interfere both with the operations of the hospital and the ability to perform her risk management functions that are required by state law. (App. 20:Ex. 1, ¶¶38-39). Instead, the Hospital should look

to those records within the risk management's reporting system to identify records as records of adverse medical incidents.

Because the trial court did not address sections 381.028(7)(b)(1) or 395.0197 in its Orders, the trial court failed to identify what process the Hospital was required to use to identify records as records of adverse medical incidents. Instead, the trial court's order requires the Hospital to identify all records relating to adverse medical incidents, without giving any guidance as to how those records should be identified. Assuming the trial court denied the Hospital relief sub silentio, the trial court either wrongly determined that the statutory procedures laid out in section 381.028 were struck down in Buster or that the statutory provisions were unconstitutional. In either event, the trial court's decision to order production of documents without addressing the threshold issue of the method of production set forth in section 381.028(7)(b)(1) was erroneous.

Like the trial court, the First District rejected the Hospital's argument, agreeing with the Fourth District that the Hospital's interpretation of section 381.028(7)(b)1 calls for an unconstitutional application of the statute, because the legislature may not limit the scope of discoverable records of adverse medical incidents in a manner inconsistent with Amendment 7. See, 18 So. 3d at 683-84 (citing Columbia Hosp. Corp. of So. Broward v. Fain, 16 So. 3d 236, 241 (Fla. 4th 2009)). Nevertheless, the First District did not otherwise explain how section

381.028(7)(b)1 should be interpreted, other than to hold that if it requires less of hospitals, then it conflicts with Amendment 7.

This Court in Buster, 984 So. 2d at 494, however, declined to strike section 381.028(7)(b)1 and severed it from other provisions found unconstitutional. To the extent the First District rejected the Hospital's interpretation of the statute, finding it in conflict with Amendment 7, without setting forth a constitutional interpretation, the decision conflicts with Buster in that it in effect finds section 381.028(7)(b)1 unconstitutional and invalidates it. As such, this Court has jurisdiction to address this issue. See Fla. R. App. P. 9.030(a)(1)(A)(ii), (2)(ii)(iv); see also Savoie v. State, 422 So. 2d 308, 310 (Fla. 1982) ("[O]nce we accept jurisdiction over a cause in order to resolve a legal issue in conflict, we may, in our discretion, consider other issues properly raised and argued before this Court."); Russell v. State, 982 So. 2d 642, 645 (Fla. 2008).

Thus, the Hospital requests that this Court find that the Hospital must use the method of production set forth in section 381.028(7)(b)1 to identify records that are records of adverse medical incidents. Otherwise, the Hospital requests that this Court determine what process the Hospital should use to identify records under Amendment 7.

III. THE TRIAL COURT ERRONEOUSLY ORDERED PRODUCTION UNDER AMENDMENT 7, WHICH VIOLATES THE UNITED STATES CONSTITUTION'S SUPREMACY CLAUSE

A. Standard of Review: De Novo

The trial court's determination that Amendment 7 does not violate the United States Constitution's Supremacy clause, because it is not preempted by the Health Care Quality Improvement Act of 1986 ("HCQIA"), is reviewed de novo. See Browning v. Fla. Hometown Democracy, Inc., PAC, 29 So. 3d 1053 (Fla. 2010) (questions of constitutional interpretation are reviewed de novo); Fla. Dept. of Revenue v. City of Gainesville, 918 So. 2d 250, 256 (Fla. 2005) (same).

B. Amendment 7 Is Impliedly Preempted By HCQIA

Although both Amendment 7 and HCQIA may have a similar ultimate goal of improving the quality of health care in the United States, Amendment 7 attempts to achieve that goal through objectives diametrically opposed to those of HCQIA. Based on this conflict, Amendment 7 is preempted by HCQIA.

In enacting HCQIA, Congress addressed the "overriding national need" for physicians to engage in effective professional peer review, which Congress deemed essential to restricting the ability of incompetent physicians to move from state to state. See 42 U.S.C. §§ 11101, et seq. Because this Court's interpretation of Amendment 7 in Buster will eviscerate effective peer review and frustrate

HCQIA's purpose, Amendment 7 must yield to HCQIA under the principles of conflict preemption.

Conflict (or obstacle) preemption exists when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992).

The analysis under the Supremacy Clause is a two step process. First, does Amendment 7's elimination of confidentiality, as interpreted in Buster, stand as an obstacle to effective and reliable peer review? Second, did Congress enact HCQIA to promote professional, effective peer review and make use of that peer review as an essential tool in limiting medical malpractice? Because these questions must be answered in the affirmative, Amendment 7 is preempted by HCQIA under the doctrine of conflict preemption.

First, confidentiality is an indispensable component of effective and reliable peer review. There is no clearer pronouncement on this subject than this Court's statement that "meaningful peer review would not be possible without a limited guarantee of confidentiality for the information and opinions elicited from physicians regarding the competence of their colleagues." Holly v. Auld, 450 So. 2d 217, 220 (Fla. 1984). As the Hospital argued below, based on record evidence and established case law, confidentiality is necessary for effective and reliable peer review. (App. 5, p. 10; App. 8, p. 9; App. 24:Exh. A-B). Because

Amendment 7 is a record access provision that has been interpreted as eliminating confidentiality of all peer review records of an "adverse medical incident," Amendment 7 stands as an obstacle to effective peer review in Florida.

Promotion of effective peer review is a major purpose and objective of HCQIA. This is because, in 1986, Congress was building upon a foundation of existing peer review protections within the states to create a mechanism to share information collected by existing peer review committees. See Bernard D. Reams, Health Care Quality Improvement Act of 1986: A Legislative History, (hereinafter "HCQIA Legislative History"), Document 2 at 2 (1990) (citing H.R. Rep. No. 99-903 at 2 (1986), reprinted in 1986 U.S.C.C.A.N. 6384-6391 ("The bill's focus is on those instances in which physicians injure patients though incompetent or unprofessional service, are identified as incompetent or unprofessional by their medical colleagues, but are dealt with in a way that allows them to continue to injure patients . . . This legislation would require organizations that discipline doctors to report their disciplinary actions to a central location and would require hospitals to seek this information before hiring doctors.")); id. 8-9 ("under current state law, most professional review activities are protected by immunity and confidentiality provisions.").

In the 1980s, hospitals were already engaged in medical quality assurance. See HCQIA Legislative History, Document 4 at 275 (citing Medical Malpractice:

Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce on H.R. 5110, 99th Cong. (March 18, 1986 and July 19, 1986) (hereinafter "Medical Malpractice Hearings") at 292 (testimony of John Horty, President of the National Council of Community Hospitals that "hospitals are the main area in which careful examination of credentials of physicians today is taking place. . . It is the hospitals of this country who bear the major burden for attempting to prevent unqualified people, physicians and others from providing care.")); id. at 321-22 (Congressman Waxman stated "a doctor licensed in any state in this country is licensed to practice medicine, which means he can perform brain surgery or anything else. The only restriction, as a practical matter, we have is what the hospitals place on these doctors by saying just because you are licensed to practice medicine doesn't mean you can perform brain surgery in our institution. . .).

Upon this foundation of existing peer review, Congress enacted HCQIA to make use of existing peer review processes to limit physicians' ability to move between hospitals and states without disclosing prior malpractice. To do this, HCQIA established the foundation for a National Practitioner Data Bank ("NPDB"). HCQIA requires healthcare facilities to make specific reports to the NPDB. Any health care entity that makes a determination affecting a physician's credentials for more than 30 days must report the following information to the

NPDB: (a) the name of the physician involved, and (b) a description of the acts or omissions or other reasons for the revocation, suspension, or surrender of license or privileges. 42 U.S.C. § 11133(a)(3). Pursuant to section 11135(a), health care facilities must consult the NPDB to review whether reports have been filed concerning (1) any new physicians, and (2) existing physicians once every two years. Thus, in enacting HCQIA, Congress required that the information generated by existing peer review activities be shared nationally.

As a result, effective peer review locally is crucial for the NPDB reporting mechanism and HCQIA to function. As a practical matter, where a health care facility fails to conduct peer review effectively, it will not generate reliable information for the NPDB and prevents HCQIA from serving its purpose.

The text and legislative history of HCQIA support the importance of effective peer review. Congress stated the importance of peer review as an essential tool to limit medical malpractice. In enacting HCQIA, Congress found:

> - The increasing occurrence of medical malpractice and the need to improve the quality of medical care have become nationwide problems that warrant greater efforts than those that can be undertaken by any individual State.
> - There is a national need to restrict the ability of incompetent physicians to move from state to state without disclosure or discovery of the physician's previous damaging or incompetent performance.

- This nationwide problem can be remedied through effective professional peer review.

42 U.S.C. § 11101.

HCQIA's legislative history further indicates that Congress considered effective peer review indispensable to achieving HCQIA's purpose. According to the House Report, HCQIA's stated purpose was "to improve the quality of medical care by encouraging physicians to identify and discipline other physicians who are incompetent or who engage in unprofessional behavior." HCQIA Legislative History, Document 2 at 2 (citing H.R. Rep. No. 99-903, 99th Cong., 2d Sess. 245 at 2), reprinted in 1986 U.S.C.C.A.N. 6384, 6384); see also id., Document 3 at 192, Medical Malpractice Hearings (Ron Wyden, Oregon Representative, introducing H.R. 5110, HCQIA, stating "[d]octors are in the best position to do something about malpractice because they see it happening around them.").

Amendment 7, as interpreted in Buster, stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress in enacting HCQIA to promote effective peer review because it strips confidentiality from peer review records. This lack of confidentiality undermines effective peer review, and thus violates the Supremacy Clause of the U.S. Constitution.

The First District in this case, as well as the Fourth District in Fain, 16 So. 3d 236, rejected this argument. Those cases, however, were wrongly decided. In each decision, the courts misconstrued the nature of obstacle or implied

preemption under the Supremacy Clause and failed to consider the conflict between the purpose of Amendment 7 - - to increase access to records, and the purpose of HCQIA - - to promote effective peer review.

As noted above, the promotion of effective peer review is one of the purposes of HCQIA. See, 18 So. 3d at 685. Furthermore, the evidence and case law demonstrates that Florida's statutory confidentiality provisions contribute to effective peer review. Holly, 450 So. 2d at 220; Cruger, 599 So. 2d at 113; Dade County Med. Ass'n v. Hlis, 372 So. 2d 117, 120 (Fla. 3d DCA 1979); (App. 25:Exh. A-B).[6]

Nevertheless, because HCQIA itself does not require confidentiality, the courts in See found no obstacle preemption. This decision misinterprets the Supremacy Clause and employs an incorrect preemption analysis in essentially determining that Amendment 7 is not preempted because it does not directly violate the provisions of HCQIA. The First District cited federal cases for the

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[6] Similarly, Congress also found confidentiality to be necessary for effective peer review. In commenting on a bill signed into law the same day as HCQIA, Congress explained the importance of providing for peer review confidentiality for Department of Defense quality assurance activities:

> To be effective, this type of collegial [peer] review process must operate in an environment of confidentiality in order to elicit candid appraisals and evaluations of fellow professionals.

S. Rep. No. 99-331 at 245 (1986), reprinted in 1986 U.S.C.C.A.N. 6413, 6440.

proposition that the decision not to include a federal confidentiality privilege in HCQIA was a policy choice by Congress. See, 18 So. 3d at 686-687 (citing In re Admin. Subpoena Blue Cross Blue Shield of Mass., Inc., 400 F.Supp.2d 386, 391-92 (D.Mass. 2005); Nilavar v. Mercy Health Sys. W. Ohio, 210 F.R.D. 597 (S.D. Ohio 2002); Johnson v. Nyack Hosp., 169 F.R.D. 550, 560-61 (S.D.N.Y. 1996); Teasdale v. Marin Gen. Hosp., 138 F.R.D. 691, 694 (N.D. Cal.1991)). The First District held that because HCQIA did not provide for confidentiality of peer review records, there was no obstacle preemption, stating, "[i]f Congress had found a peer review privilege necessary to the effectiveness of peer review processes, it would have included such a privilege in the HCQIA. Because Petitioner has not shown that effective peer review is impossible without the confidentiality of peer review materials . . . the HCQIA does not preempt Amendment 7." See, 18 So. 3d at 687.

This construction is problematic in two ways. First, it sets aside the legal backdrop against which HCQIA was based. Specifically, in passing HCQIA, Congress created legislation to centralize existing peer review information collected under existing state statutes, which already provided confidentiality for peer review records. See Virmani v. Novant Health Inc., 259 F.3d 284 (4th Cir. 2001) (noting "fact that all fifty states and the District of Columbia have recognized some form of medical peer review privilege"); Sanderson v. Frank S.

Bryan, M.D., Ltd., 361 Pa. Super. 491 (Penn. 1987) (describing strong policies favoring protecting peer review records);[7] HCQIA Legislative History"), Document 2 at 8-9 (1990) (citing H.R. Rep. No. 99-903 at 8-9 (1986), reprinted in 1986 U.S.C.C.A.N. 6384, 6391 ("under current state law, most professional review activities are protected by immunity and confidentiality provisions.")). Indeed, Congressional findings in HCQIA in 42 U.S.C. § 11101(3), (4) and (5) explicitly

[7] Citing Ala. Code § 22-21-8(b) (1984); Alaska Stat. § 18.23.030 (1981); Ariz. Rev. Stat. Ann. § 36-445.01 (Supp.1975-84); Ark. Stat. Ann. § 28-934 (1979); Cal. Evid. Code § 1157 (West Supp.1985); Colo. Rev. Stat. Ann. § 13-21-110(1) (1973 & Supp.1984); Conn. Gen. Stat. Ann. § 19a-25 (West Supp.1984); Del. Code Ann. tit. 24, § 1768 (1981); Fla. Stat. Ann. § 768.40(4) (West Supp.1984); Ga. Code Ann. § 88-1908 (Supp.1984); Hawaii Rev. Stat. § 624-25.5 (Supp.1983); Idaho Code § 39-1392b (1977 & 1984 Supp.); Ill. Ann. Stat. ch. 110 § 8-2101 (1984); Ind. Code Ann. § 16-4-3-1 (Burns 1983); Iowa Code Ann. § 135.42 (West 1972); 1984 Kan. Sess. Laws ch. 238 § 7(c); Ky. Rev. Stat. § 311.377(2) (1983); La. Rev. Stat. Ann. 13 § 3715.3 (West Supp.1984); Me. Rev. Stat. Ann. tit. 24 § 2510(3) (1964); Md. Health Occ. Code Ann. § 14-601(d) (1981 & Supp.1984); Mich. Comp. Laws Ann. § 333.2632 (West 1980); Minn. Stat. Ann. § 145.64 (West Supp.1984); Miss. Code Ann. § 41-63-9 (1972 & Supp.1984); Mo. Ann. Stat. § 537.035.4 (Vernon Supp.1985); Mont. Code Ann. §§ 50-16-203, 50-16-205 (1983); Neb. Rev. Stat. § 71-2048 (1981); Nev. Rev. Stat. § 49.265 (1981); N.H. Rev. Stat. Ann. § 151:13-a (Supp.1983); N.J. Stat. Ann. § 2A:84A-22.8 (West Supp.1984-85); N.M. Stat. Ann. § 41-9-5 (1982 Supp. Pamphlet); N.Y. Admin. Code tit. 10 § 405.24(k) (1984); N.C. Gen. Stat. § 131E-95 (Supp.1983); N.D. Cent. Code § 23-01-02.1 (Supp.1983); Ohio Rev. Code Ann. § 2305.251 (Page 1983); Okla. Stat. Ann. tit. 63, § 1-709 (West 1984); Or. Rev. Stat. § 41.675 (1983); Pa. Stat. Ann. tit. 63 § 425.4 (Purdon Supp. 1984-85); R.I. Gen. Laws § 5-37.3-7 (Supp.1984); S.D. Codified Laws Ann. § 36-4-26.1 (1977); Tex. Rev. Civ. Stat. Ann. 4447d § 3 (Vernon 1973); Vt. Stat. Ann. tit. 18, §§ 1958-1960 (Supp.1984); Va. Code § 8:01-581.17 (1984); Wash. Rev. Code Ann. § 4.24.250 (Supp.1963-1985); W.Va. Code § 30-3C-3 (Supp.1984); Wis. Stat. Ann. § 146.38 (West Supp.1975-1984); Wyo. Stat. § 35-2-602 (1977).

recognize that effective professional peer review existed, and should be further encouraged by the federal government.

In light of these state law provisions, the existence of a federal confidentiality privilege is inapposite. Whether Congress declined to create a federal peer review confidentiality privilege does not alter that HCQIA depends on state law confidentiality to create effective peer review.

In an attempt to dismiss the importance of existing state law that protected peer review confidentiality, the First District noted that Congress was well aware that state laws could be repealed. See, 18 So. 3d at 687. However, this begs the question of whether a state law, which repeals the foundation of a federal law, is preempted. Congress was equally aware of obstacle preemption principles. Where peer review confidentiality was protected under state law, and Congress used that peer review for its own purposes in the NPDB databank, state law that weakens peer review constitutes an obstacle to the purpose of HCQIA and is preempted.

Furthermore, the First District's conclusion that Congress did not believe state law confidentiality was necessary to effective peer review is wrong. The same Congress that approved HCQIA recognized the necessity of peer review confidentiality in Public Law 99-661, signed into law the same day as HCQIA, which mandated that peer review records for the Department of Defense be privileged and confidential. See also 10 U.S.C. § 1102(a) (2009). Congress noted

that confidentiality was imperative for effective peer review in the Department of Defense, explaining that "[l]acking the protection of confidentiality, members of military medical care review committees have become increasingly reluctant to make candid appraisals of their peers." S. Rep. No. 99-331 at 245 (1986), reprinted in 1986 U.S.C.C.A.N. 6413, 6440. Congress further noted that confidentiality is equally necessary for the civilian medical community, but recognized that such confidentiality was already provided for in the states.

> This problem is not unique to the Military Health Care system. The Joint Commission on Accreditation of Hospitals, the nationally recognized hospital accrediting body, recommends legislation to protect quality assurance records from unwarranted disclosure. The civilian medical community enjoys such protection since all states have confidentiality laws preventing disclosure of these records in litigation.

Id. Thus, the view in Congress was that while civilian physicians needed the same confidentiality protections as the Department of Defense, state law already provided for the confidentiality of peer review records in litigation. As such, the lack of an explicit confidentiality provision in HCQIA does not preclude a finding that Amendment 7 creates an obstacle to the purpose of effective peer review.

Instead, rather than focus on whether federal peer review confidentiality was recognized in HCQIA, the First District in this case should have determined whether Amendment 7 constitutes an obstacle to HCQIA's full purposes and

objectives, i.e. the promotion of effective peer review to be used nationally to prevent the movement of incompetent physicians from state to state.

An express intent to preempt state law is not required before conflict or obstacle preemption can be found. See Geier v. Am. Honda Motor Co., 529 U.S. 861, 884-85 (2000). Instead, "[a] decision about [obstacle preemption] requires the court independently to consider national interests and their putative conflict with state interests.... [P]reemption under [an obstacle preemption] theory is more an exercise of policy choices by a court than strict statutory construction." Columbia Venture, LLC v. Dewberry & Davis, LLC, No. 08-1318, 2010 WL 1904926, *4 (4th Cir. May 12, 2010). "[A]n aberrant or hostile state rule is preempted to the extent it actually interferes with the methods by which the federal statute was designed to reach [its] goal." Ting v. AT&T, 319 F.3d 1126, 1137 (9th Cir. 2003) (citations omitted).

HCQIA's method is to take peer review information generated throughout the country and to make that information available nationwide to improve the ability of state governments, hospitals and the medical profession to self-police physicians. Amendment 7 interferes with HCQIA's method because Amendment 7's elimination of confidentiality undermines the effectiveness of peer review at the local level.

While HCQIA and Florida's statutory provisions regarding peer review have the objective of improving health care quality by facilitating the frank exchange of information among professionals conducting peer review inquiries, see Ming Wei Liu v. Board of Trustees of the University of Alabama, 330 Fed. Appx. 775, 2009 WL 1376498, *2 (11th Cir. May 19, 2009), Amendment 7 attempts to improve health care quality through medical choice of patients by opening 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." In re Advisory Opinion to the Attny. Gen. re Patients' Right To Know About Adverse Med. Incidents, 880 So. 2d 617, 618 (Fla. 2004). Amendment 7 must give way to the extent that its record access provisions create an obstacle to the frank exchange of information among professionals conducting peer review. See, e.g., Cruger, 599 So. 2d at 113 ("to make meaningful peer review possible, the legislature provided a guarantee of confidentiality for the peer review process."); Hlis, 372 So. 2d at 120 ("Confidentiality is essential to effective functioning of these staff meetings; and these meetings are essential to the continued improvement in the care and treatment of patients."); see also Advisory Opinion, 880 So. 2d at 622 (noting peer review system could be affected by Amendment 7).

This Court previously recognized this policy conflict in Buster, 984 So. 2d at 494:

> It is not for us to judge the wisdom of the constitutional amendments enacted or the change in public policy pronounced through those amendments, even in instances where the change involves abrogation of long-standing legislation that establishes and promotes an equally or arguably more compelling public policy.

While the conflict between the methods to achieving effective peer review and the methods utilized by Amendment 7 were not at issue in Buster, they are squarely presented in this case. Because the elimination of confidentiality by Amendment 7 constitutes an obstacle to the purpose and objective of HCQIA, Amendment 7 is unconstitutional.

CONCLUSION

Based on the foregoing, Petitioner, West Florida Regional Medical Center, respectfully requests that this Court reverse the First District's decision with instructions that the trial court's February 6, 2009 and February 9, 2009 Orders be quashed to the extent they require production of the blank application for medical staff privileges and to the extent that they require production of privileged and confidential records protected by sections 395.0191, 395.0193 and 766.101, on the basis that Amendment 7 is preempted. Should this Court determine that Amendment 7 is not preempted, then this Court should instruct that the Hospital

may use the process set forth in section 381.028(7)(b)1 to identify records of adverse medical incidents, under Amendment 7.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that this brief complies with the font requirements set forth in Florida Rule of Appellate Procedure 9.210 by using Times New Roman 14-point font.

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