IN THE SUPREME COURT OF THE STATE OF FLORIDA

TALLAHASSEE, FLORIDA

CASE NO. SC09-1997

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

Petitioner,

-VS-

LYNDA S. SEE and RODNEY C. SEE,

Respondents.	

BRIEF OF RESPONDENTS ON THE MERITS

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

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PREFACE

This proceeding involves discretionary review of a decision of the First District Court of Appeal. The parties will be referred to by their proper names or as they appeared in the trial court. The following designation will be used:

(A) – Petitioners' Appendix

STATEMENT OF THE CASE AND FACTS

The Plaintiffs accept the Hospital's Statement of the Case and Facts with the following correction. The Hospital contends that it argued in the trial court that "it should be allowed to identify records of adverse medical incidents using the "process" set forth in §395.0197, Fla. Stat. (IB, p.5). In fact, the "process" for identifying documents subject to Plaintiffs' Amendment 7 request was never at issue in the trial court or the district court. The Hospital's argument was only that §381.028(7)(b)1, Fla. Stat., limited the Plaintiffs to receiving Code 15 reports and annual reports pursuant to §395.0197, Fla. Stat., to the exclusion of any other documents.

The Hospital's entire argument on this issue in its Amended Motion for Protective Order was as follows (A21, pp.4-5):

The Florida Supreme Court's opinion in Florida Hospital Waterman, Inc. v. Buster, 33 Fla. L. Weekly S154 (Fla. Mar. 6, 2008) left intact §381.028(7)(b)1., which provides that "[u]sing the process provided in s. 395.0197, the health care facility shall be responsible for identifying records of an adverse medical incident, as defined in s. 25, Art. X of the State Constitution." The plain language of this sub-section means that the "records of an adverse medical incident" under Amendment 7 are those records identified in §395.0197, other than attorney work-product protected records under §395.0197(4) or common law. The records identified in §395.0197 which fall under the category of "records of adverse medical incidents" are therefore limited to incidents in Code 15

reports identified in § 395.0197(7) and the annual report to AHCA identified in § 395.0197(5).

To the extent that Plaintiff's discovery request seeks the production of records other than incidents in Code 15 reports and the annual reports, the requests are overly broad.

This identical paragraph was repeated in the Memorandum of Law section of the Amended Motion (A21, p.23).

As a result, the trial court was never faced with the necessity of addressing the "process" by which the Hospital identified documents responsive to Plaintiffs' Amendment 7 request. It was only faced with the issue of whether the Hospital could limit its document production to Code 15 reports and annual reports under \$395.0197, Fla. Stat. The trial court simply ruled that the Hospital had to produce records of adverse medical incidents in accordance with Amendment 7, thereby implicitly rejecting the Hospital's argument (A12, 13). The First District found no error in that ruling, and explicitly rejected the Hospital's argument that it could rely on \$381.028(7)(b)1, Fla. Stat., to limit the documents available under Amendment 7 to Code 15 reports and annual reports required by \$395.0197, Fla. Stat. (A1).

SUMMARY OF ARGUMENT

The trial court and the First District court properly determined that the blank application form for medical staff privileges was not protected from discovery by any statutory privilege. The relevant statute provides that the standards and procedures for granting staff privileges are a matter of public record, and it is only the information provided by people to the relevant membership or credentials committees, or the comments of the committee members that is entitled to statutory protection. The blank application for medical staff privileges is not confidential even under the Hospital's Bylaws, and nothing in this Court's prior decisions indicates that the statutory privileges should be expanded to protect this document.

The trial court and the First District properly rejected the Hospital's argument that under §381.028(7)(b)1, Fla. Stat., the only records a patient can obtain under Amendment 7 are Code 15 reports and annual reports as defined in §395.0197, Fla. Stat. This argument has been rejected by the Fourth District as well as the First District (in the case <u>sub judice</u>) and is simply an attempt to limit the scope of the constitutional provision through application of a statute. It is settled law that a statute cannot restrict the rights created by the Constitution and, therefore, the Hospital's argument was properly rejected by the lower tribunals.

The trial court and the First District properly determined that Amendment 7 is not impliedly preempted by the Health Care Quality and Improvement Act of 1986 ("HCQIA"), 42 U.S.C. §11101, et seq. As the United States Supreme Court has noted, there is a presumption against preemption, even when the sole ground is implied conflict preemption, as the Hospital argues here. Additionally, the United States Supreme Court has held that where the federal statutory scheme recognizes state law and contains provisions indicating an intent to preserve it, the argument for preemption is particularly weak. That is the case here, as demonstrated by multiple provisions in the HCQIA. Also, it is established that Congress did not create a federal peer review privilege in the HCQIA, and the only confidentiality provision in that Act has a savings clause whereby the confidential information can be disclosed, if authorized by state law. Therefore, there are no grounds to justify preemption and Amendment 7 does not violate the supremacy clause of the United States Constitution.

ARGUMENT

POINT I

THE TRIAL COURT DID NOT ERR IN ORDERING PRODUCTION OF THE BLANK APPLICATION FOR MEDICAL STAFF PRIVILEGES.

Standard of Review

Respondents agree that, based on the record in this case, the determination of whether the blank application for medical staff privileges is immune from discovery is a question of law reviewed under the <u>de novo</u> standard.

Argument

The First District declined to disturb the trial court's ruling which ordered production of the blank application form for medical staff privileges at the Hospital. The trial court's order did not rely on Amendment 7, but on a determination that the form was not protected by any statutory privilege. The First District disagreed with the Fourth District decision in <u>Tenet Health System Hospitals</u>, Inc. v. Taitel, 855 So.2d 1257, 1258 (Fla. 4th DCA 2003), which held that a blank hospital form used for testing the competency of nurses was protected from discovery by §766.101(5), Fla. Stat. In <u>Taitel</u>, the record revealed that the form at issue had been "created by a hospital committee for the purposes of quality

assurance and peer review" (855 So.2d at 1258). In the case <u>sub judice</u>, there was no such evidence.¹

The First District summarized its disagreement with the <u>Taitel</u> case as follows (<u>West Florida Regional Medical Center, Inc. v. See</u>, 18 So.2d 3d 676, 691 (Fla. 1st DCA 2009)):

We do not agree with the <u>Taitel</u> court that the <u>Cruger [v. Love</u>, 599 So.2d 111 (Fla. 1992)] standard requires the protection of blank forms. It is the information provided on the forms, not the blank forms themselves, that are considered by credentialing committees. Moreover, on the record before us, it has not been shown that the hospital's credentialing committee or review board created the form in question.

An analysis of the decisions of this Court regarding the scope of the statutory privileges for healthcare facilities demonstrates that the First District properly resolved this issue.

The genesis of statutory provisions granting privilege status to peer review materials was Chapter 73-50, Laws of Florida. This Court first addressed the issues raised by those statutory provisions in <u>Holly v. Auld</u>, 450 So.2d 217 (Fla. 1984). In <u>Holly</u>, this Court noted that the Act was designed to encourage self-regulation by the medical profession through peer review and evaluation.

¹ On this factual distinction alone, this Court could find there is no direct decisional conflict and discharge jurisdiction.

However, the need for confidentiality was limited to "the information and opinions elicited from physicians regarding the competence of their colleagues" (450 So.2d at 220).

The issue in <u>Holly</u> was whether the discovery privilege for proceedings and records of peer review committees applied in defamation actions, such as the one the plaintiff physician brought in that case, or whether the privilege was to be limited to medical malpractice actions. This Court determined that the privilege applied regardless of the nature of the civil action, stating (450 So.2d at 220):

A doctor questioned by a review committee would reasonably be just as reluctant to make statements, however truthful or justifiable, which might form the basis of a defamation action against him as he would be to proffer opinions which could be used against a colleague in a malpractice suit.

In <u>Feldman v. Glucroft</u>, 522 So.2d 798 (Fla. 1988), this Court addressed the statutory privileges relating to medical review committees. This Court determined that those privileges did not abolish a cause of action for defamation, but simply limited such actions to cases in which the plaintiff could establish extrinsic evidence of malice or fraud. In doing so, this Court noted that (522 So.2d at 801): "The shield of confidentiality protects what is presented or spoken to the committee at its meetings."

In <u>Cruger v. Love</u>, 599 So.2d 111 (Fla. 1992), the plaintiff sought the defendant physician's application for privileges at three local hospitals, and the issue was whether those completed applications were protected by §395.011(9), Fla. Stat., and §766.101(5), Fla. Stat. This Court held that those statutes required the denial of plaintiff's discovery request, because the application was clearly considered by the committee or board as part of its decision-making process, and the policy of encouraging full candor required that the completed application be protected. This Court stated (599 So.2d at 114):

[I]t 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.

Recently, in <u>Brandon Regional Hospital v. Murray</u>, 957 So.2d 590 (Fla. 2007), this Court held that while the plaintiff was not entitled to the actual records of the credentials committee that determined the defendant doctor's privileges, the plaintiff was entitled to discovery of the actual privileges granted to the physician by the hospital. This Court affirmed the decision of the Second District that while the records of the investigative portion of the peer review panel were privileged and protected from disclosure, the report of the results did not carry the same privilege (957 So.2d at 592-93). This Court concluded (957 So.2d at 595):

We find nothing in the statutory scheme protecting the internal activities of a peer review committee and its records that would exempt a hospital from disclosure of its decision to grant or deny certain practice privileges to a physician. Similarly, while the statutory scheme grants explicit protection to peer review committee records, there is no such statutory protection extended to separate hospital records that may contain information provided by or partially based upon peer review committee action.

Thus, this Court's prior decisions addressing the scope of the peer review privileges demonstrate that they are limited to protecting information provided to, and the deliberative processes of, peer review committees. The Plaintiff here was not seeking any of that information. The Plaintiff's discovery request sought the blank Hospital membership application, and a review of the relevant statutory provisions demonstrates that the contents of that application were not intended to be confidential.

Section 395.0191, Fla. Stat., addresses staff membership and clinical privileges in licensed hospitals. In addition to noting that each applicant should be considered individually pursuant to criteria relevant to the chapter regulating their particular specialty, that statute provides (§395.0191(4)):

The applicant's eligibility for staff membership or clinical privileges shall be determined by the applicant'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.

That statute also makes it clear that the standards and procedures relevant to granting membership on the medical staff are not confidential, but are a matter of public record (§395.0191(5)):

The governing board of each licensed facility shall 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. These standards and procedures shall be available for public inspection. [Emphasis supplied.]

Clearly, a blank application form falls within the category of the standards and procedures relevant to an application for staff membership or clinical privileges and, therefore, should be available for public inspection.

The statutory privilege created in §395.0191(8), Fla. Stat., does not apply to the standards and procedures relevant to the consideration of applications for staff membership or clinical privileges. That statute states (<u>Id.</u>):

The investigations, proceedings, and records of the board, or agent thereof with whom there is a specific written contract for the purposes of this section, as described in this section shall not be subject to discovery or introduction into evidence in any civil action against a provider of professional health services arising out of matters which are the subject of evaluation and review by such board.

As the First District stated, the credentialing committee or review board of the hospital that evaluates applications for staff membership or clinical privileges, does not consider the blank application form, but rather the information on it which is provided by the applicant (18 So.2d at 691). The Plaintiffs herein were not seeking the information which the applicant/physician put on the membership application. In fact, case law clearly establishes that that information is entitled to the privilege consistent with this Court's decision in Cruger, supra. See also, Columbia Hospital Corp. of S. Dade v. Barrera, 738 So.2d 505 (Fla. 3d DCA 1999). The Plaintiffs here were only seeking the blank application form.

The Fourth District in <u>Taitel</u>, <u>supra</u>, held that the hospital's blank forms for testing the competency of nurses in regard to sedation and analgesia (which were created by a quality assurance peer review committee) were entitled to the statutory privilege. However, the Fourth District has also ruled that the documents pertaining to "the procedures involved in granting staff privileges to doctors are not privileged, <u>see Liberatore v. NME Hospitals, Inc.</u>, 711 So.2d 1364 (Fla. 4th DCA 1998). Consistent with that decision and the provisions of §395.0191, Fla. Stat., the First District correctly held that the Plaintiff's request for a blank application form was properly granted by the trial court.

The Hospital's reliance on its Bylaws does not support its argument on this issue. Contrary to the statements in its brief, nothing in the Bylaws demonstrates that the blank application for privileges is considered by the Hospital Credentials Committee, Medical Review Committee, or Board of Trustees (IB, p.16). Indeed, Bylaw 3.7.5. states that an application shall only be reviewed and processed by the committees after all the information is received and the verification process is fully completed (A24, Exh. C, pp.3-11). Nothing in Article 3 of the Bylaws, which addresses the appointment/reappointment provisions, states anything about a blank application form being considered or developed by any of the relevant committees.

The Hospital also suggests that the form is deemed confidential pursuant to Article 12 of its Bylaws which is, frankly, irrelevant to whether it is entitled to statutory protection. Clearly, a hospital cannot create a discovery privilege for itself merely by adopting self-serving bylaws. Nonetheless, a review of the Bylaws demonstrates that, in fact, the blank application form is not confidential. While the medical staff office screens persons requesting staff membership prior to sending an application form, see Bylaw 3.7.1., it is not until that form is actually filled out and submitted that the applicant is bound by the confidentiality provisions of Article 12, see Bylaw 12.1. Moreover, the confidentiality only extends to "any act, communication, report, recommendation or disclosure

concerning any applicant for membership or clinical privileges...." Bylaw 12.2 (A24, Exh. C., p.12-1). Therefore, while the Respondents do not accept that a hospital can grant its own records a privilege against discovery through its bylaws, it is clear that the Bylaws in this case do not establish confidentiality for the blank application form. There is also nothing in the Hospital's Bylaws indicating that the blank form is ever considered by the committees which determine staff membership or the granting of clinical privileges.

For these reasons, the First District did not err in declining to disturb the trial court's order requiring production of the blank application form.

POINT II

THE TRIAL COURT DID NOT ERR IN REJECTING THE HOSPITAL'S ARGUMENT THAT SECTION 381.028, FLORIDA STATUTES LIMITED THE SCOPE OF DOCUMENTS AVAILABLE UNDER AMENDMENT 7.

Standard of Review

Respondents agree that this issue is reviewed under the de novo standard.

Argument

The Hospital's argument before this Court does not resemble the argument it presented in the trial court and and the First District. There was never a request by any party for the trial court or the First District to rule on the "process" which the Hospital must use to locate documents responsive to the Plaintiff's Amendment 7 request. The sole argument made by the Hospital in the trial court regarding subsection (7)(b)1 of §381.028, Fla. Stat., was that it could limit its document production to Code 15 reports and annual reports identified in subsections (5) and (7) of §395.1097, Fla. Stat. That attempt to limit the scope of documents available under Amendment 7, based on the Hospital's strained interpretation of §381.028(7)(b)1, Fla. Stat., was rejected by the trial court and the First District. Those rulings were correct and entirely consistent with Florida Hospital Waterman, Inc. v. Buster, 984 So.2d 478 (Fla. 2008).

The Hospital's entire argument in its Amended Motion for Protective Order regarding subsection (7)(b)1, of §381.028, Fla. Stat., was as follows (A21, pp.4-5):²

The Florida Supreme Court's opinion in Florida Hospital Waterman, Inc. v. Buster, 33 Fla. L. Weekly S154 (Fla. Mar. 6, 2008) left intact §381.028(7)(b)1., which provides that "[u]sing the process provided in s. 395.0197, the health care facility shall be responsible for identifying records of an adverse medical incident, as defined in s. 25, Art. X of the State Constitution." The plain language of this sub-section means that the "records of an adverse medical incident" under Amendment 7 are those records identified in § 395.0197, other than attorney work-product protected records under s. 395.0197(4) or common law. The records identified in §395.0197 which fall under the category of "records of adverse medical incidents" are therefore limited to incidents in Code 15 reports identified in §395.0197(7) and the annual report to AHCA identified in §395.0197(5).

To the extent that Plaintiff's discovery request seeks the production of records other than incidents in Code 15 reports and the annual reports, the requests are overly broad.

As such, it is clear that the Hospital never requested a ruling on the "process" referred to in §381.028(7)(b)1, Fla. Stat., but rather argued for a specific result; that the statute limited the records available under Amendment 7 to Code 15

² The identical language was later repeated in the Memorandum portion of the Hospital's Amended Motion for Protective Order (A21, p.23).

reports and annual reports as defined in §395.1097, Fla. Stat. While the trial court did not directly address that issue, it did rule that the Hospital was required to produce "documents relating to 'adverse medical incidents' as defined in Article X, §25(3)(c), Florida Constitution." As discussed below, that was a correct ruling and a proper rejection of the Hospital's attempt to limit the Plaintiffs' constitutional rights based on §381.028, Fla. Stat.

The Hospital acknowledges that this Court declared six subsections of §381.028, Fla. Stat., to be unconstitutional in <u>Buster</u>, because they were improper attempts to limit the right of access granted under Amendment 7. While this Court did not strike subsection (7)(b)1, that does not mean that this Court is obligated to accept the Hospital's <u>interpretation</u> of that subsection, nor apply it to limit Plaintiff's constitutional rights. Of course, the Hospital's Initial Brief does not mention that it is seeking to limit the scope of documents available under Amendment 7; it only discusses the "process" which §381.028(7)(b)1, Fla. Stat., addresses. This transformation of its argument allows it to contend that subsection (7)(b) only implements Amendment 7 when, in fact, the Hospital is seeking to restrict Amendment 7 document production in all situations to Code 15 reports and annual reports under §395.0197, Fla. Stat.

The Hospital's actual argument was properly rejected by the trial court and the First District, since it would impermissibly limit Amendment 7 in the same manner as two of the subsections which were stricken in Buster. §381.028(3)(j), Fla. Stat., defined the records available under Amendment 7 as only final reports of any adverse medical incident. In Buster, this Court struck that provision from the statute on the basis that it was an impermissible limitation on the scope of records available under Amendment 7 (984 So.2d at 492-93). Additionally, subsection (7)(a) of §381.028, Fla. Stat., limited the patient to obtaining final reports relating to the same or substantially similar condition, treatment, or diagnosis of the patient requesting access to the documents. Buster, this Court also struck that provision on the basis that it was an impermissible attempt to limit the scope of documents available under Amendment 7. Id.

The Hospital's argument here must be rejected based on that same rationale. While the Hospital is arguing that the statute is entitled to determine the "process" that a hospital must engage in to locate documents responsive to Amendment 7 requests, its argument in the trial court and the district court related to the "result," i.e., a limitation on the documents available to Code 15 reports and annual reports as provided in §395.0197, Fla. Stat. Thus, by its interpretation of subsection 7(b)1,

the Hospital is attempting to achieve the same result that this Court determined the legislature could <u>not</u> achieve by two of the subsections of §381.028, Fla. Stat., which limited the scope of documents available under Amendment 7.

The argument that subsection 7(b)1 of §381.028, Fla. Stat., can be interpreted and applied as limiting the scope of documents under Amendment 7 was first rejected by the Fourth District in Columbia Hospital Corporation of So. Broward v. Fain, 16 So.3d 236 (Fla. 4th DCA 2009). The Fourth District stated (16 So.3d at 241):

Columbia's argument that pursuant to this statute it must provide only certain reports ("Code 15" reports under section 395.0197) is expressly contrary to the amendment. The amendment provides that it is "not limited to" incidents that already must be reported under law. Art. X, § 25(c)(3), Fla. Const. (emphasis supplied). As the Florida Supreme Court held in Buster, the legislature may not limit the scope of discoverability of adverse incident reports in a manner inconsistent with the amendment. Columbia's argument calls for an unconstitutional application of the statute.

In the case <u>sub judice</u>, the First District expressly agreed with the <u>Fain</u> decision stating (18 So.3d at 683-84):

The trial court's order used Amendment 7 as the basis for ordering production of documents. If section 381.028(7)(b)1 requires less of hospitals, as Petitioner suggests, then it conflicts with Amendment 7. See id. Like the Fain court, we observe that Petitioner's

argument calls for an unconstitutional application of the statute.

The First District's decision is entirely consistent with <u>Buster</u>, and should not be disturbed by this Court. It is a fundamental constitutional principle that the legislature cannot, by statute, limit or impede rights created by the Constitution, <u>Gray v. Bryant</u>, 125 So.2d 846, 851 (Fla. 1960). The legislature is entitled to implement constitutional provisions and to supplement them, but it cannot nullify the will of the people by restricting the rights available under the Constitution. <u>Id.</u>
That was the principle applied in <u>Buster</u> to strike down six provisions in §381.028, Fla. Stat., and it is the same principle which compelled the Fourth District in <u>Fain</u> and the First District here to reject the Hospital's argument.

Amendment 7 addresses the scope of documents available through its definition of the term "adverse medical incident" as follows (Art. X, §25(c)(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.

As noted by the Fourth District in <u>Fain</u> and the First District in the case <u>sub judice</u>, that provision specifically states that the records of adverse medical incidents are not limited to those that are required to be reported to any governmental agency or body. Nonetheless, acceptance of the Hospital's argument would limit Amendment 7 documents to those required to be reported to a governmental agency. Additionally, the definition in Article X, §25(c)(3), does not limit the scope of documents to risk management documents as the Hospital's argument attempts to do, but explicitly includes peer review, quality assurance, credential committees, as well as any "similar committee."

There is no way to reconcile the Hospital's argument limiting the documents available under Amendment 7 to Code 15 reports and annual reports, as defined in §395.0197, Fla. Stat., with the language or intent of Article X, §25. Therefore, consistent with this Court's decision in <u>Buster</u>, the First District and the trial court properly rejected the Hospital's argument that §381.028(7)(b)1, Fla. Stat., operates to limit the scope of documents available under Amendment 7.

POINT III

AMENDMENT 7 DOES NOT VIOLATE THE SUPREMACY CLAUSE OF THE UNITED STATES CONSTITUTION.

Standard of Review

Respondents agree that this issue is reviewed under the <u>de novo</u> standard.

Argument

The Hospital contends that Amendment 7 conflicts with the Health Care Quality and Improvement Act ("HCQIA"), 42 U.S.C. §11101, et. seq., and, therefore, this Court should hold that it is pre-empted by that Act pursuant to the supremacy clause of the United States Constitution. However, there is no conflict between Amendment 7 and the HCQIA, nor is the state constitutional provision an obstacle to the federal act so as to justify pre-emption.

The United States Supreme Court recently discussed the "two cornerstones of our pre-emption jurisprudence," Wyeth v. Levine, 129 S.Ct. 1187, 1194-95 (March 4, 2009), as follows:

First, "the purpose of Congress is the ultimate touchstone in every pre-emption case." Medtronic, Inc. v. Lohr, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (internal quotation marks omitted); see Retail Clerks v. Schermerhorn, 375 U.S. 96, 103, 84 S.Ct. 219, 11 L.Ed.2d 179 (1963). Second, "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated...in a field which the States have traditionally

occupied,'...we 'start with the assumption that the historic policy powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." <u>Lohr</u>, 518 U.S., at 485, 116 S.Ct. 2240 (quoting <u>Rice v. Santa Fe Elevator Corp.</u>, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)). [Footnote deleted.]

The HCQIA does <u>not</u> contain any express pre-emption provision, so Defendant has the burden to prove implied conflict pre-emption.¹ In order to demonstrate conflict pre-emption "compliance with both federal and state regulations [must be] a physical impossibility," <u>Florida Lime and Avocado Growers, Inc. v. Paul,</u> 373 U.S. 132, 142-43 (1963); or the state law must be "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," <u>Hines v. David Owitz</u>, 312 U.S. 52, 67 (1941). The Defendant does not contend it is impossible to comply with both Amendment 7 and HCQIA and, thus, is limited to the latter theory of implied conflict pre-emption.

In <u>Wyeth</u>, <u>supra</u>, the United States Supreme Court noted that there is presumption against pre-emption, even in the context of implied conflict pre-emption (129 S.Ct. at 1195, n.3).³ It is also significant that in <u>Wyeth</u>, when the

Defendant does not argue that the other form of implied pre-emption, field pre-emption, applies here.

In <u>Wyeth</u>, the defendant drug manufacturer contended that the plaintiff's common law negligence and strict liability claims, which were premised on the

Court addressed the obstacle pre-emption argument of the defendant, it noted its prior decision in <u>Bonito Boats</u>, <u>Inc. v. Thunder Craft Boats</u>, <u>Inc.</u>, 489 U.S. 141, 166-67, 109 S.Ct. 971, 103, L. Ed. 2d 118 (1989), quoting as follows:

The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.

As discussed below, in the HCQIA Congress expressed its awareness of the extensive state law regarding medical malpractice and professional regulation of doctors and repeatedly took steps in the HCQIA to ensure the preservation of state law in this area.

The problems that the HCQIA were intended to remedy were specified in the explicit congressional findings in 42 U.S.C. §11101, as follows:

(1) 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.

failure to warn of certain risks, were pre-empted by federal law, specifically the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §301, et. seq. The defendant relied on both theories of implied conflict preemption, i.e., that it was impossible to comply with both the FDA's labeling requirements and the state law, and that the tort claims created an unacceptable obstacle to the objectives of the federal statutory scheme (129 S.Ct. at 1193-94). The United States Supreme Court rejected both contentions.

(2) 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.

In Meyers v. Columbia/HCA Healthcare Corp., 341 F.3d 461, 467 (6th Cir. 2003), the Sixth Circuit described the HCQIA's remedial goals as "to provide for effective peer review and interstate monitoring of incompetent physicians, and to grant qualified immunity from damages for those who participate in peer review activities." The Act requires that health care entities report to the Board of Medical Examiners whenever certain actions are taken against a physician, and for that information to be provided to, and retained in, a federal database, see 42 U.S.C. §11133(a). The HCQIA also provides for the federal government to share that information with state licensing boards, hospitals, HMO's and other entities, 42 U.S.C. §11137(a).

The Hospital concedes, as it must, that Congress did not create a federal peer review privilege of confidentiality in peer review documents or information in the HCQIA. Federal courts have repeatedly rejected arguments by healthcare providers and facilities asserting such a privilege, see Robertson v. Neuromedical Center, 169 F.R.D. 80, 83-84 (N.D. La. 1996); Atteberry v. Longmont United Hospital, 221 F.R.D. 644, 647 (D. Colo. 2004); In Re Administrative Subpoena

Blue Cross Blue Shield of Mass., Inc., 400 F.Supp.2d 386, 390-91 (D. Mass. 2005).

In fact, as noted in <u>Teasdale v. Marin General Hospital</u>, 138 F.R.D. 691, 694 (N.D. Cal. 1991), the failure to create such a privilege in HCQIA is significant:

First, the passage of a statute specifically addressing peer review issues and, indeed, the giving of qualified immunity to peer reviewers, is strong evidence that Congress not only considered the importance of maintaining the confidentiality of the peer review process, but took the action it believed would best balance protecting such confidentiality with other important federal interests. Congress spoke loudly with its silence in not including a privilege against discovery of peer review materials in the HCQIA. [Emphasis supplied.]

Additionally, in <u>Johnson v. Nyack Hospital</u>, 169 F.R.D. 550, 560-61 (S.D.N.Y. 1996), the court explained why it was clear that Congress considered, but rejected creating a peer review privilege:

That Congress did consider the relevant competing interests in declining to create a privilege for medical peer review materials in the HCQIA is demonstrated by a number of factors. First, the findings accompanying the statute clearly show that Congress looked at a variety of ways to give doctors protection and incentives to participate in peer review programs. Id. §11101. Second, the statute provides that some materials created in a medical peer review program are confidential, so that Congress must have considered what types of materials should be granted this protection, yet did not accord protection to the materials here in question. Id.

§11137(b)(1). Finally, the HCQIA specifically denies immunity under the Civil Rights Act for participants in peer review proceedings, showing that Congress accorded more weight to vindication of civil rights than to the interests in the confidentiality of the peer review process.

Furthermore, as noted above, there are multiple times in the HCQIA where Congress made it clear that it had no intent to pre-empt or otherwise disturb state law with respect to privileges or rights in the context of health care law. In 42 U.S.C. §11115(a), it states:

Except as specifically provided in this subchapter, nothing in this subchapter shall be construed as changing the liabilities or immunities under law or as preempting or overriding any State law which provides incentives, immunities, or protection for those engaged in a professional review action that is in addition to or greater than that provided by this subchapter.

Additionally, in subsection (d) of §11115, Congress made it clear that the HCQIA was not intended to alter in any way state law relating to medical malpractice actions:

Nothing in this chapter shall be construed as affecting in any manner the rights and remedies afforded patients under any provision of Federal or State law to seek redress for any harm or injury suffered as a result of negligent treatment or care by any physician, health care practitioner, or health care entity, or as limiting any defenses or immunities available to any physician, health care practitioner, or health care entity.

While Congress did not create a federal peer review privilege, it did include a confidentiality provision limited to certain information which is reported to the federal government pursuant to the Act; however, it included an express savings clause for state law which authorized disclosure of such information, 42 U.S.C. §11137(b)(1):

Information reported under this subchapter is considered confidential and shall not be disclosed (other than to the physician or practitioner involved) except with respect to professional review activity, as necessary to carry out subsections (b) and (c) of section 11135 of this title (as specified in regulations by the Secretary), or in accordance with regulations of the Secretary promulgated pursuant to subsection (a) of this section. Nothing in this subsection shall prevent the disclosure of such information by a party which is otherwise authorized, under applicable State law, to make such disclosure. [Emphasis supplied.]

The House Report makes it clear that HCQIA was not intended to affect rights regarding disclosure of peer review information under state law (H. Rep. No. 99-903, 99th Cong.2d Sess. 245, reprinted in 1986 U.S.C.C.A.N. 6303):

This subsection also makes clear that any party, such as a state licensing board, which is authorized under other provisions of law to release such information, may continue to release it.

The Hospital contends that the HCQIA must be construed in light of the preexisting law on peer review privilege, and references the many states that have

such provisions. However, it does not suggest that there is any uniformity in the state law provisions, so it is unclear how the suggested pre-emption would be implemented. What is clear is that the peer review privilege in Florida is riddled with exceptions and limitations,⁴ and is not even effective to bar discovery of peer review material in federal courts. In fact, the many exceptions and the legislature's ability to modify or repeal such provisions was one of the reasons that this Court determined in <u>Buster</u> that Amendment 7 could be applied retroactively, since medical providers did not have a vested right in the existing law on peer review privilege, see <u>Buster</u>, 984 So.2d at 490-92.

Prior to the enactment of the HCQIA, federal courts had held that state peer review privileges did not bar discovery of such materials with respect to a federal cause of action, see Feminist Women's Health Center, Inc. v. Mohammed, 586 F.2d 530, 545, n.9 (5th Cir. 1978); Memorial Hosp. v. Shadur, 664 F.2d 1058, 1063 (7th Cir. 1981). Congress is, of course, presumed to know the state of law

The Hospital contends that there is record evidence that confidentiality is necessary for effective and reliable peer review (IB p.25). The only "evidence" submitted below on this subject was an opinion of an attorney who is employed by the American College of Physicians and statements of one legislator at a committee hearing (App. 24: Ex. A-B). Clearly, that is not compelling "evidence." Moreover, while the Hospital cites Florida appellate decisions which address confidentiality in peer review proceedings, no court has made a factual finding that it is essential. The quotations to that effect are merely in the context of interpreting statutory provisions based on the legislature's conclusion that such confidentiality is necessary.

relevant to statutory provisions it enacts, and obviously decided not to create a federal peer review privilege, nor grant state peer review privilege any effect in federal causes of action.

Federal courts have also concluded that the HCQIA does not operate to create a federal peer review privilege, or elevate state peer review privileges with regard to their enforceability in federal cases. In Virmani v. Novant Health Inc., 259 F.3d 284 (4th Cir. 2001), a physician brought an action alleging racial discrimination against the hospital that terminated his privileges. In the context of that suit, he sought all peer review records of the Defendant Hospital relating to all reviews of physicians during the twenty years preceding his request. The trial court granted his discovery request, but limited it to all documents pertaining to competency reviews of physicians in his specialty for the previous fifteen years (259 F.3d at 286).

In <u>Virmani</u>, The hospital appealed argued, <u>inter alia</u>, that "confidentiality is essential to the effectiveness of medical peer review committees" (259 F.3d at 287). The hospital also argued that recognition of the privilege was required by the HCQIA. The Fourth Circuit rejected the hospital's arguments, including its reliance on the HCQIA, and upheld the trial court's order requiring production of the fifteen years of peer review documents.

Numerous other courts have allowed discovery of peer review materials in federal proceedings, rejecting the applicability of state law privileges for peer review, see e.g., Atteberry v. Longmont United Hosp., 221 F.R.D. 644 (D. Colo. 2004) (EMTALA action); Accreditation Ass'n for Ambulatory Health Care, Inc. v. United States, 2004 WL 783106 (N.D. Ill. 2004) (federal health care fraud criminal investigation); Nilavar v. Mercy Health Sys. - Western Ohio, 210 F.R.D. 597 (S.D. Ohio 2002) (federal antitrust claim); Marshall v. Spectrum Medical Group, 198 F.R.D. 1 (D. Me. 2000) (Americans with Disabilities Act claim); United States v. OHG of Indiana, Inc., 1998 WL 1756728 (N.D. Ind. 1998) (False Claims Act qui tam action); Johnson v. Nyack Hosp., 169 F.R.D. 550 (S.D.N.Y. 1996) (racial discrimination claim).

The Hospital argues that the fact that Congress enacted a peer review privilege in 10 U.S.C. §1102(a), relating to the quality assurance proceedings of the Department of Defense and Department of Veteran Affairs, compels the conclusion that it considers such confidentiality to be essential. However, this argument was quickly and effectively rejected in Virmani, supra, where the hospital relied on that same argument in claiming that the physician should not be entitled to the fifteen years of peer review records. After determining that the HCQIA did not create a federal peer review privilege, the Fourth Circuit noted that

the privilege created in 10 U.S.C. §1102(a), only "demonstrate[d] that Congress will create a medical peer review privilege when it is so inclined," 259 F.3d at 292.

In summary, the Hospital has failed to overcome the presumption against federal pre-emption that must be applied in this case. Congress repeatedly recognized in the HCQIA that there was a body of preexisting state law on the subjects governed by the Act, and consistently stated that it had no intention to disturb it, only to supplement it. Additionally, while the HCQIA provides for certain information submitted to the federal data bank to be confidential, it expressly states that it can be disclosed if authorized by state law, 42 U.S.C. §11137(b)(1). Therefore, clearly Congress did not intend to preempt state law by enactment of the HCQIA. Rather, Congress was aware that state law operated in the field of peer review and "decided to stand by both concepts and to tolerate whatever tension there [is] between them," Bonito Boats, supra, 489 U.S. at 167, quoted in Wyeth, 129 S.Ct. at 1200. Therefore, this is a "particularly weak" case for pre-exemption, id.; and the trial court and the First District did not err in rejecting it.

CONCLUSION

For the reasons stated above, this Court should either discharge jurisdiction or affirm the First District's decision.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY a true copy of the foregoing was furnished to STEPHEN J. BRONIS, ESQ., 4000 International PL, 100 S.E. 2nd Ave., Miami, FL 33131-2114; JAMES M. WILSON, ESQ., P.O. Box 13430, Pensacola, FL 32591-3430; S. WILLIAM FULLER, JR., ESQ., 2565 Barrington Cir., Tallahassee, FL 32308; JAMES J. EVANGELISTA, ESQ., P.O. Box 3914, Tampa, FL 33602; and HONORABLE TERRY D. TERRELL, M.C. Blanchard Judicial Bldg., 190 Governmental Center, Pensacola, FL 32501, by mail, on July 21, 2010.

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