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 REPLY BRIEF ON THE MERITS

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


CARLTON FIELDS, P.A.
215 S. Monroe Street
Suite 500
Tallahassee, Florida 32301
Telephone: (850) 224-1585
Facsimile: (850) 222-0398
By: CHRISTINE DAVIS GRAVES

CARLTON FIELDS, P.A.
100 SE 2nd Street, Suite 4200
Miami, Florida 33131
Telephone: (305) 530-0050
Facsimile: (305) 530-0055
By: STEPHEN J. BRONIS
WALTER J. TACHÉ
CRISTINA ALONSO
JESSICA ZAGIER WALLACE

*Counsel for Petitioner West Florida Regional Medical Center*

## TABLE OF CONTENTS

**Page**

## TABLE OF AUTHORITIES

**Page**

Cases



Constitutional Provisions

## TABLE OF AUTHORITIES
**(Continued)**

**Page**

### Statutes



### Rules



### Other Authorities

# ARGUMENT

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

Plaintiffs do not dispute that whether the blank application for medical staff privileges is protected is governed by the privilege and confidentiality provisions of chapters 395 and 766, Florida Statutes, not Amendment 7. Instead, Plaintiffs argue that this case is distinguishable from Tenet Healthsystem Hospitals, Inc. v. Taitel, 855 So. 2d 1257 (Fla. 4th DCA 2003), where the Fourth District determined that a blank form created by a hospital committee to evaluate hospital employees is statutorily privileged as a credentialing record. Plaintiffs contend Taitel is distinguishable from this case, because the form at issue in Taitel was "created by a hospital committee for the purposes of quality assurance and peer review." (Ans. Br. at 6-7, citing Taitel, 855 So. 2d at 1258). On the basis of this contended distinction, Plaintiffs argue that there is no direct decisional conflict and that this Court should discharge jurisdiction. (Ans. Br. at 7).[1]

[1] Even if this Court were to determine that there is no decisional conflict on this issue, it remains that this Court has jurisdiction to review issues I and II on appeal: (II) the First District's decision expressly construes Amendment 7 of the Florida Constitution and conflicts with Florida Hospital Waterman, Inc. v. Buster, 984 So. 2d 478, 493-94 (Fla. 2008), to the extent it effectively invalidates section 381.028(7)(b)1, Florida Statutes, and (III) the First District's decision expressly construes state and federal constitutional provisions. See Fla. R. App. P. 9.030(a)(1)(A)(ii), (a)(2)(A)(ii), (a)(2)(A)(iv).

Plaintiffs, however, are mistaken. The blank form in this case was also created for the purposes of quality assurance and peer review in that the form is used not only for credentialing, but also for recredentialing. (App. 24:Exh. C at Art. 12.1-12.2).[2] Indeed, the First District found that the trial court departed from the essential requirement of law in failing to follow Taitel. See West Fla. Reg'l Med. Ctr., Inc. v. See, 18 So. 3d 676, 691 (Fla. 1st DCA 2009). The First District went on to expressly disagree with Taitel on the question of whether a blank form is privileged, without making any and irrespective of any alleged factual distinction. Id. As such, there is direct decisional conflict.

Next, Plaintiffs argue that blank application forms fall within the category of "standards and procedures in considering and acting upon applications for staff membership or clinical privileges" and therefore are public records under section 395.0191(5), Florida Statutes. (Ans. Br. at 11). This argument runs contrary to the plain language of the statute, which does not say that blank applications are available for public inspection. Section 395.0191(5), provides:

> 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

[2] 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 Exhibit No.).

> privileges. These standards and procedures shall be available for public inspection.

The standards and procedures referenced in section 395.0191(5) are set forth in the Hospital's Medical Staff Bylaws ("Bylaws") and are available to the public. (App. 24:Exh.C at Art. 3.7.1, 3.7.3.1-3.7.3.22).

By contrast, the medical staff application is part of the credentialing and recredentialing committee's investigation and records and is confidential under sections 395.0191(8) and 766.101(5), which provide that the investigations, proceedings, and records of the governing board and its agents involved in determining staff membership or clinical privileges and of a medical review committee shall not be subject to discovery. Indeed, in Cruger v. Love, 599 So. 2d 111, 114 (Fla. 1992), this Court found that a physician's application for medical staff membership or clinical privileges was privileged and confidential under these statutes.

This runs contrary to Plaintiffs' contention that this Court's prior decisions addressing the scope of the peer review privileges demonstrate that the privilege is limited to protecting information provided to, and the deliberative process of, peer review committees. (Ans. Br. at 10). This Court's decisions are not so limiting. As Cruger demonstrates, privilege extends to the investigation and records of credentialing committees, not just peer review committees. Similarly, Brandon Regional Hospital v. Murray, 957 So. 2d 590 (Fla. 2007), held that while a plaintiff

is entitled to discovery of the privileges granted to a physician, he is not entitled to the actual records of the credentials committee. Here, the blank application form reflects the deliberative process of the credentialing committee in that it includes the questions asked of applicants by the committee and is privileged.

Additionally, Plaintiffs' reliance on Liberatore v. NME Hospitals, Inc., 711 So. 2d 1364 (Fla. 4th DCA 1998), for the proposition that documents pertaining to "the procedures involved in granting staff privileges to doctors are not privileged," is misplaced. (Ans. Br. at 12). Liberatore does not stand for this broad proposition. The case simply holds that the trial court correctly denied the hospital's motion for protective order, because the plaintiffs did not seek privileged documents. 711 So. 2d at 1366. Rather, the plaintiffs sought to depose a representative of the hospital with knowledge of the procedures involved in granting staff privileges to doctors, and sought documents pertaining to those procedures. Id. The case does not discuss what documents were at issue.

Lastly, Plaintiffs argue that the Bylaws do not demonstrate that the application form is considered by the Hospital Credentials Committee, Medical Review Committee, or Board of Trustees, or that the form is confidential. (Ans. Br. at 13-14). To the contrary, article 3.7.2 provides that when an individual is initially requesting appointment to the medical staff or for privileges, he/she shall be provided with the application form only after he/she is deemed eligible to apply.

(App. 24:Exh.C at Art. 3.7.2). Eligibility is determined by the Medical Staff Office in accordance with the Bylaws. Id. at Art. 3.7.1. The applicant is also provided with the Bylaws, which set forth in article 12 the confidentiality requirements that the applicant is required to abide by. Those confidentiality requirements extend to the application. Id. at Art. 12.2.[3] Indeed, it is because the Hospital considers the application form to be confidential that an applicant must first be determined eligible before he/she is given the form. Similarly, an individual with expiring privileges is sent a notice of expiration and an application for reappointment or renewal. Id. at Art. 3.7.2.

While the Medical Staff, Credentials Committee and Board of Trustees reviews the application once it is completed, (Art. 3.7.3 and 3.7.5), it remains that they consider not only the information submitted, but also how that information relates to the questions and information sought through the blank form itself. As such, the form is part and parcel of the investigation conducted by the Hospital in determining whether to grant privileges and whether to renew privileges and credentialing. The written questions posed to an applicant merit the same protection as those questions that are verbally asked of applicants. The distinction

[3] The application is confidential pursuant to sections 395.0191(8) and 766.101(5). The Hospital references that confidentiality is provided through its Bylaws by way of explanation as to how it protects that statutory confidentiality.

Plaintiffs attempt to draw is meaningless. Accordingly, the trial court erred when it ordered production of the application 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

Plaintiffs acknowledge that this Court in Florida Hospital Waterman, Inc. v. Buster, 984 So. 2d 478, 493-94 (Fla. 2008), declined to find section 381.028(7)(b)(1), Florida Statutes, unconstitutional. (Ans. Br. at 17). But, Plaintiffs argue that the Hospital's interpretation of the statute would result in an unconstitutional application, because it would limit the scope of documents available under Amendment 7. Plaintiffs urge that the Hospital's interpretation of section 381.028(7)(b)(1) cannot be reconciled with Amendment 7, because Amendment 7 does not limit the scope of discoverable documents to risk management documents, but explicitly includes documents related to peer review, quality assurance, credential committees, as well as any similar committee. (Ans. Br. at 21). But the Hospital's interpretation of the statute would not limit the scope of documents to risk management documents. Rather, the Hospital argued that it should use section 381.028(7)(b)(1) to identify which events are events that are adverse medical incidents. Pursuant to section 381.028(7)(b)(1) that would mean those events described in subsections (5) and (7) of section 395.0197. Once it is determined that the event is an adverse medical incident using that method of

identification, then it is not just the risk management documents of the event that are potentially discoverable but also any peer review, quality assurance, credentialing or other similar record of the event is discoverable.

While Plaintiffs take issue with the Hospital's interpretation of section 381.028(7)(b)(1), Plaintiffs fail to explain what a constitutional application would be or how the statute should be interpreted. There must, however, be a constitutional application of the statute. Otherwise, this Court would have found the statute unconstitutional and stricken it in Buster. As such, the Hospital is entitled to use the process set forth in section 381.028(7)(b)(1) for purposes of production.

Plaintiffs contend that the Hospital did not raise the issue of production under section 381.028(7)(b)1 before the trial court, but rather, only argued that section 381.028(7)(b)1 limited the Plaintiffs to receiving Code 15 reports and annual reports pursuant to section 395.0197, Florida Statutes, to the exclusion of any other documents. (Ans. Br. at 2). The Hospital did present this narrower argument, as noted by Plaintiffs. The Hospital also generally argued that pursuant to section 381.028(7)(b)1, records responsive to the pending Amendment 7 discovery requests are those records of incidents identified in subsection (5) and (7) of section 395.197. (App. 21:4-5, 23; 14:7; 16-19). The Hospital also provided the court with orders entered in other cases on the issue. (App. 14:18-19).

If the Hospital's interpretation of section 381.028(7)(b)1 was too narrow, as Plaintiffs urge, then the trial court should have made that determination and otherwise indicated what the appropriate interpretation and application should be. By arguing for a particular interpretation of the statute, the Hospital brought the issue of the interpretation and application of section 381.028(7)(b)1 to the trial court's attention, which would necessarily have required that the trial court address the appropriate method of production under the statute. The trial court, however, never addressed the Hospital's arguments or the statute in its orders of production. (App. 12; 13). See See, 18 So. 3d at 683-84. In failing to do so, the trial court erred.

Additionally, the Hospital raised the issue of the appropriate method of production under the statute in its petition for writ of certiorari from the February 6, 2009 Order, reply in support of the petition and in its motion for clarification and for certification of questions before the First District. (App. 3:2-4, 12; 8: 8-9; 10: 21-22, 23-25). The First District declined to ratify the Hospital's interpretation of section 381.028(7)(b)1 as limiting the records it must produce under Amendment 7 to the Code 15 reports and annual reports required by subsections (5) and (7) of section 395.1097. The First District also declined to address what an appropriate method of production under the statute would be. See, 18 So. 3d at 683-84. In declining to ratify the Hospital's interpretation and failing to address an

appropriate constitutional interpretation, the First District effectively invalidated section 381.028(7)(b)1, which conflicts with this Court's decision in Buster.

The Hospital should not be left in the position of guessing at the meaning of a valid statute, nor should it be prohibited from relying on it. The trial court erred in entering an order requiring production, while declining to address the Hospital's request to employ the method of production under section 381.028(7)(b)1.

## III. THE TRIAL COURT ERRONEOUSLY ORDERED PRODUCTION UNDER AMENDMENT 7, WHICH VIOLATES THE SUPREMACY CLAUSE

Plaintiffs' response has no bearing on whether Amendment 7 constitutes an obstacle to the Health Care Quality Improvement Act ("HCQIA")'s purpose. First, Plaintiffs' reliance on the "presumption against preemption" is inapposite. For this proposition, Plaintiffs rely on Wyeth v. Levine, 129 S.Ct. 1187, 1199-1204 (2009), where the Supreme Court indicated that the presumption against preemption applied in the context of conflict or obstacle preemption, but went on to analyze whether a conflict existed without reference to the "presumption." At most, the Court in Wyeth explained that conflict preemption requires an analysis of Congress' purpose -- rather than an agency's purpose -- in enacting legislation to determine whether state law conflicted with the purpose of federal law. Id. at 1200. In this case, Congress's purpose of promoting effective professional peer review created under state laws to restrict the ability of incompetent physicians to move

from state to state is evident from the statute itself and was not adopted by any agency. 42 U.S.C. § 11101.

In an attempt to mirror the analysis in Wyeth, Plaintiffs argue that Congress "made it clear" that it had no intent to preempt or otherwise disturb state laws such as Amendment 7 that deal with privileges or rights in the context of health care law. (Ans. Br. at 27-28). In support of this argument, they cite: (1) two express preemption provisions of HCQIA, 42 U.S.C. § 1115(a) and (d), which do not preempt records access provisions, (2) a provision of HCQIA, 42 U.S.C. § 11137(b)(1) and a section of the House Report, which indicate that HCQIA does not prevent information reported to the NPDB and other peer review information from being disclosed, to the extent such a disclosure is otherwise authorized under state law. Id.

Plaintiffs' argument does not find any support in Wyeth or other Supreme Court preemption cases. In Wyeth, the Supreme Court found that Congress' failure to preempt state tort litigation "coupled with its certain awareness of the prevalence of state tort litigation," is evidence that Congress did not intend to preempt state law claims. 129 S.Ct. at 1200. By contrast, in Geier v. American Honda Motor Co., 529 U.S. 861, 869-74 (2000), cited in Wyeth, the Court held that the existence of an inapposite express preemption provision or a savings clause did not create any special burden to demonstrate obstacle preemption. In

that case, without any reference to the presumption against preemption, the Court found that state law claims for failure to install passive restraints in cars constituted an obstacle to the regulatory scheme on the subject and were therefore preempted. Furthermore, in Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 166-67 (1989), also cited by the Supreme Court in Wyeth, the Court explained that the case for federal preemption is stronger where Congress has not indicated awareness of state law constituting an obstacle to its purposes, and has not decided to tolerate tension between state and federal law. In Bonito Boats, the Court found obstacle preemption based on a novel state statute.

In this case, similar to Geier, none of the express preemption provisions in HCQIA relate to a record access provision such as Amendment 7. As such, the existence of these provisions does not create any special burden on the Hospital to demonstrate that Amendment 7 conflicts with HCQIA. Furthermore, and in accordance with Bonito Boats, at the time of passage of HCQIA in 1986, Congress was not aware of the existence of any state law records access provisions such as Amendment 7. Instead, Congress believed that state law uniformly protected confidentiality of peer review information. See S. Rep. No. 99-331 at 245 (1986), reprinted in 1986 U.S.C.C.A.N. 6413, 6440 (noting, "The civilian medical community enjoys [protection of quality assurance records] since all states have confidentiality laws preventing disclosure of these records."). Thus, the lack of any

express preemption of state laws, such as Amendment 7, and the existence of provisions that permit disclosure under state law do not negate the conflict that exists between Amendment 7 and HCQIA because there is no evidence that Congress was aware of similar record access provisions to Amendment 7 and agreed with the tension between such a provision and the purpose of HCQIA.

Next, Plaintiffs argue that the nonexistence of a discovery privilege at the federal level for peer review information in the context of anti-trust and racial discrimination claims within the peer review process means that Amendment 7 does not present an obstacle to HCQIA. The Hospital explained in its initial brief that the lack of a federal mandate for peer review confidentiality is not determinative as to whether HCQIA preempts Amendment 7 for two reasons. First, federal peer review confidentiality was not necessary to HCQIA because HCQIA was not a new peer review statute. Instead, HCQIA made use of already existing peer review created under state laws, which already contained protections for peer review confidentiality. Second, Congress demonstrated that it was aware of these state law confidentiality provisions and their importance to effective peer review. Specifically, when Congress created its own peer review statutes, for the Department of Defense and Veteran's affairs, it included confidentiality provisions. Furthermore, in the Senate Report for the Department of Defense bill, signed into law the same day as HCQIA, Congress explicitly recognized the

importance of peer review confidentiality to creating effective peer review and explained that such confidentiality already existed in all state law. Thus, while federal confidentiality provisions were not necessary to HCQIA, Congress recognized that state law confidentiality provisions were. (See Int. Br. at 31-34).

Plaintiffs further argue that the Hospital's arguments above were rejected in Virmani v. Novant Health Inc., 259 F.3d 284 (4th Cir. 2001). This is incorrect. Virmani addressed whether the court should recognize a new federal common law privilege for peer review records. In that case, the court declined to recognize the privilege based on a weighing of the effect on candor in the peer review process versus the need for the evidence in question. The court found that the evidence was vital, and outweighed the effect on candor in the peer review process,[4] because the privilege would render it impossible for plaintiffs to prove federal claims of discrimination occurring within the peer review process. This analysis offers a possible explanation as to why Congress did not create a federal law peer review privilege in HCQIA. However, the case does not shed light on the issue in this case, whether HCQIA preempts state laws which eliminate the confidentiality

[4] The court noted in weighing these interests that the trial court could and had entered a protective order requiring that the use of peer review records ordered discovered be restricted to that action. Id. at 288, n.4. By contrast, Amendment 7 purports to make records available to any patient or prospective patient and does not provide for any protection as to the use of such information. See Art. X, §25(a), (b)(2), Fla. Const.

previously afforded to peer review under state law in actions such as this. In fact, the Virmani court specifically distinguishes the privilege with respect to state court malpractice actions, noting that peer review records were not similarly vital in a state malpractice action, which arises "from actions that occurred independently of the [peer] review proceedings." Virmani, 259 F.3d at 290-91.

To the extent Plaintiffs argue that the Hospital did not submit sufficient evidence or authority demonstrating the elimination of confidentiality presents an obstacle to effective peer review, Florida case law on the subject demonstrates that this was not only the conclusion of the state legislature, but also the conclusion adopted by courts for the past several decades. (Int. Br. at 30, 36). Congress' recognition of the importance of state law peer review confidentiality, as noted above, supports that conclusion. Additionally, Plaintiffs did not provide any evidence before the trial court to counter the Hospital's evidence on this point.

Finally, to the extent Plaintiffs argue that there is a lack of uniformity among the various states' peer review statutes, rendering preemption difficult to implement, that argument fails. (Ans. Br. at 28-29). The Hospital has never requested that this Court consider whether any state law, apart from Amendment 7, is preempted.

Plaintiffs' arguments do not address the fundamental conflict that exists between Amendment 7 and HCQIA, which is at the heart of the Hospital's petition.

Because Amendment 7 attempts to increase patient choice by giving access to previously confidential information, it constitutes an obstacle to the purpose of HCQIA, which aims to promote and harness effective professional peer review created under state laws to restrict the ability of incompetent physicians to move from state to state. Without effective peer review created under state law, the purpose of HCQIA will not be carried out. On that basis, the Hospital requests that this Court find Amendment 7 is preempted by HCQIA.

## CONCLUSION

Based on the foregoing, Petitioner, West Florida Regional Medical Center, respectfully requests that this Court grant the relief requested in its initial brief.


CARLTON FIELDS, P.A.
215 S. Monroe Street
Suite 500
Tallahassee, Florida 32301
Telephone: (850) 224-1585
Facsimile: (850) 222-0398
CHRISTINE DAVIS GRAVES
Florida Bar No. 569372
cdavis@carltonfields.com

CARLTON FIELDS, P.A.
Miami Tower
100 SE 2nd Street, Suite 4200
Miami, Florida 33131
Telephone: (305) 530-0050
Facsimile: (305) 530-0055
STEPHEN J. BRONIS
Florida Bar No. 145970
sbronis@carltonfields.com
WALTER J. TACHÉ
Florida Bar No. 28850
wtache@carltonfields.com
CRISTINA ALONSO
Florida Bar No. 327580
calonso@carltonfields.com
JESSICA ZAGIER WALLACE
Florida Bar No. 956171

*Counsel for Petitioner West Florida Regional Medical Center*

## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the foregoing has been furnished by U.S. Mail this 13th day of August 2010, to the following:

Philip M. Burlington
Burlington & Rockenbach, P.A.
Courthouse Commons/Suite 430
444 West Railroad Avenue
West Palm Beach, FL 33401
*Counsel for Respondents*
*Lynda S. See and Rodney C. See*

H.E. Ellis, Jr.
Staples, Ellis & Associates, P.A.
PO Box 12786
Pensacola FL 32591
*Counsel for Respondents*
*Lynda S. See and Rodney C. See*

S. William Fuller
Fuller Mitchell Hood & Stephens
2565 Barrington Circle
Tallahassee FL 32308
*Counsel for Co-Defendants*
*George C. Rees, M.D. and George C. Rees, M.D., P.A.*

James J. Evangelista
Bush Ross, P.A.
PO Box 3914
Tampa FL 33602
*Co-Counsel for Petitioner*

By:_____
CRISTINA ALONSO

## 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.

By:_____
CRISTINA ALONSO

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