IN THE SUPREME COURT OF FLORIDA

FLORIDA HOSPITAL WATERMAN, INC., d/b/a FLORIDA HOSPITAL WATERMAN,

Petitioner,

v. Case Number SC06-688

TERESA M. BUSTER, as Personal Representative of the Estate of LARRY BUSTER, deceased; JEFFREY B. KEELER, M.D., and KELLER & GOODMAN, M.D., P.A.,

Respondents.

PROPOSED *AMICUS CURIAE* BRIEF OF FLORIDA PATIENT SAFETY CORPORATION, INC., ON BEHALF OF ALL PATIENTS IN FLORIDA IN THE INTEREST OF PATIENT SAFETY

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PRELIMINARY STATEMENT

Abbreviations used in this brief by *Amicus* Florida Patient Safety Corporation, Inc., are consistent with abbreviations used in Petitioner Hospital's Initial Brief on the Merits.

All emphasis is supplied by counsel unless otherwise indicated.

All references to Florida Statutes are to Florida Statues (2005) unless indicated otherwise.

INTRODUCTION

Amicus Florida Patient Safety Corporation, Inc. ("FPSC"), is the patient safety corporation authorized by the Florida Legislature by § 381.0271(2)(a), Florida Statutes, Appendix 1.

FPSC is a 501(c)(3) learning organization dedicated to assisting healthcare providers in Florida improve the quality and safety of healthcare and to reduce harm to patients. FPSC promotes a healthcare system that provides quality care within a system emphasizing patient safety. FPSC does not regulate providers but it does work with patient safety centers and other patient safety programs.

The current focus on patient safety in the U.S. healthcare system is generally attributed to the 1999 publication of *To Err is Human: Building a Safer Health System*, (www.nap.edu/readingroom) by the Institute of Medicine. According to that report, at page 1:

> When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1999, the results of the study in Colorado and Utah imply that at least 44,000 Americans die each year as a result of medical errors. The results of the New York Study suggest the number may be as high as 98,000.

Since that time, Florida established itself as a leader among states in prioritizing patient safety efforts and has

been credited with creating one of the most comprehensive models for patient safety.

Formal calls for the creation of a Florida Patient Safety Organization began in 2000 with the creation of the Commission on Excellence in Health Care. In 2002, the Governor's Select Task Force on Health Care Professional Liability Insurance recommended legislative creation of a patient safety authority. As a result, Chapter 2003-416, Laws of Florida, was passed. It included several specific provisions aimed at improving patient safety[1].

Subsequently, by § 381.0271, Appendix 1, the Florida Legislature created the FPSC.

In this brief, FPSC speaks on behalf of all patients in Florida in the interest of patient safety.

Buster concluded that Amendment 7, Appendix 2, "preempts statutory privileges afforded healthcare providers regarding their self-policing procedures to the extent that such information is obtainable through a formal discovery request made by a patient or a patient's legal representative during the course of litigation."

[1] The statute required each healthcare facility to have a patient safety system and plan, including a patient safety officer and committee; mandated that patients must be notified in person by the facility or licensed healthcare practitioner in the event of harm; and required patient safety continuing education for licensed healthcare practitioners.

Although the *Buster* opinion referred to several Florida statutes, including a patient safety data statute, § 766.1016(2), it did not mention a single Federal law and did not discuss whether, under § (b) of Amendment 7, "any privacy restrictions imposed by Federal law shall be maintained."

Buster certified three questions to this Court, only one of which, the preemption issue (discussed in Part IIA of Petitioner Hospital's Initial Brief on the Merits), is addressed by FPSC.

SUMMARY OF ARGUMENT

In addition to positions taken by Petitioner Florida Hospital Waterman, Inc., expressed in Part IIA of its Initial Brief on the Merits, and by *Amicus* Florida Defense Lawyers Association, Federal privacy restrictions protect Patient Safety Work Product — patient safety data and health information — that identifies or constitutes deliberations or analysis of a Patient Safety Evaluation System or identifies the fact of reporting Patient Safety Work Product to a Patient Safety Evaluation System, regardless of when collected or made; and Patient Safety Work Product reported to a Patient Safety Organization.

Although Federal privacy restrictions permit an individual to obtain his/her *own* health information, they prohibit an individual from obtaining health information about *another* individual without an authorization or Court Order.

Section (b) of Amendment 7 contains a self-limiting inferiority clause under which "any privacy restrictions imposed by Federal law shall be maintained." By operation of this self-limiting inferiority clause, health information protected by Federal privacy restrictions is not within, governed by, subject to or affected by Amendment 7. Health information privacy restrictions

thought removed by Amendment 7 and Court opinions such as *Buster* are actually maintained by Amendment 7's self-limiting inferiority clause (b), which, by its own terms, "maintains any privacy restrictions imposed by Federal law."

Two federal laws, the Patient Safety and Quality Improvement Act of 2005, Public Law 109-41, ("2005 Act"), Appendix 3; and the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 and its implementing rules ("HIPAA"), maintain privacy restrictions superior to Amendment 7 and should be recognized by this Court such.

Amendment 7 should be construed in such a manner that objections to obtaining privileged and confidential Patient Safety Work Product can be raised on the grounds that Amendment 7's self-limiting inferiority clause (b) maintains:

(1) Federal privacy restrictions imposed by the 2005 Act that make Patient Safety Work Product privileged and confidential regardless of when collected or made, and

(2) Federal privacy restrictions imposed by HIPAA that prohibit an individual from obtaining health information about *another* individual without an authorization or Court Order.

POINT ON APPEAL

SECTION (B) OF AMENDMENT 7 CONTAINS A SELF-LIMITING INFERIORITY CLAUSE UNDER WHICH "ANY PRIVACY RESTRICTIONS IMPOSED BY FEDERAL LAW SHALL BE MAINTAINED"

A. The federal Patient Safety and Quality Improvement Act of 2005; and the federal Health Insurance Portability and Accountability Act of 1996 and its implementing rules contain privacy restrictions superior to Amendment 7.

Section (b) of Amendment 7 contains a self-limiting inferiority clause under which "any privacy restrictions imposed by Federal law shall be maintained." By operation of this self-limiting inferiority clause, Patient Safety Work Product made privileged and confidential by federal privacy restrictions is not within, governed by, subject to or affected by Amendment 7.

Health information privacy restrictions previously thought removed by Amendment 7 and Court opinions such as *Buster* are actually maintained by Amendment 7's self-limiting inferiority clause (b), which, by its own terms, "maintains any privacy restrictions imposed by Federal law."

Two federal laws, the Patient Safety and Quality Improvement Act of 2005, Public Law 109-41 ("2005 Act"), Appendix 3; and the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 and its implementing rules ("HIPAA"), maintain privacy

restrictions, even after Amendment 7, and should be recognized by this Court as doing so.

Privacy restrictions in federal law make Patient Safety Work Product — health information and patient safety data — privileged and confidential regardless of when collected or made.

Privacy restrictions in Federal law permit an individual to obtain his/her *own* health information, but prohibit an individual from obtaining health information about *another* individual without an authorization or Court Order.

B. Privacy restrictions in the federal Patient Safety and Quality Improvement Act of 2005 make Patient Safety Work Product privileged and confidential regardless of when collected or made.

Under the 2005 Act, healthcare providers voluntarily generate *Patient Safety Work Product* as part of *Patient Safety Evaluation Systems*[2]. *Patient Safety Organizations* such as FPSC conduct *patient safety activities* such as analysis of medical error data that result in recommendations for improved patient safety practices.

[2] Under § 921(6) of the 2005 Act, Appendix 4, a Patient Safety Evaluation System is the "collection, management, or analysis of information for reporting to or by a Patient Safety Organization."

Patient Safety Organizations collect, aggregate and analyze Patient Safety Work Product assembled and voluntarily reported by providers. By analyzing patient safety event information, they identify patterns of failures and propose measures to eliminate patient safety risks and hazards.

FPSC operates a Near-Miss Patient Safety Evaluation System that receives "near miss" information voluntarily reported anonymously by providers. A "near miss" is an event where chance or intervention prevented harm from occurring. FPSC's Near-Miss reporting system is voluntary, anonymous, and is independent and *separate* from any mandatory reporting system used for regulatory purposes. Near-Miss data submitted to FPSC is Patient Safety Work Product as that term is defined in the 2005 Act.

Reports of Near-Miss data will be published on a regular basis and special alerts will be published as needed regarding newly identified, significant risks. Aggregated Near-Miss data will be made available publicly.

The FPSC's Near-Miss reporting system is the type of *separate* Patient Safety Evaluation System described in the 2005 Act and is exactly what a Patient Safety Evaluation System should be.

Patient Safety Work Product developed, assembled or reported as part of a Patient Safety Evaluation System such as the FPSC's Near-Miss reporting system is privileged and confidential under the 2005 Act, even in the absence of an actual report to a Federally-certified Patient Safety Organization. FPSC meets the federal definition of a Patient Safety Organization and will become federally certified upon promulgation of certification rules.

Privacy protections in the 2005 Act make Patient Safety Work Product such as reported to FPSC privileged and confidential regardless of when collected or made. Amendment 7 should be construed in such a manner that its self-limiting inferiority clause (b) "maintains federal privacy restrictions" imposed by the 2005 Act to make Patient Safety Work Product privileged and confidential regardless of when collected or made.

The 2005 Act defines Patient Safety Work Product[3] at § 921(7)(A), as:

[3] The Federal definition of Patient Safety Work Product is virtually identical to the definition of patient safety data in § 766.1016(1)(a): "Patient safety data" means reports made to patient safety organizations, including all healthcare data, interviews, memoranda, analyses, root cause analyses, products of quality assurance or quality improvement processes, corrective action plans, or information collected or created by a healthcare facility licensed under chapter 395, or a healthcare practitioner as defined in s. 456.001(4), as a result of an occurrence

> (A)ny data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—
>
> (i) which--
>
> (I) are assembled or developed by a provider for reporting to a Patient Safety Organization and are reported to a Patient Safety Organization; or
>
> (II) are developed by a Patient Safety Organization for the conduct of patient safety activities;
>
> and which could result in improved patient safety, health care quality, or health care outcomes; or
>
> (ii) which ***identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system***.

Under § 921(7)(A)(ii), Appendix 5, Patient Safety Work Product is any "data, report, record, memoranda, analysis (such as root cause analyses) or written or oral statement" that identifies or constitutes the deliberations or analysis of, or identifies the fact of reporting pursuant to a Patient Safety Evaluation System[4].

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related to the provision of healthcare services which exacerbates an existing medical condition or could result in injury, illness, or death.

[4] Under § 921(7)(A)(ii), Appendix 5, Patient Safety Work Product also includes healthcare information that may result in improved patient safety, healthcare quality or healthcare outcomes gathered by a provider for reporting to a patient safety organization and actually reported, or

Under § 921(7)(B) of the 2005 Act, Appendix 5, a patient's medical record, billing and discharge information, other original patient or provider records and other information *separate* from a Patient Safety Evaluation System is not protected. Patient Safety Work Product does not include such original patient or provider records or information "collected, maintained or developed *separately*, or exists *separately*" (emphasis supplied) from a Patient Safety Evaluation System[5]. This is consistent with the Act's legislative history:

> (W)e negotiated a definition … which takes great care to make clear to provider that the assembly of data, its analysis, deliberations about it, and its reporting to a patient safety organization will be firmly protected. We also clarified that information that is collected, maintained, or developed separate from the patient safety system will continue to be treated the same as it is under current law. (Appendix 6.)

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developed by a patient safety organization for patient safety activities.

[5] The distinctions among Patient Safety Work Product and "separate information" and the explicit exclusion of non-Patient Safety Work Product from protections of the 2005 Act are meant to preserve the status quo regarding information compiled by providers as part of quality assurance, risk management, peer review and other functions. Depending on how such information is gathered and processed, information gathered as part of these functions may be protected as Patient Safety Work Product.

1. Patient Safety Work Product is privileged and confidential under the federal Patient Safety and Quality Improvement Act of 2005.

Privacy restrictions in the 2005 Act make Patient Safety Work Product privileged (§ 922[a]) and confidential (§ 922[b]). Appendix 7. As a result, Patient Safety Work Product in Florida within a Patient Safety Evaluation System or reported to a Patient Safety Organization is privileged and confidential, even after Amendment 7.

Patient Safety Work Product is ***privileged*** because it is not subject to ***discovery***, may not be ***admitted*** as evidence in connection with any civil, criminal or administrative action, and may not be disclosed. § 922(a)(1), Appendix 7. Under § 922(a)(1) of the 2005 Act, Patient Safety Work Product is not ***subject*** to a Federal, State or local civil, criminal or administrative subpoena or order, including in a Federal, State or local civil or administrative disciplinary proceeding against a provider; or discovery in connection with a Federal, State, or local civil, criminal or administrative disciplinary proceeding against a provider. Similar admissibility restrictions for Patient Safety Work Product are found in § 922(a)(4) and (5). Appendix 7.

Patient Safety Work Product is ***confidential*** because it "shall not be disclosed." § 922(b), Appendix 7.

2. The federal Patient Safety and Quality Improvement Act of 2005 Act maintains federal privacy protections for Patient Safety Work Product assembled and reported by providers through a Patient Safety Evaluation System.

Consistent with § (b) of Amendment 7, the 2005 Act "maintains" Federal privacy protections — legal privilege and confidentiality protections — for Patient Safety Work Product assembled and reported by providers through a Patient Safety Evaluation System. These same privileges apply to information developed by a Patient Safety Organization for conducting patient safety activities.

Information sought in the Trial Court, Appendix 8, may have included privileged and confidential Patient Safety Work Product[6]. Amendment 7 should be construed in such a manner that objections to obtaining privileged and confidential Patient Safety Work Product can be raised on the grounds that Amendment 7's self-limiting inferiority clause (b) maintains:

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[6] For example, documents relating to "investigations of any incident of medical negligence; or acts, neglects or defaults which caused or could have caused unintended injury to a patient and caused or could have caused the death of a patient." Appendix 8, Paragraphs 6 and 7. Information was also sought in Paragraphs 8 and 10 about communications and minutes of "any committee relating directly or indirectly to the quality of care rendered by, or the skill, competence, diligence, reliability, or integrity of defendants" and digital recordings of meetings held by specified committees.

(1) Federal privacy restrictions imposed by the 2005 Act that make Patient Safety Work Product privileged and confidential regardless of when collected or made, and

(2) Federal privacy restrictions imposed by HIPAA and its implementing rules that prohibit an individual from obtaining health information about *another* individual without an authorization or Court Order.

The 2005 Act makes Patient Safety Work Product privileged and confidential when assembled and reported by providers through a Patient Safety Evaluation System. Legislative history of the 2005 Act confirms as follows:

> It is not the intent of this legislation to establish a legal shield for information that is already currently collected or maintained separate from the new patient safety process, such as a patient's medical record. That is, information which is currently available to plaintiffs' attorneys or others will remain available just as it is today. Rather, what this legislation does is create a new zone of protection to assure that the assembly, deliberation, analysis and reporting by providers to Patient Safety Organization of what we are calling "Patient Safety Work Product" will be treated as confidential and will be legally privileged. (Appendix 6.)

C. Privacy provisions of the federal Patient Safety and Quality Improvement Act of 2005 preempt other provisions of Federal, State or local law such as Amendment 7.

The 2005 Act provides both privilege and confidentiality protections for Patient Safety Work Product. As discussed above, the privileged and confidential nature of Patient Safety Work Product prohibits it from being disclosed. Subject to exceptions noted in the 2005 Act, none of which are material here, the privilege of the 2005 Act at § 922(a), Appendix 7, preempts[7] any other provision of Federal, State or local law, including Amendment 7.

Similar to the privilege protection, the protections for confidentiality of the 2005 Act at § 922(b), Appendix 7, also preempt any other provision of Federal, State or local law, including Amendment 7.

The 2005 Act preempts all inconsistent Federal, State or local laws, but permits application of a Federal, State or local law that provides *greater* privilege and confidentiality protections, § 922(g)(1), Appendix 7. Amendment 7 does not provide greater privilege and confidentiality protections and is preempted.

[7] §§ 922 (a) and 922(b) of the 2005 Act. Exceptions at 922(c) and (g) in Appendix 7 are not material to this case.

The 2005 Act does not preempt or otherwise affect state laws requiring a provider to report, and provide protection for, information that is *not* Patient Safety Work Product. § 922(g)(5), Appendix 7.

Information in a Patient Safety Evaluation System or gathered and reported to a Patient Safety Organization such as FPSC is Patient Safety Work Product and is therefore privileged and confidential under Federal law. As such, it is excluded from Amendment 7 by Amendment 7's own self-limiting inferiority clause in § (b). To the extent Amendment 7 provides otherwise, its provisions are preempted by the 2005 Act.

D. Federal HIPAA privacy restrictions permit an individual to obtain his/her *own* health information, but federal HIPAA privacy restrictions prohibit an individual from obtaining health information about *another* individual without authorization or Court Order.

Subject to limitations not material here, and consistent with Amendment 7, an individual has the right of access under HIPAA and its implementing rules to his or her *own* health information[8] under 45 CFR 164.524(a)(1). Appendix 10.

In the Trial Court, Plaintiff sought health information about *other* individuals. Appendix 8. Under

[8] Under HIPAA rule 45 CFR 164.502(g)(1), Appendix 9, a personal representative, such as Mrs. Buster, may have access to health information of the decedent.

HIPAA rules, however, *another* individual's health information may not be disclosed without a written HIPAA authorization, 45 CFR 164.508(a)(1), Appendix 11; or a Court Order 45 CFR 164.508(e), Appendix 11. Amendment 7 is contrary to HIPAA privacy restrictions and is preempted by HIPAA to the extent it provides access to and discovery of health information about *another* individual without an authorization or Court Order.

Under HIPAA rule 45 CFR 164.514, Appendix 12, health information is "individually identifiable" if it identifies an individual or if there is a reasonable basis to believe that the information can be used to identify an individual. Amendment 7 attempts to "de-identify" health information by removing the patient's "identity".

To actually "de-identify" health information under HIPAA rule 45 CFR 164.514, it must be stripped of: (1) at least 18 identifiers[9]; and (2) "any other unique identifying number, characteristic or code"; and (3) the healthcare provider must not have actual knowledge that the

[9] Name; geographic subdivisions of certain sizes; dates; telephone numbers; fax numbers; email addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plates; device identifiers and serial numbers; URLs; internet protocol addresses; biometric identifiers, including finger and voice prints and full face photographs and comparable images.

information could be used alone or in combination with other information to identify an individual who is the subject of the information.

E. The federal Health Insurance Portability and Accountability Act of 1996 and its implementing rules preempt contrary state laws such as Amendment 7.

Subject to exceptions not material here, the federal HIPAA statute, at Section 1178, Appendix 13, establishes a general rule that a HIPAA provision, requirement, standard or implementation specification supersedes any contrary provision of state law such as Amendment 7.

As specified in Subpart B of 45 CFR, specifically 45 CFR 160.203, Appendix 14, HIPAA rules that are “contrary to” or are “more stringent than” a provision of state law (defined in 45 CFR 160.202, Appendix 15, to include a *constitution*) preempt the provision of state law such as Amendment 7.

Under 45 CFR 160.202, a State law is “contrary” if compliance both with the State law and HIPPA is impossible or creates an obstacle to achieving HIPAA’s full purpose and objectives. Compliance with both Amendment 7 and HIPAA is, of course, not possible.

To be “more stringent than” HIPAA, Amendment 7 must further limit or prohibit circumstances under which health information is used or disclosed, which it does not.

Although Amendment 7 permits access to an individual's *own* health information, it does not confer greater access rights than currently exist under HIPAA rules. As a result of HIPAA preemption principles found in 45 CFR 160.202 and 203, Amendment 7 is not "more stringent than" HIPAA[10] and is consequently preempted by federal privacy restrictions of HIPAA and its implementing rules.

CONCLUSION

This Court should construe federal privacy protections maintained by Amendment 7 as prohibiting access to and discovery of Patient Safety Work Product made privileged and confidential by Federal law and permit access *only* to health information of that individual.

[10] Specifically, under 45 CFR 160.202, Amendment 7 does not: allow individuals to receive more information about a proposed use or disclosure; confer more rights or remedies than HIPAA rules; narrow the scope or duration of consent or authorization for use or disclosure of protected health information; increase privacy protections; require more detailed collection, reporting and/or accounting than HIPAA; establish a longer retention period; otherwise provide greater privacy protection to the individual; is not necessary to prevent fraud or abuse, regulate insurance or health plans or report healthcare delivery or costs; or serve a compelling public health, safety or welfare interest that would warrant an intrusion into privacy.

Respectfully submitted July 5, 2006.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and accurate copy of the foregoing was furnished by United States mail on July 5, 2006, to counsel in the attached Certificate of Service list.

CERTIFICATE OF TYPE SIZE & STYLE

I HEREBY CERTIFY that the type size and style of the Amicus Curiae Brief is Courier New 12 point.

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APPENDIX

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