

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: CS/SB 1276

INTRODUCER: Health Policy Committee and Senator Grimsley

SUBJECT: Trauma Service Areas

DATE: March 25, 2014

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	Fav/CS
2.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1276 caps trauma activation fees at \$15,000 and places a moratorium on new verified, designated, or provisional trauma centers until July 1, 2015. Notwithstanding the moratorium, the Department of Health (DOH) must verify or designate a hospital as a Level II trauma center within 30 days after the request from that hospital, if the hospital has operated continuously as a Level II trauma center for a 12-month period, is in operation on July 1, 2014, and meets statutory requirements regarding quality of care and patient outcomes.

The bill requires the DOH to convene the Trauma System Plan Advisory Council in order to review the Trauma System Consultation Report issued by the American College of Surgeons and make recommendations to the Legislature, including recommendations for statutory change, by February 1, 2015.

The bill also strikes language allowing hospitals to protest DOH decisions based on the DOH's preliminary or in-depth reviews of applications.¹

II. Present Situation:

The regulation of trauma centers in Florida is established under part II of ch. 395, F.S. Trauma centers treat individuals who have incurred single or multiple injuries because of blunt or

¹ This would not affect a hospital's ability to protest final DOH action under the provisions of ch. 120, F.S.

penetrating means or burns, and who require immediate medical intervention or treatment. Currently, there are 27 verified and provisional trauma centers in the state.²

Trauma centers in Florida are divided into several categories including Level I, Level II, and Pediatric trauma centers.

- A Level I trauma center is defined as a trauma center that:
 - Has formal research and education programs for the enhancement of trauma care; is verified by the DOH to be in substantial compliance with Level I trauma center and pediatric trauma center standards; and has been approved by the DOH to operate as a Level I trauma center;
 - Serves as a resource facility to Level II trauma centers, pediatric trauma centers, and general hospitals through shared outreach, education, and quality improvement activities; and
 - Participates in an inclusive system of trauma care, including providing leadership, system evaluation, and quality improvement activities.³
- A Level II trauma center is defined as a trauma center that:
 - Is verified by the DOH to be in substantial compliance with Level II trauma center standards and has been approved by the DOH to operate as a Level II trauma center or is designated pursuant to s. 395.4025(14);
 - Serves as a resource facility to general hospitals through shared outreach, education, and quality improvement activities; and
 - Participates in an inclusive system of trauma care.⁴
- A Pediatric trauma center is defined as a hospital that is verified by the DOH to be in substantial compliance with pediatric trauma center standards and has been approved by the DOH to operate as a pediatric trauma center.^{5,6}

The Florida Trauma System Plan Advisory Council

The Florida Trauma System Plan Advisory Council (council), is an interagency group that operates under the leadership of the DOH. The committee is made up of members from the DOH, the Agency for Health Care Administration, the Board of Medicine, and the Board of Nursing and has the responsibility of developing guidelines, standards, and rules for those portions of the inclusive state trauma system within the authority of each agency.⁷ The council last met in 2010 to review and revise Florida's statewide trauma system plan for 2011-2015.⁸

² See <http://www.floridahealth.gov/licensing-and-regulation/trauma-system/documents/%20traumacenterlisting2014.pdf>, (last visited on Mar. 18, 2014).

³ Section 395.4001(6), F.S.

⁴ Section 395.4001(7), F.S.

⁵ Section 395.4001(8), F.S.

⁶ For Level I, Level II, and pediatric trauma center standards see <http://www.floridahealth.gov/licensing-and-regulation/trauma-system/documents/%20traumacntrstandpamphlet150-9-2009rev1-14-10.pdf> (last visited on Mar. 21, 2014).

⁷ Section 395.40(4), F.S.

⁸ See http://www.associationdatabase.com/aws/ACS/asset_manager/get_file/26063/third_quarter_report_january_-_september_2010_.pdf (last visited on Mar. 25, 2014).

Trauma Center Apportionment

Pursuant to s. 395.402, F.S., Florida is divided into 19 “trauma service areas.” A trauma service area is determined based on population density and an ability to respond to a specified number of patients in a trauma center environment. For purposes of medical response time, the trauma service area should have at least one Level I or Level II trauma center, and the DOH is required to allocate, by rule, the number of trauma centers for each trauma service area. There cannot be more than 44 trauma centers in the state.

On November 30, 2012, the Florida First District Court of Appeal upheld a circuit court ruling which invalidated DOH Rule 64J-2.010, F.A.C.⁹ The rule mirrored exactly the allocation of trauma service areas in s. 395.402(4), F.S., even though the statute required the DOH to review the assignment of counties to trauma service areas annually. In its opinion the court stated that the trauma statutes were substantially amended in 2004 but the rule remained unchanged since 1992. As such, the rule continued to implement the outdated provisions of these statutes.¹⁰ In response to this ruling, the DOH began a series of 12 workshops to gather input from the public in order to rewrite Rule 64J-2.010, F.A.C. When these workshops concluded, the DOH published a new proposed rule¹¹ using the input from these workshops and the final report of the American College of Surgeons Committee on Trauma Systems consultation team.¹² The DOH then initiated negotiated rulemaking which took place on January 23, 2014, in order to allow “an opportunity for interested parties to come together and discuss the draft rule text directly with each other.”¹³ After the public comment period, the DOH was in a position to certify the proposed rule but received rule challenge petitions in early March 2014.¹⁴ The rule challenges are scheduled to be heard by the Department of Administrative Hearings between March 31 and April 11, 2014.¹⁵

American College of Surgeons Trauma System Consultation Report

Due to the continuing and contentious legal battle between the DOH and trauma system stakeholders beginning in 2012 with *DOH v. Bayfront Medical Center*,¹⁶ ongoing trauma system development in Florida has been at a standstill.¹⁷ Due to this longstanding impasse, the DOH requested the American College of Surgeons Committee on Trauma (ACS) evaluate Florida’s trauma system.¹⁸ The 117-page ACS report was released on May 6, 2013,¹⁹ and made numerous

⁹ *Department of Health v. Bayfront Medical Center, Inc.*, (Fla. App. 1 Dist., 2012), (on file with Health Policy Committee)

¹⁰ *Id.*, p. 5

¹¹ Available at <https://www.flrules.org/gateway/RuleNo.asp?title=Trauma&ID=64J-2.010> (last visited on Mar. 18, 2014).

¹² Available at http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/fl-report-final-5-6-13.pdf. (last visited on Mar. 18, 2014).

¹³ Press Release, The DOH, (Dec. 20, 2013) available at <http://newsroom.doh.state.fl.us/wp-content/uploads/newsroom/2013/05/122013-Trauma-Rulemaking-Negotiation.pdf> (last visited on Mar. 18, 2014).

¹⁴ Email from Gary Landry, Legislative Planning Office Manager, DOH (on file with Senate Health Policy Committee)

¹⁵ *Id.*

¹⁶ *Id.* n. 9

¹⁷ Trauma System Consultation Report, American College of Surgeons Committee on Trauma, Feb. 2 - 5, 2013, available at <http://newsroom.doh.state.fl.us/wp-content/uploads/newsroom/2013/05/Report-Final.pdf>, p. 6 (last visited on Mar. 25, 2014).

¹⁸ See <http://www.fha.org/news/latest/show-details/ACS-Evaluates-Floridas-Trauma-System/28>, last visited on Mar. 25, 2014.

¹⁹ See <http://newsroom.doh.state.fl.us/wp-content/uploads/newsroom/2011/08/050613TraumaStudyReleased.pdf> (last visited Mar. 25, 2013).

recommendations including convening a small work group to analyze existing statutes and regulations pertaining to the trauma system, appointing a new Florida Trauma System Advisory Council, establishing a moratorium on new trauma centers,²⁰ revising the Florida trauma system plan, and reviving the Performance Improvement Committee within the Trauma system Advisory Council to develop a statewide performance improvement plan.²¹

Trauma Center Approval

Section 395.4025, F.S., provides a scheduled application process and specific trauma center selection criteria. Standards for verification and approval are based on national guidelines established by the American College of Surgeons.²² Standards for verification and approval as a pediatric center are developed in conjunction with Children's Medical Services.

Acute care hospitals that submit a Letter of Intent to the DOH by October 1 are eligible to submit a trauma center application by April 1.²³ Once an applicant hospital receives the DOH's notification letter of provisional status designation, the hospital may begin operation as a provisional trauma center. During the provisional phase, the DOH conducts an in-depth review of the hospital's application. An onsite visit is conducted by an out-of-state survey team to verify compliance with the *Trauma Center Standards, DH Pamphlet 150-9*.²⁴ Based on the recommendations from the out-of-state survey team, the DOH makes the decision to approve or deny the hospital to operate as a verified trauma center.²⁵

Hospitals verified by the DOH receive a seven year certificate. A verified trauma center that intends to renew its verification must submit a renewal application form to the DOH at least 14 months prior to the expiration of the certificate. All renewing verified trauma centers receive an onsite visit by an out-of-state survey team after the DOH's receipt of the completed renewal form. Hospitals that have been verified by the DOH to be in compliance with the requirements of s. 395.4025, F.S., are approved to operate as a verified trauma center.²⁶

In 2013, the Legislature passed ch. 2013-153, L.O.F., which created an exception to the standard process of verifying new trauma centers for certain Level II trauma centers. As amended, s. 395.4025(14), F.S., requires that a hospital must be designated by the DOH as a Level II trauma center if the hospital:

- Is located in a TSA with a population greater than 600,000 persons and a population density of less than 225 persons per square mile;

²⁰ See supra n. 17 at p. 7.

²¹ See Supra n. 17 at pp. 12-14 for priority recommendations.

²² The ACS requirements for Level I, Level II, and pediatric trauma centers are available at: <http://www.facs.org/trauma/verifivisitoutcomes.html> (last visited on Mar. 21, 2013).

²³ The required criteria included in the application package is outlined in the department's *Trauma Center Standards, DH Pamphlet 150-9*, in accordance with s. 395.401(2), F.S., and is incorporated by reference in Rule 64J-2.011, F.A.C. The criteria is based on the American College of Surgeons (ACS) national guidelines entitled -- *Hospital and Prehospital Resources for Optimal Care of the Injured Patient*. See DOH Analysis, *SB 1276* (Feb. 28, 2014) (on file with Senate Health Policy Committee).

²⁴ Available at <http://www.floridahealth.gov/licensing-and-regulation/trauma-system/documents/%20traumacntrstandpamphlet150-9-2009rev1-14-10.pdf> (last visited on Mar. 18, 2014).

²⁵ Id.

²⁶ Id.

- Is located in a county with no verified trauma centers;
- Is located at least 15 miles or 20 minutes away from the nearest verified trauma center; and,
- Has a valid certificate of trauma center verification from the American College of Surgeons.

Trauma Activation Fees

Trauma activation fees are fees charged by a hospital “any time ambulance crews bring in patients believed to have traumatic injuries.”²⁷ Although these fees are common among hospitals and they help hospitals cover their overhead costs, the amounts charged vary widely. For example, in 2012, Shands Jacksonville charged a trauma activation fee of \$7,000, while Lawnwood Regional Medical Center in Ft. Pierce, Florida, charged \$29,000, and Orange Park Medical Center in Orange Park, Florida, charged \$20,000.²⁸

III. Effect of Proposed Changes:

Section 1 of the bill amends s. 395.401, F.S., to cap trauma activation fees at \$15,000 until July 1, 2015.

Section 2 of the bill amends s. 395.402, F.S., to require the DOH to convene the Florida Trauma System Advisory Council no later than October 1, 2014, in order to review the ACS Trauma System Consultation Report and submit recommendations to the Legislature, including recommendations for statutory changes, by February 1, 2015.

Section 3 of the bill amends s. 395.4025, F.S., to:

- Strike language that allows a hospital to protest a decision made by the DOH based on the DOH’s preliminary or in-depth review of applications or on the recommendations of the site visit review team and which requires the DOH to hold a hearing as provided in ch. 120, F.S.²⁹
- Require the DOH to verify or designate a hospital as a Level II trauma center if the hospital:
 - Has operated continuously as a Level II trauma center for a 12-month period;
 - Is in operation on July 1, 2014; and
 - Meets statutory requirements regarding quality of care and patient outcomes designated in s. 395.4025(5) and (6), F.S.;³⁰ and
- Place a moratorium on verifying, designating, or provisionally approving new trauma centers until July 1, 2015.

Section 4 of the bill establishes an effective date of July 1, 2014.

²⁷ Phil Galewitz, *Boom in Trauma Centers Can Help Save Lives, But at What Price?*, KAISER HEALTH NEWS, Sep. 24, 2012, available at <http://www.kaiserhealthnews.org/stories/2012/september/25/trauma-centers.aspx> (last visited on Mar. 25, 2014).

²⁸ *Id.*

²⁹ This would not affect a hospital’s ability to protest final DOH action under the provisions of ch. 120, F.S.

³⁰ Subsection (5) requires an out-of-state review team to visit all provisional trauma centers between Oct. 1 and June 1 of each year, requires the DOH to develop a survey instrument for the reviewers to use, and requires that hospitals being considered meet all the requirements of a trauma center and be located in a TSA that has need for a trauma center. Subsection (6) requires the DOH to select trauma centers by July 1 based on the recommendations of the review team unless the hospital requests an extension of their provisional status and submits a corrective plan of action to the DOH.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 1276 may have an indeterminate fiscal impact on existing and provisional trauma centers, as well as potential trauma center applicants.

C. Government Sector Impact:

The DOH may incur indeterminate costs associated with convening the Trauma System Plan Advisory Council.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.401, 395.402 and 395.4025.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 25, 2014:

The CS amends SB 1276 to:

- Remove all provisions related to the apportionment of trauma centers;
- Remove provisions requiring the DOH to complete an annual assessment of the trauma system;
- Cap trauma activation fees at \$15,000 until July 1, 2015;
- Require the DOH to reactivate the Trauma System Plan Advisory Council in order to study the American College of Surgeons Trauma System Consultation Report and make recommendations, including recommendations for statutory changes, to the Legislature by February 1, 2015; and,
- Place a moratorium on new trauma centers until July 1, 2015.

B. Amendments:

None.