

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: SB 1276

INTRODUCER: Senator Grimsley

SUBJECT: Trauma Service Areas

DATE: March 21, 2014

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Looke</u>	<u>Stovall</u>	<u>HP</u>	<u>Pre-meeting</u>
2.	_____	_____	<u>AP</u>	_____

I. Summary:

SB 1276 revises the selection and allocation of trauma centers, emphasizing performance related to quality standards. It requires the Department of Health (DOH) to conduct an annual assessment of the state trauma system and report to the Governor and the Legislature by February 1 of each year. Several factors are enumerated for inclusion in the assessment as well as consideration of the performance of the trauma system compared to specific standards for access and quality.

The bill reduces the number of trauma service areas (TSA) enumerated in statute from 19 to 18.¹ The total number of trauma centers statewide is limited to 33 and a specific number of trauma centers is allocated to each TSA, ranging from one to three trauma centers per TSA.² Any new Level I or Level II trauma centers must be located 10 miles or more from an existing Level I or II trauma center.

The DOH is directed to select which hospitals are to be recognized as trauma centers based on documentation of the hospital's ability to meet established quality standards. The bill strikes language allowing hospitals to protest DOH decisions based on the DOH's preliminary or in-depth reviews of applications.³

Finally, the DOH is required to redesignate a hospital as a Level II trauma center within 30 days after the request for redesignation if the hospital has operated continuously as a Level II trauma center for a 12-month period; is in operation on July 1, 2014; meets statutory requirements regarding quality of care and patient outcomes; and if resignation would not cause the total number of trauma centers in the TSA to exceed the number designated in s. 395.402, F.S.

¹ By eliminating current TSA 17 and moving Charlotte County in TSA 13 and Collier County into TSA 15.

² TSAs 2, 3, 4, 7, 11, 12, 14, and 15 are assigned one trauma center; TSAs 5, 6, 10, 13, and 16 are assigned two trauma centers; and TSAs 1, 8, 9, 17, and 18 are assigned three trauma centers.

³ This would not affect a hospital's ability to protest final DOH action under the provisions of ch. 120, F.S.

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 penetrating means or burns, and who require immediate medical intervention or treatment. Currently, there are 27 verified and provisional trauma centers in the state.⁴

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.⁵
- 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.⁶
- 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.^{7,8}

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.

⁴ See http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/%20traumacenterlisting2014.pdf, last visited on Mar. 18, 2014.

⁵ Section 395.4001(6), F.S.

⁶ Section 395.4001(7), F.S.

⁷ Section 395.4001(8), F.S.

⁸ 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.

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

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.¹⁶ 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 1.¹⁷ 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*.¹⁸ Based on the

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 DOH press release, 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 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.

¹⁷ 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 of SB 1276, (on file with Senate Health Policy Committee).

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

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.¹⁹

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.²⁰

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;
- 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.

III. Effect of Proposed Changes:

Section 1 of the bill amends s. 395.402, F.S., to:

- Require the DOH to conduct an annual assessment of the state trauma system which must be reported to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the substantive legislative committees by February 1 of each year. The DOH must determine whether the existing trauma system is effective in providing trauma care uniformly throughout the state and, when creating the assessment, is required to:
 - Review the number and level of trauma centers needed for each trauma service area to provide an integrated trauma system statewide;
 - Identify criteria used for determining the number and level of trauma centers needed to serve the population in a defined TSA or region;
 - Evaluate the level of integration of the trauma system planning with interagency regional emergency and disaster planning and identify any action needed to reduce duplication of planning efforts and to promote effective responses to mass casualty events;
 - Report the amounts, sources, and uses of financial support for the trauma system;
 - Make recommendations regarding the distribution of state funds for trauma centers; and
 - Consider:
 - Recommendations submitted by regional trauma agencies;
 - Stakeholder recommendations; and
 - The performance of the trauma system compared to specific standards for access and quality;²¹
- Modify the existing TSAs to:

¹⁹ Id.

²⁰ Id.

²¹ These specific standards are not specified in the bill or in statute and would likely need to be determined by the DOH.

- Eliminate TSA 17²² and place Collier County in TSA 15 along with Glades, Hendry, and Lee Counties; and,
- Move Charlotte County from TSA 15 to TSA 13;
- Designate a statewide total of 33 trauma centers, reduced from a maximum of 44, so that each TSA is granted a specific maximum number of allowed trauma centers.²³ The trauma centers are allocated so that:
 - TSAs 2, 3, 4, 7, 11, 12, 14, and 15 may have only one trauma center;
 - TSAs 5, 6, 10, 13, and 16 may have up to two trauma centers; and
 - TSAs 1, 8, 9, 17, and 18 may have up to three trauma centers;
- Prohibit approval of a new Level I or Level II trauma center if located less than 10 miles from an existing Level I or Level II trauma center;
- Strike language requiring the DOH to review the assignment of counties to TSAs; and
- Strike outdated provisions and make other technical changes.

Section 2 of the bill amends s. 395.4025, F.S., to:

- Require the DOH to select which hospitals to recognize as trauma centers based on documentation of the hospital's ability to meet established quality standards;²⁴
- 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.²⁵
- Require the DOH to redesignate 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;
 - The hospital is in operation on July 1, 2014;
 - The hospital meets statutory requirements regarding quality of care and patient outcomes designated in s. 395.4025(5) and (6), F.S.;²⁶ and
 - Redesignation would not cause the total number of trauma centers in the TSA to exceed the number designated in s. 395.402, F.S.
- Strike outdated language, conform to changes made to s. 395.402, F.S., in the bill and make other technical changes.

Section 3 of the bill establishes an effective date of July 1, 2014.

²² Consisting solely of Collier County.

²³ No TSA currently has more trauma centers than the limits placed on them by the bill. TSAs 1, 5, 6, 9, and 13 are under their limits by 1 trauma center and TSA 8 is under its limit by 2 trauma centers.

²⁴ *See supra* n. 18.

²⁵ This would not affect a hospital's ability to protest final DOH action under the provisions of ch. 120, F.S.

²⁶ Subsection (5) requires an out-of-state review to team 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:

SB 1276 may have an indeterminate fiscal impact on existing and provisional trauma centers, as well as potential trauma center applicants, due to the revisions made to the manner in which trauma centers are allocated among the TSAs.

C. Government Sector Impact:

The DOH may incur indeterminate costs associated with producing the annual assessment of the state trauma system required in the bill and for adopting new rules to implement the changes made by the bill.

VI. Technical Deficiencies:

Lines 212 and 213 of the bill refer to the allocation of trauma centers to TSAs “under s. 395.402(4)”, however those allocations are made in s. 395.402(5), F.S.

VII. Related Issues:

Lines 207-213 of the bill allow the DOH to grant an applicant additional time if the applicant is unable to meet all the necessary requirements and if “at the time of application the number of applicants in the service area in which the applicant is located is equal to or less than the service area allocation.” The DOH states that this provision should include current trauma centers and, as such, should read “the number of trauma centers and applicants in the service area...”²⁷

²⁷ See supra n. 13

VIII. Statutes Affected:

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

IX. Additional Information:

A. **Committee Substitute – Statement of Changes:**

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

None.

B. **Amendments:**

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
