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 1876
INTRODUCER:	Health Policy Committee and Senator Young
SUBJECT:	Trauma Services
DATE:	January 23, 2018
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.			AHS	
3.			AP	
4.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1876 amends various sections of law related to the selection and licensure of trauma centers and the reporting of trauma center data. The bill:

- Eliminates outdated language related to a Department of Health (DOH) assessment of the trauma system and continuing annual reviews of the assignment of counties to trauma service areas (TSA).
- Eliminates TSA 19 and revises the county make up of certain TSAs.
- Restricts the DOH from designating additional Level I trauma centers in the same TSA where a Level I trauma center currently exists.
- Restricts the DOH from designating a Level II trauma center as a pediatric or a Level I trauma center.
- Designates the number of trauma centers allowed in each TSA for a total of 35 trauma centers statewide.
- Requires the DOH to establish the Florida Trauma System Advisory Council (FTSAC) by October 1, 2018. The bill specifies the makeup of the FTSAC and requires the FTSAC to submit a biennial report, beginning January 5, 2020, to the Governor and the Legislature on whether an increase of the number of trauma centers within each TSA is recommended.
- Revises the procedure for the DOH to choose and license new trauma centers if there is statutory capacity within a TSA.

- Provides grandfathering language for currently verified trauma centers and for certain provisionally approved trauma centers.
- Requires the DOH to designate any hospital as a Level II trauma center if the hospital receives a final recommended order from the Division of Administrative Hearings or a final determination from the DOH or a court that it was entitled to be a Level II trauma center and was provisionally approved and operating within specified dates.
- Eliminates the trauma registry under the DOH in favor of requiring trauma centers to participate in the National Trauma Data Bank. Trauma centers and acute care hospitals are still required to report all transfers and outcomes of trauma patients to the DOH.

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 36 verified and provisional trauma centers in the state.[1]

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.[2]
- 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), F.S.;
  - 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.[3]
- 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.[4,5]

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[1] Department of Health, *Senate Bill 1876 Analysis* (January 17, 2018) (on file with the Senate Committee on Health Policy).
[2] Section 395.4001(6), F.S.
[3] Section 395.4001(7), F.S.
[4] Section 395.4001(9), F.S.
[5] For Level I, Level II, and pediatric trauma center standards *see* http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/traumacntrstandpamphlet150-9-2009rev1-14-10.pdf, (last visited on Jan. 19, 2018).

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.

Rule Litigation

Since 2011, the DOH has been involved in constant litigation involving its annual assessment of need for trauma centers. The majority of this litigation is based on the state's TSA allocation methodology which imposes limitations on hospitals seeking trauma center verification. Protests have been levied regarding the validity of the DOH's allocation of new trauma centers in specific geographic areas. Despite prevailing in an administrative rule challenge in 2014 that validated the DOH's allocation methodology, the DOH has been unable to promulgate the required annual rule change since 2014 due to litigation.

In 2016, the DOH attempted to promulgate an apportionment rule that interpreted need to mean the "minimum" number of trauma centers in a TSA. The proposed rule was subsequently challenged by seven existing trauma centers. The Division of Administrative Hearings issued an order that invalidated the proposed rule in March of 2017. The administrative law judge recognized the challenges faced by the DOH and Florida's trauma system in his final order by stating, "After considering all of the evidence and testimony, the undersigned is of the opinion that it would be impossible to draft a set of rules that would satisfy the concerns/interests of all the relevant stakeholders." Since the invalidation of the rule, the DOH has been unable to promulgate a new rule.

In 2015, an Administrative Law Judge outlined in a recommended order that the DOH must grant provisional trauma center status to all applicants that demonstrate compliance with the critical elements of the trauma center standards, regardless if there is an allocated slot in the TSA. In addition, he indicated the DOH's determination of need happens at the point in which a trauma center is granted verification. This point was upheld in December 2017 per a ruling from the 1st District Court of Appeals. In a separate ruling, the first DCA also stated that a hospital may apply over multiple years without jeopardizing the previous application. In combination, a hospital may essentially operate indefinitely as a provisional trauma center so long as they submit and receive approval of their application annually.

The DOH has been unable to promulgate a valid allocation rule since July, 2014.[6]

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

[6] Supra note 1

established by the American College of Surgeons.[7] Standards for verification and approval as a pediatric trauma center are developed in conjunction with the DOH 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.[8] 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*.[9] 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.[10]

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.[11]

Florida's current trauma center verification process has experienced a number of challenges. Section 395.4025(7), F.S., allows any hospital in the state to protest verification decisions by the DOH. Hypothetically, under this subsection, a 25-bed acute care hospital in northwest Florida can protest the verification of a trauma center in Miami-Dade County. In actual application, the DOH has been involved in litigation numerous times where one or more parties operating a trauma center in one geographic area of the state have challenged trauma center verification in another area of the state.[12]

Florida Trauma Registry

The DOH has maintained a trauma registry since at least 2000. Currently, only a small number of states nationwide do not have a state trauma registry. In 2014, the DOH upgraded the trauma registry and receives patient data from every verified trauma center in the state. Changes made to the registry in 2016, based on feedback received from trauma stakeholders, allow a Florida trauma center to submit the same data elements as those required by the National Trauma Data Bank (NTDB).

The trauma registry serves two critical functions. First, the DOH is able to perform statewide, local and regional data analysis much faster than the NTDB. The NTDB does not perform local and regional analysis and due to the reporting requirements of the NTDB, data analysis is not

[7] 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 Jan. 19, 2018).
[8] 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.
[9] Section 395.4025(5), F.S.
[10] Section 395.4025(6), F.S.
[11] Id.
[12] Supra note 1. A list of current litigation is on file with Senate Health Policy Committee staff.

available for 18 months after the initial reporting period and is limited to standardized reports provided to all participants. In contrast, the DOH is able to provide information as quickly as six months after the end of the reporting period. The Department is also able to create customized, analytical reports not currently available from the NTDB. Second, s. 305.4036, F.S. requires that patient volumes from the Florida Trauma Registry be used as part of the formula to calculate the distribution of traffic fine revenues.[13]

III. Effect of Proposed Changes:

Section 1 amends s. 395.402, F.S., to:

- Strike language requiring Level I and Level II trauma centers to be capable of annually treating a minimum of 1,000 and 500 (or 1,000 in a county with 500,000 or more population) patients with an injury severity score (ISS) of 9 or greater, respectively. These requirements are republished as part of the report that the FTSAC must present to the Governor and the Legislature biennially.
- Strike outdated language requiring the DOH to conduct a one-time assessment of the trauma system.
- Strike a requirement that the DOH conduct annual assessments of the assignment of the counties in TSAs.
- Rework the make-up of the TSAs as follows:
  - Eliminate TSA 19 and place Miami-Dade and Monroe Counties into TSA 18;
  - Move Broward County from TSA 18 to TSA 17;
  - Move Collier County from TSA 17 to TSA 15; and
  - Move Charlotte County from TSA 15 to TSA 13.
- Restrict the DOH from designating an additional Level I trauma center in a TSA where a Level I trauma center already exists or from designating a Level II trauma center as a Level I or pediatric trauma center.
- Eliminate the DOH's responsibility to allocate trauma centers by TSA and, instead, specify the number of trauma centers allowed in each TSA as follows:
  - TSAs 2, 3, 4, 6, 7, 11, 12, 14, and 15 are allocated one trauma center;
  - TSAs 10, 13, and 16 are allocated two trauma centers;
  - TSAs 1, 5, 8, 9, and 17 are allocated three trauma centers; and
  - TSA 18 is allocated five trauma centers.
- By October 1, 2018, the DOH is required to establish the FTSAC. The FSTAC will consist of the following 15 Governor-appointed members:
  - The State Surgeon General;
  - A representative from the Agency for Health Care Administration;
  - A representative from an emergency medical services organization;
  - A representative of a local or regional trauma agency;
  - A trauma program manager or trauma medical director representing an investor-owned hospital with a trauma center;
  - A trauma program manager recommended by the Teaching Hospital Council of Florida;
  - A representative of the Florida Hospital Association;
  - A trauma program manager or trauma medical director representing a public hospital;

[13] Supra note 1.

  - A trauma program manager or trauma medical director representing a nonprofit hospital with a trauma center;
  - A trauma surgeon representing an investor-owned hospital with a trauma center;
  - A trauma surgeon recommended by the Teaching Hospital Council of Florida;
  - A trauma surgeon representing a not-for-profit hospital with a trauma center;
  - A representative of the American College of Surgeons Committee on Trauma;
  - A representative of Associated Industries of Florida; and
  - A representative of the Safety Net Hospital Alliance of Florida.
- The FTSAC is required to conduct its first meeting no later than January 5, 2019. By January 5, 2020, and biennially thereafter, it must submit a report to the Governor and the Legislature which assess whether an increase in the number of trauma centers within each TSA is recommended. Additionally, the report must state whether each Level I and II trauma center is capable of annually treating at least 1,000 and 500 (or 1,000 in counties with a population of greater than 500,000) patients with an ISS of 9 or greater, respectively.
- The FTSAC may also submit recommendations to the DOH on the adequacy and continuing development of the state's trauma system.
- In order to make recommendations required by the section, the FTSAC must review and consider materials submitted by the DOH and stakeholders, materials published by the American College of Surgeons Committee on Trauma (ACS), and other relevant materials as the FTSAC deems appropriate. The FTSAC must base its recommendation to the Governor and the Legislature on the following factors:
  - Population changes within a trauma service area;
  - The impact of tourism on a trauma service area;
  - The number of patients with an injury severity score of less than 0.9 who are treated in hospitals that are not trauma centers;
  - Ground and air transport times to a trauma center within each service area;
  - The number of patients treated in existing trauma centers;
  - The capacity of existing trauma centers to treat additional trauma patients;
  - The potential financial impact on existing trauma centers of the designation of additional trauma centers;
  - The financial impact on commercial and government payors of health care insurance and on Florida taxpayers caused by the designation of additional trauma centers;
  - A cost comparison of the charges of existing trauma centers as contrasted with the charges of any prospective trauma centers;
  - Any impacts on graduate medical education programs and resident training for trauma and surgical specialties in the state;
  - The negative impacts, if any, of the designation of new trauma centers on the ability of existing centers to meet standards established by the American College of Surgeons Committee on Trauma;
  - A survey of literature relating to trauma center allocation, including peer-reviewed and academic publications; and
  - Any other factor the advisory council deems appropriate.

Section 2 amends s. 395.4025, F.S., to rework how the DOH selects and licenses trauma centers.[14] The process under the bill will proceed under the following steps:

Letter of Intent

The bill requires the DOH to notify hospitals that the DOH is accepting letters of intent from applicants when there is statutory capacity for an additional trauma center based on the limits established in section one of the bill. The DOH may not accept a letter of intent from a hospital if there is not statutory capacity or if the hospital is located in a TSA or a contiguous TSA where a current Level I trauma center is located that has failed to exceed 1,000 patients annually.

Letters of Intent must be postmarked by October 1 of year one.

Application

By October 15 of year one[15] the DOH must send each hospital that provided a letter of intent an application package. Completed applications must be received by the DOH by April 1 of year two. Between April 1 and April 30 of year two, the DOH will conduct an initial review of the application packages it received to determine if each application shows that the hospital will be capable of attaining and operating with specified criteria by April 30 of year three. The operating criteria include:

- Equipment and physical facilities necessary to provide trauma services.
- Personnel in sufficient numbers and with proper qualifications to provide trauma services.
- An effective quality assurance process.
- A submitted written confirmation by the local or regional trauma agency that the hospital applying to become a trauma center is consistent with the plan of the local or regional trauma agency, as approved by the DOH, if such agency exists.

After April 30 of year two, the DOH must select one or more hospitals that meet the criteria detailed above, up to the statutory capacity designated in s. 395.402, F.S., for each TSA. If the DOH receives more applications than available capacity, the DOH must select one or more applicants, as necessary, that the DOH determines will provide the highest quality patient care using the most recent technological, medical, and staffing resources available as well as any other criteria as determined by the DOH in rule. At this point, the applicant may begin preparing to operate, but the bill restricts an applicant from operating until the DOH completes its final evaluation. A hospital that is not ready to operate by April 30 of year three may not be designated as trauma center.

In-Depth Evaluation

Between May 1 of year two and April 30 of year three the DOH must conduct an in-depth evaluation of each application against the criteria enumerated in the application packages. Also during this time frame the DOH must assemble a review team of out of state experts to make

[14] Note: Some of what is described in this section is current law. However, for the sake of providing a timeline for how the process will work after changes made by SB 1876, the portions that are current law are integrated into the changes made by the bill.

[15] The timeframes in the bill use dates over multiple years. In order to simplify the timeline, the timeframes will be referred to as happening in year one, year two, or year three.

onsite visits to all existing trauma centers. The bill maintains current law regarding the survey instrument that the out of state experts must use.

Designation as a Trauma Center

Based on the recommendations from the review team, the DOH may designate a trauma center that is in compliance with trauma center standards and the requirements in s. 395.4025, F.S. An applicant may not operate as a trauma center until it is designated and it must maintain the operating requirements detailed above. A trauma center is designated for a seven year approval period after which it must apply for renewal of its designation.

Under changes made by the bill, the DOH will no longer provisionally approve trauma centers prior to fully verifying them. The bill also restricts protests against any decision made by the DOH unless the protest is made by a hospital in the same or contiguous TSA.

Grandfathering

The bill deems certain currently operational trauma centers to be compliant with trauma center application and operational standards as follows::

- A trauma center that was verified by the DOH before December 15, 2017, is deemed to have met the trauma center application and operational requirements of this section.
- A trauma center that was not verified by the DOH before December 15, 2017, but that was provisionally approved by the DOH to be in substantial compliance with Level II trauma standards before January 1, 2017, and is operating as a Level II trauma center is deemed to have met the application and operational requirements of this section for a trauma center.
- A trauma center that was not verified by the DOH before December 15, 2017, as a Level I trauma center but that was provisionally approved by the DOH as a Level I trauma center in calendar year 2016 is deemed to have met the application and operational requirements for a Level I trauma center, if the trauma center complies with the American College of Surgeons Committee on Trauma standards for adult Level I trauma centers and does not treat pediatric trauma patients.
- A trauma center that was not verified by the DOH before December 15, 2017, as a pediatric trauma center but that was provisionally approved by the DOH to be in substantial compliance with the pediatric trauma standards established by rule before January 1, 2018, and is operating as a pediatric trauma center is deemed to have met the application and operational requirements of this section for a pediatric trauma center.
- Notwithstanding the statutory capacity limits established in s. 395.402(1), F.S., a trauma center is eligible for designation if all of the following apply:
    - The trauma center was not verified by the DOH before December 15, 2017;
    - The DOH initially provisionally approved the trauma center to begin operations in May 2017;
    - The trauma center is currently operating as a provisional Level II trauma center;
    - The DOH determines that the trauma center has met the application and operational requirements of this section for a Level II trauma center; and
    - The DOH's decision to provisionally approve the trauma center is:
        - Supported by a recommended order from the Division of Administrative Hearings and, if the order is appealed, the DOH's decision is upheld on appeal; or

- Not supported by a recommended order from the Division of Administrative Hearings, but the department's decision is upheld on appeal.

Section 3 of the bill amends s. 395.404, F.S., to eliminate the trauma registry under the DOH in favor of requiring trauma centers to participate in the National Trauma Data Bank. Trauma centers and acute care hospitals are still required to report all transfers and outcomes of trauma patients to the DOH.

The bill also eliminates a public records exemption for the DOH's trauma registry and eliminates the requirement that pediatric trauma centers report certain data to the DOH's brain and spinal cord injury central registry.

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 1876 may have an indeterminate positive fiscal impact on hospitals that do not currently have verified trauma centers but that become designated as a trauma center due to changes made by the bill.

Hospitals that have currently verified trauma centers in TSAs where new trauma centers are designated under the provisions of the bill may see an indeterminate negative fiscal impact due to the potential loss in volume of trauma patients and other economic impacts of competition.

C. Government Sector Impact:

The bill requires the DOH to make on-site visits to "all existing trauma centers." This provision could be interpreted to mean that the DOH is required to conduct on-site visits

to all 36 trauma centers every time it designates a new hospital as a trauma center. The estimated cost to visit all existing trauma centers is $500,000.[16]

VI. Technical Deficiencies:

None.

VII. Related Issues:

The timing on when the DOH must engage out-of-state surveyors to conduct an on-site visit of a trauma center applicant is unclear. The bill seems to require that such a visit be conducted before the trauma center is operational. If this is the case, it is unclear how the on-site visit would be completed without being able to survey the trauma center's actual operations. The timing in the bill should be clarified so that the on-site visit by the out-of-state surveyors occurs while the trauma center is operational.

The bill creates specific, date-based timeframes for the DOH and trauma center applicants to complete certain aspects of the application and approval process for new trauma centers. The bill also provides that applicants that are not ready to operate by April 30 of year three may not be designated as a trauma center. The bill does not provide any exception to this requirement for applicants that are in litigation over the DOH's selection process or that are otherwise delayed through no fault of their own.

The bill establishes grandfathering provisions for currently verified trauma centers and certain provisionally approved trauma centers on lines 496-538. However, the bill does not automatically designate such trauma centers as trauma centers under the requirements established by the bill. Rather, the bill deems such trauma centers to be compliant with trauma center application and operational standards. It is possible that the grandfathering provisions may be interpreted to require the DOH to perform a ministerial task to officially designate such trauma centers after the bill becomes effective. Additionally, the bill restricts any trauma center from operating if it has not been designated as a trauma center by the DOH. These two provisions, when taken together, may require all currently operating trauma centers to cease operations for the period of time between when the bill takes effect and when the DOH is able to officially designate them as trauma centers.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.402, 395.4025, and 395.404.

[16] Supra note 1

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 January 23, 2018:
The CS replaces grandfathering language related to Level II trauma centers in ongoing court proceedings to clarify that it is the DOH, and not a court, that must determine that the trauma center has met application and operational requirements, to specify the required court actions that qualify a trauma center under the paragraph, and to conform the title of the bill to changes made by the amendment.

B. Amendments:

None.