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 Rules

BILL: CS/CS/CS/SB 1876

INTRODUCER: Rules Committee; Appropriations Committee (Recommended by Appropriations Subcommittee on Health and Human Services); Health Policy Committee; and Senator Young

SUBJECT: Trauma Services

DATE: March 1, 2018 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.	Loe	Williams	AHS	**Recommend: Fav/CS**
3.	Loe	Hansen	AP	**Fav/CS**
4.	Looke	Phelps	RC	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/CS/SB 1876 amends various sections of law related to the selection and approval 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- Eliminates outdated language related to a Department of Health (DOH) assessment of the trauma system and continuing annual reviews of the assignment of counties to trauma service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 composition of certain TSAs.
- Restricts the DOH from designating a Level II trauma center as a pediatric or a Level I trauma center in a TSA that has a Level I or pediatric trauma center.
- Designates the number of trauma centers assigned to each TSA for a total of 35 trauma centers statewide and specifies that each TSA may have no more than five total Level I, Level II, Level II/pediatric, and stand-alone pediatric trauma centers, and no more than one standalone pediatric trauma center.
- Requires the DOH to establish the Florida Trauma System Advisory Council (FTSAC) by October 1, 2018. The bill specifies the composition of the FTSAC and allows the FTSAC to submit recommendations to the DOH on how to maximize existing resources to achieve an inclusive trauma system.
- Requires the DOH to prepare an analysis of the Florida trauma system every three years, beginning August 31, 2020, to include information on the population growth in each TSA,

the caseload levels of high-risk patients for each trauma center and acute care hospital in the TSA, and the percentage of minimum caseload levels established under the bill for each trauma center.
- Defines "high-risk patient" as an injured patient with an International Classification Injury Severity Score (ICISS) of less than 0.85.
- Revises the procedure for the DOH to select and approve new trauma centers if there is statutory capacity within a TSA.
- Allows the DOH to approve new trauma centers that exceed the statutory limit in a TSA if there is a sufficient volume of high-risk patients.
- Provides grandfathering language for currently verified trauma centers and for certain provisionally approved trauma centers and provides that if any of the grandfathering provisions are found to be invalid, the entire act is invalid.
- 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 (DOAH) 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.
- Replaces provisions requiring the use of data in the trauma registry with provisions requiring the use of data reported to the Agency for Health Care Administration (AHCA) pursuant to s. 408.061.

The DOH may experience an increase in workload. The cost of this additional workload will be absorbed within existing resources of the DOH.

The Office of Program Policy Analysis and Governmental Accountability (OPPAGA) may experience an increase in workload. The cost of this additional workload will be absorbed within existing resources of OPPAGA.

The bill takes effect upon becoming a law.

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 three 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

[1] Department of Health, *Senate Bill 1876 Analysis* (January 17, 2018) (on file with the Senate Committee on Health Policy).

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]

Trauma Center Apportionment

Pursuant to s. 395.402, F.S., Florida is divided into 19 trauma service areas (TSA). A TSA 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.

Administrative Rule Litigation

Since 2011, the DOH has been involved in 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 June 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.[6]

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[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).
[6] Shands Teaching Hospital and Clinics, Inc., d/b/a UF Shands Hospital v. Dep't of Health and Osceola Regional Hospital, Inc., d/b/a Osceola Regional Medical Center, DOAH Case No. 14-1022RP (June 20, 2014). This order also resolved the rule challenges filed by The Public Health Trust of Miami-Dade County (DOAH Case No. 14-1027RP); St. Joseph's Hospital, Inc., d/b/a St. Joseph's Hospital (DOAH Case No. 14-1028RP); Florida Health Sciences Center, Inc., d/b/a Tampa General Hospital (DOAH Case No. 14-1034RP); and Bayfront HMA Medical Center, LLC, d/b/a Bayfront Medical Center (DOAH Case No. 14-1035RP).

In 2016, the DOH attempted to promulgate an apportionment rule that interpreted need to mean the "minimum" number of trauma centers in a TSA. Several hospitals subsequently challenged the proposed rule.[7] The DOAH issued an order that invalidated the proposed rule in March 2017.[8] The administrative law judge recognized the challenges faced by the DOH and Florida's trauma system in his final order by stating, "[a]fter 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."[9] The case was appealed to the First District Court of Appeals (DCA) and is awaiting final disposition.[10] Since the invalidation of the rule, the DOH has been unable to promulgate a new rule.

In 2016, 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.[11] In addition, he indicated the DOH's determination of need happens at the point in which a trauma center is granted verification.[12] On appeal, the First DCA stated that a hospital may apply over multiple years without jeopardizing the previous application.[13] In a separate case, the First DCA addressed the issue of need and concurred that need is not addressed at the provisional licensure and is relevant only upon verification.[14]In combination, a hospital may essentially operate indefinitely as a provisional trauma center so long as they submit and receive approval of their provisional application annually.

The DOH has been unable to promulgate a valid allocation rule since July 2014.[15]

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[7] According to the DOAH's website, the challenges were filed by St. Joseph's Hospital, Inc., d/b/a St. Joseph's Hospital (Tampa) (DOAH Case No. 16-5841RP); Bayfront HMA Medical Center, LLC, d/b/a Bayfront Heath – St. Petersburg (DOAH Case No. 16- 5840RP); Lee Memorial Health System, d/b/a Lee Memorial Hospital (DOAH Case No. 16-5839RP); Florida Health Sciences Center, Inc., d/b/a Tampa General Hospital (DOAH Case No. 16-5838RP); and Shands Jacksonville Medical Center, Inc., d/b/a U.F. Hospital Jacksonville (DOAH Case No. 16-5837RP). Intervenors included JFK Medical Center Limited Partnership, d/b/a JFK Medical Center (Atlantis); The Public Health Trust of Miami-Dade County, Florida, d/b/a Jackson South Community Hospital; and Orange Park Medical Center, Inc., d/b/a Orange Park Medical Center.
[8] Shands Jacksonville Medical Center, Inc., d/b/a UF Health Jacksonville v. Dep't of Health, DOAH Case No. 16-5837RP (March 28, 2017). This order also resolved the rule challenges filed by Florida Health Science Center, Inc., d/b/a Tampa General Hospital (DOAH Case No. 16-5838RP); Lee Memorial Health System, d/b/a Lee Memorial Hospital (DOAH Case No. 16-5839RP); Bayfront HMA Medical Center, LLC, d/b/a Bayfront Health – St. Petersburg (DOAH Case No. 16-5840RP); and St. Joseph's Hospital, Inc., d/b/a St. Joseph's Hospital (DOAH Case No. 16-5841RP).
[9] Id.
[10] Dep't of Health, et al. v. Shands Jacksonville Medical Center, Inc., et al., Case No. 1D17-1713.
[11] The Public Health Trust of Miami-Dade County, Florida d/b/a Jackson South Community Hospital v. Dep't of Health and Kendall Healthcare Group, Ltd., d/b/a Kendall Regional Medical Center, DOAH Case No. 15-3171)
[12] Id. *See also* Public Health Trust of Miami-Dade County, Florida, d/b/a Jackson Medical Center and Jackson South Community Hospital v. Dep't of Health et al., DOAH Case No. 16-3370, 16-3372 ("Order Granting Motion to Partially Dismiss Petition for Administrative Hearing," pg. 4).
[13] The Public Health Trust of Miami-Dade County, Florida, d/b/a Jackson South Community Hospital v. Dep't of Health and Kendall Healthcare Group, Ltd., d/b/a Kendall Regional Medical Center, Case No. 1D16-3244.
[14] State of Florida, Department of Health v. Bayfront HMA Medical Center, LLC, d/b/a Bayfront Health-St. Petersburg, Case No. 1D17-2174 (consolidated with Galencare, Inc., d/b/a Northside Hospital v. Bayfront HMA. Medical Center, LLC, d/b/a Bayfront Health-St. Petersburg, Case No. 1D17-2229).
[15] Supra note 1

Trauma Center Approval

Section 395.4025, F.S., provides a scheduled application process and specific criteria for trauma center selection. 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 trauma center are developed in conjunction with the DOH's Division of 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 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 comply with the requirements of s. 395.4025, F.S., are approved to operate as a verified trauma center.[20]

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.[21]

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 to receive 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

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[16] The American College of Surgeons 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).
[17] The required criteria included in the application package is outlined in the DOH'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.
[18] Section 395.4025(5), F.S.
[19] Section 395.4025(6), F.S.
[20] Id.
[21] Supra note 1. A list of current litigation is on file with Senate Health Policy Committee staff.

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 local, regional, and statewide 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 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 DOH 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.[22]

International Classification Injury Severity Score (ICISS)

The ICISS is a score that indicates the likelihood of survival and is calculated from the set of injury-related diagnostic codes available in the patient's medical record. The ICISS ranges from 0 to 1, and a patient who has a score of .85 or less is considered a severely injured patient. The score is based on the International Classification of Diseases, 9th revision, with conversion tables in place to allow the use of the International Classification of Diseases, 10th revision.[23]

Health Care Data Submitted to the AHCA

Section 408.061, F.S., requires health care facilities to submit data to the AHCA including:
- Case-mix data;
- Patient admission and discharge data;
- Hospital emergency department data which includes the number of patients treated in the emergency department reported by patient acuity level;
- Data on hospital-acquired infections as specified by rule;
- Data on complications as specified by rule:
- Data on readmissions as specified by rule, with patient and provider-specific identifiers included;
- Actual charge data by diagnostic groups or other bundled groupings as specified by rule;
- Financial data, accounting data, operating expenses, expenses incurred for rendering services to patients who cannot or do not pay, interest charges, and depreciation expenses based on the expected useful life of the property and equipment involved; and
- Demographic data.

Additionally, s. 408.05, F.S., creates the Florida Center for Health Information and Transparency (Center) within the AHCA to collect, compile, coordinate, analyze, index, and disseminate health-related data and statistics. Among its other duties, the Center is required to promote data sharing through dissemination of state-collected health data by making such data available,

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[22] Supra note 1.
[23] Email from Steve A. McCoy, Emergency Services Administrator for the DOH, Feb. 22, 2018, on file with Senate Health Policy Committee staff.

transferable, and readily usable[24] and to develop written agreements with local, state, and federal agencies to facilitate the sharing of data related to health care.[25]

III. Effect of Proposed Changes:

Sections 1 through 4 and 8 amend ss. 318.14, 318.18, 318.21, 395.4001, and 395.4036, F.S., respectively, to replace provisions requiring the use of data in the trauma registry with provisions requiring the use of data reported to the AHCA pursuant to s. 408.061, F.S.

Section 4 amends s. 395.4001, F.S., to:
- Define the term "high-risk patient" to mean an injured patient with an ICISS of less than 0.85.
- Amend the definition of "International Classification Injury Severity Score" to mean the method for computing the severity of injuries sustained by trauma patients, based on the International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Clinical Modification, and adopted by the DOH by rule, in consultation with the FTSAC, along with any conversion tables or analytical tools used in its computation. This change updates the definition of ICISS to refer to the current version of the International Statistical Classification of Diseases and Related Health Problems.

Section 5 amends s. 395.402, F.S., to:
- Delete language requiring Level I and Level II trauma centers to be capable of treating a minimum of 1,000 and 500 patients annually (or 1,000 in a county with 500,000 or more population) with an injury severity score (ISS) of 9 or greater, respectively.
- Delete outdated language requiring the DOH to conduct a one-time assessment of the trauma system.
- Delete a requirement that the DOH conduct annual assessments of the assignment of the counties in TSAs.
- Revise the composition 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; and
  - Move Collier County from TSA 17 to TSA 15.
- Restrict the DOH from designating a Level II trauma center as a Level I or pediatric trauma center in a TSA that already has a Level I trauma center or pediatric trauma center.
- Delete the delegation of authority to the DOH to allocate the number of trauma centers by TSA and, instead, set by law the number of trauma centers allowed in each TSA for a total of 35, 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.
- Specify that no TSA may have more than five total Level I, Level II, Level II with a pediatric, jointly certified pediatric, and stand-alone pediatric trauma centers, and more than one stand-alone pediatric trauma center.

[24] Section 408.05(3)(b), F.S.
[25] Section 408.05(3)(d), F.S.

- Require the DOH to establish the FTSAC by October 1, 2018. The FSTAC will consist of the following 11 members appointed by the Governor:
  - The State Trauma Medical Director;
  - A standing member of the Emergency Medical Services Advisory Council;
  - A representative of a local or regional trauma agency;
  - A trauma program manager or trauma medical director actively working in a trauma center who represents an investor-owned hospital with a trauma center;
  - A trauma program manager or trauma medical director actively working in a trauma center who represents a nonprofit or public hospital with a trauma center;
  - A trauma surgeon who is board-certified in critical care and actively practicing medicine in a Level II trauma center who represents an investor-owned hospital with a trauma center;
  - A trauma surgeon who is board-certified in critical care and actively practicing medicine who represents a nonprofit or public hospital with a trauma center;
  - A representative of the American College of Surgeons Committee on Trauma;
  - A representative of the Safety Net Hospital Alliance of Florida;
  - A representative of the Florida Hospital Association;
  - A Florida-licensed, board-certified emergency medicine physician who is not affiliated with a trauma center; and
  - A trauma surgeon who is board-certified in critical care and actively practicing medicine in a Level I trauma center.
- Specify that the DOH must use existing and available resources to administer and support the activities of the FTSAC.
- Specify that members of the FTSAC serve without compensation and are not entitled to reimbursement for per diem and travel expenses.
- Require members of the FTSAC to be appointed for staggered terms and no two members may be employed by the same health care facility.
- Require the FTSAC to conduct its first meeting no later than January 5, 2019 and quarterly thereafter.
- Allow the FTSAC to submit recommendations to the DOH on how to maximize existing trauma center, emergency department, and emergency medical services infrastructure and personnel to achieve the statutory goal of developing an inclusive trauma system.

Section 6 amends s. 395.4025, F.S., to:

- Require the DOH to prepare an analysis of the Florida trauma system every three years, beginning in August 31, 2020. The DOH must use discharge data collected by the AHCA pursuant to s. 408.061, F.S., and the most current five years of population data for Florida available from the American Community Survey Five-Year Estimates by the United States Census Bureau. The DOH must make available all data, formulas, methodologies, calculations, and risk adjustment tools used to prepare the report. The report must include the following:
  - The population growth for each trauma service area and for the state of Florida;
  - The number of high-risk patients treated at each trauma center within each trauma service area, including pediatric trauma centers;
  - The total number of high-risk patients treated at all acute care hospitals inclusive of non-trauma centers in the trauma service area; and

  - The percentage of each trauma center's sufficient volume of trauma patients, as described in subparagraph (3)(d)2., in accordance with the Injury Severity Score for the trauma center's designation, inclusive of the additional caseload volume required for those trauma centers with graduate medical education programs.
- Rework how the DOH selects and licenses trauma centers.[26] 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 5** of the bill, the analysis prepared by the DOH as detailed above, and the exception to the statutory capacity limits established in s. 395.4025(3)(d), F.S. The DOH may not accept a letter of intent from a hospital if there is not statutory capacity, in accordance with the limits established in **Section 5** of the bill, the DOH's report, and exceptions to the statutory capacity limits provided in the bill.

Letters of Intent must be postmarked by October 1 of year one. [27]

Application

By October 15 of year one, 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].[28] Between April 1 and May 1 [of year two], the DOH will conduct an initial review of each application package 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.

The bill specifies that the DOH may not approve an application for a trauma center if the approval would exceed the limits on the number of trauma centers established in **Section 5** of the bill. However, the DOH may approve an application that will exceed the limits if the applicant demonstrates, using the analysis of the Florida trauma system prepared by the DOH, and the DOH determines that:
- Each existing trauma centers' caseload volume of high-risk patients in that TSA is double the minimum volume requirement for Level I and Level II trauma centers and more than triple the minimum volume requirements for stand-alone pediatric trauma centers and the population growth for the trauma service area exceeds the statewide population growth by more than 15 percent based on the American Community Survey Five-Year Estimates by the

[26] Note: Some of the information presented in this section is current law. However, for the sake of providing a timeline for how the process will work after changes are made by SB 1876, the portions that are current law are integrated into the changes made by the bill.
[27] 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.
[28] The actual year that this takes place is not specified in the bill; however for the purposes of the timeline in this analysis the year will be assumed to be year two.

United States census data for the five-year period before the date the applicant files its letter of intent; and

- A sufficient volume of potential trauma patients exists within the trauma service area to ensure that existing trauma centers' volumes are at the following levels:[29]

Level I trauma center; In a TSA with a population > 1.5 million.	1,200 high-risk patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.[30]
Level I trauma center; In a TSA with a population < 1.5 million.	1,000 high-risk patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.[31]
Level II or Level II/Pediatric trauma center; In a TSA with a population > 1.25 million.	1,000 high-risk patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.[32]
Level II or Level II/Pediatric trauma center; In a TSA with a population < 1.25 million.	500 high-risk patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.[33]
All pediatric stand-alone trauma centers.	500 high-risk patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.[34]

- The bill specifies that ICISS calculations and caseload volumes must be calculated using the most recent available hospital discharge data collected by the AHCA from all acute care hospitals.
- The AHCA, in consultation with the DOH, must adopt rules for the submission of data from trauma centers and acute care hospitals as required to allow the DOH to perform its duties under ch. 395, F.S.

By May 1 [of year two],[35] the DOH must select one or more hospitals that meet the operating criteria detailed above, up to the statutory capacity designated in s. 395.402, F.S., or allowed by the exception detail above 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 and which is the farthest away from an existing trauma center in the applicant's TSA. At this point, the applicant may begin preparing to operate, but the bill restricts

[29] Calculations of patient caseloads must be based on the most recent available hospital discharge data collected by the AHCA pursuant to s. 408.061, F.S.
[30] These additional patients apply if the hospital has a trauma or critical care residency or fellowship program.
[31] Supra note 30.
[32] Supra note 30.
[33] Supra note 30.
[34] Supra note 30.
[35] Supra note 28.

an applicant from operating until the DOH completes its initial and in-depth review and approves the applicant to operate as a provisional trauma center. A hospital that is not ready to operate by April 30 of year three may not be designated as a trauma center.

In-Depth Evaluation

Following the initial review, the DOH must conduct an in-depth evaluation of each application against the criteria enumerated in the application packages. An applicant may not operate as a provisional trauma center until the DOH completes and approves the applicant through the initial and in-depth review stages. Within the year after the hospital begins operating as a provisional trauma center, the DOH must assemble a review team of out-of-state experts to make 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 out-of-state review team, the DOH must designate a trauma center that complies with trauma center standards, as established by the DOH in rule, and the requirements in s. 395.4025, F.S. A trauma center is designated for a seven-year approval period after which it must apply for renewal of its designation.

The bill also restricts protests against any decision made by the DOH regarding approval of an application or whether need has been established for a new trauma center unless the protest is made by an applicant or a hospital with an existing trauma center in the same or contiguous TSA.

Grandfathering

Notwithstanding any other provision of the act including statutory capacity limits and the limits placed on protests of DOH decisions, 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 and must be verified and designated as a trauma center.
- 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 and must be verified and designated as a Level II 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 before January 1, 2017, and is operating as a Level I trauma center is deemed to have met the application and operational requirements for a Level I trauma center and must be verified and designated as a Level I trauma center.
- 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 and, upon successful

completion of the in-depth and site review process, must be verified and designated as a pediatric trauma center. The bill prohibits protests of the in-depth review, site survey, and verification decisions made by the DOH regarding an applicant that meets the requirements of this paragraph.

Notwithstanding the statutory capacity limits established in s. 395.402(1), F.S., or any other provisions of the act, a hospital operating as a Level II after January 1, 2017, must be designated and verified if all of the following apply:

- The hospital was provisionally approved after January 1, 2017, to operate as a Level II trauma center, and was in operation on or before June 1, 2017;
- The department's decision to approve the hospital to operate a provisional Level II trauma center was in litigation on or before January 1, 2018;
- The hospital receives a recommended order from the Division of Administrative Hearings, a final order from the department, or an order from a court of competent jurisdiction that it was entitled to be designated and verified as a Level II trauma center; and
- The department determines that the hospital is in substantial compliance with the Level II trauma center standards, including the in-depth and site reviews.

A provisional trauma center operating under this provision may not be required to cease operations unless a court of competent jurisdiction or the DOH determines that is has failed to meet the trauma center standards established by the DOH in rule.

The bill specifies that, notwithstanding the statutory capacity limits established in s. 395.402(1), F.S., or any other provision of this act, a joint pediatric trauma center involving a Level II trauma center and a specialty licensed children's hospital which was verified by the DOH before December 15, 2017, is deemed to have met the application and operational requirements of this section for a pediatric trauma center and shall be verified and designated as a pediatric trauma center even if the joint program is dissolved upon the expiration of the existing certificate and the pediatric trauma center continues operations independently through the specialty licensed children's hospital, provided that the pediatric trauma center meets all requirements for verification by the DOH.

The bill specifies that nothing in the grandfathering provisions limits the DOH's authority to review and approve trauma center applications.

Section 9 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. The bill requires the DOH to solely use the National Trauma Data Bank for quality and assessment purposes. 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.

Section 13 creates an undesignated section of Florida law to require that the DOH and the Office of Program Policy Analysis and Government Accountability (OPPAGA) study the DOH's

licensure requirements, rules, regulations, standards, and guidelines for pediatric trauma services and compare them to the licensure requirements, rules, regulations, standards, and guidelines for verification of pediatric trauma services by the American College of Surgeons. The OPPAGA must submit a report to the Governor, the Legislature, and the FTSAC by December 31, 2018. The bill specifies that this section expires on January 31, 2019.

Section 14 creates an undesignated section of Florida law to specify that if any provision in the act relating to the grandfathering provisions established in s. 395.4025(16), F.S., is found to be invalid or inoperative for any reason, the remaining provisions of the act shall be deemed void and of no effect, it being the legislative intent that this act as a whole would not have been adopted had any provision of the act not been included.

Sections 7, 10, 11, and 12 amend ss. 395.403, 395.401, 408.036, and 409.975, F.S., respectively, to make conforming and cross-reference changes.

Section 15 provides that the bill takes effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues

When establishing the grandfathering provisions in s. 395.4025(16), F.S., the bill provides that "notwithstanding the provisions of subsection (8), no existing trauma center in the same trauma service area or in a trauma service area contiguous to the trauma service area where the applicant is located may protest the in-depth review, site survey, or verification decision of the department regarding an applicant that meets the requirements of this paragraph." Additionally, the provisions of s. 395.4025(8), F.S., restrict any party from brining protests of DOH decisions related to application approval and need determination unless the party is the applicant or a hospital with a trauma center in the same trauma service area or in a trauma service area contiguous to the trauma service area where the applicant is located. These provisions together may provide an unconstitutional restriction on access to the courts.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

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

Hospitals that are currently verified trauma centers in TSAs where new trauma centers are designated under the provisions of the bill may experience a loss in volume of trauma patients and other economic impacts of competition.

C. Government Sector Impact:

The DOH may experience an increase in workload. The cost of this additional workload will be absorbed within existing resources of the DOH.

OPPAGA may experience additional workload and costs associated with the report required in Section 13. The costs will be absorbed within existing workload.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The DOH may need to adopt rules or amend existing rules to implement the bill. Rule authority exists for the DOH in s. 395.405, F.S.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 318.14, 318.18, 318.21, 395.4001, 395.401, 395.402, 395.4025, 395.403, 395.4036, 395.404, 408.036, and 409.975.

The bill creates two undesignated sections of Florida law.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS/CS by Rules on March 1, 2018:
The CS revises the definition of “high-risk patient” to refer to injured patients, rather than trauma patients, with an ICISS of less than 0.85, and amends the definition of

"International Classification Injury Severity Score" to mean the method for computing the severity of injuries sustained by trauma patients, based on the International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Clinical Modification, and adopted by the DOH by rule, in consultation with the FTSAC, along with any conversion tables or analytical tools used in its computation.

This change updates the definition of ICISS to refer to the current version of the International Statistical Classification of Diseases and Related Health Problems.

CS/CS by Appropriations on February 22, 2018:
The committee substitute:

- Adds references to AHCA discharge data collected pursuant to s. 408.061, F.S., to replace data reported to the DOH's Trauma Registry in multiple sections of the Florida Statutes.
- Corrects additional cross-references related to the elimination of the Trauma Registry.
- Defines the term "high risk" to mean a trauma patient with an International Classification Injury Severity Score less than .85 and uses this term in place of referencing "severely injured patients."
- When referencing types of trauma centers throughout the bill, clarifies the list to include a "Level II with a pediatric trauma center" and a "jointly certified pediatric trauma center."
- Specifies that no TSA may have more than five total Level I, Level II, Level II/pediatric, jointly certified pediatric trauma centers, and stand-alone pediatric trauma centers and no more than one stand-alone pediatric trauma center.
- Revises the make-up and duties of the Florida Trauma System Advisory Council (FTSAC).
  - Eliminates the requirement that the Council determine the need for additional trauma centers and the adequacy of the existing trauma system.
  - Eliminates the requirement to submit a biennial report to the Governor and the Legislature on whether to recommend an increase in the number of trauma centers within each service area.
  - Allows the Council to submit recommendations to the DOH on how to maximize existing trauma center, emergency department, and emergency medical services infrastructure and personnel to achieve the statutory goal of developing an inclusive trauma system.
  - Eliminates the following members of the Council: The State Surgeon General, a representative from the AHCA; a trauma program manager recommended by the Florida Teaching Hospital Council of Florida; a trauma surgeon recommended by the Florida Teaching Hospital Council of Florida, a representative of the Associated Industries of Florida, and a trauma program manager or medical director representing a public hospital.
  - Adds the state Trauma Medical Director and a trauma surgeon board-certified in critical care actively practicing medicine in a Level I trauma center to the council.
  - Adds a Florida-licensed, board-certified emergency medicine physician who is not affiliated with a trauma center.
  - Clarifies that the representative from an EMS organization must be a standing member of the Emergency Medical Services Advisory Council.

  - Requires the Council to meet quarterly.
- Specifies that the DOH must use existing resources to administer and support the activities of the FTSAC and the FTSAC members serve without compensation or reimbursement for travel or per diem expenses.
- Requires the DOH to prepare an analysis of the Florida trauma system by August 31, 2020, and every three years thereafter.
- Requires the analysis to use AHCA discharge data and the Florida population data from the American Community Survey Five-Year Estimates by the United States Census Bureau and must include:
  - The population growth for each TSA and for the state of Florida;
  - The number of high-risk patients at each trauma center within each TSA;
  - The total number of high-risk patients at all acute care hospitals, including non-trauma centers in each TSA; and
  - The percentage of each trauma center's sufficient volume of trauma patients as established in the bill.
- Specifies that the DOH must make calculations, data, formulas, methodologies, and risk adjustment tools used in preparing the analysis available.
- Allows the DOH accept a letter of intent and to approve an application for a new trauma center in a TSA that is already at its statutory maximum if each existing trauma centers' case load volume of high-risk patients is double the minimum volume requirement for Level I and Level II trauma centers and more than triple the minimum volume requirements for stand-alone pediatric trauma centers.
  - Specifies that, when demonstrating a need for an additional trauma center in a particular TSA over the statutory caps, the applicant must use the analysis prepared by the DOH.
  - Specifies that the determination for the required population growth must be based on the American Community Survey Five-Year Estimates by the United States Census Bureau for the five-year period before the date the applicant files its letter of intent.
  - Specifies that additional caseload volumes for certain residents and fellows apply to hospitals with a trauma or critical care residency or fellowship program.
- The minimum caseload volumes established in the bill are as follows:
  - Level I trauma center in a TSA with a population > 1.5 million: 1,200 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.
  - Level I trauma center in a TSA with a population < 1.5 million: 1,000 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.
  - Level II or Level II/Pediatric trauma center in a TSA with a population > 1.25 million: 1,000 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.
  - Level II or Level II/Pediatric trauma center in a TSA with a population < 1.25 million: 500 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.

  - All pediatric stand-alone trauma centers: 500 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.
- Requires the AHCA, in consultation with the DOH, to develop rules to ensure that hospitals and trauma centers are submitting data required by the DOH to perform its duties under ch. 395, F.S.
- Specifies that, when selecting from a pool of applicants, the DOH must select the highest quality applicant that is farthest away from an existing trauma center in the TSA.
- Allows an applicant to operate as a provisional trauma center after the DOH has completed the initial and in-depth review processes.
- Requires the out-of-state review team to perform an onsite visit within the year after the trauma center has begun provisionally operating.
- Requires (rather than allows) the DOH to designate a trauma center that is in compliance with trauma center standards based on the recommendation from the review team.
- Allows the applicant, as well as hospitals with trauma centers in the same or contiguous TSAs, to protest decisions made by the DOH regarding application approval and determination of need.
- Restricts such protests for the designation of a pediatric trauma center that is grandfathered in.
- Specifies that certain provisional trauma centers must be allowed to continue operations until a court or the DOH determines that they have failed to meet the Florida trauma standards.
- Specifies that none of the grandfathering provisions limit the DOH's authority to review and approve trauma center applications.
- Specifies that if the grandfathering provisions of the act are found to be invalid or inoperative, the entire act becomes invalid.
- Requires the DOH and OPPAGA to study the DOH's licensure requirements, rules, regulations, standards, and guidelines for pediatric trauma services to compare them with the American College of Surgeon's requirements. The OPPAGA must submit a report to the Governor and the Legislature by December 31, 2018. The section expires on January 31, 2019.
- Makes other technical and conforming changes.

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; specifies the required court actions that qualify a trauma center under the paragraph; and conforms the title of the bill to changes made by the amendment.

B. Amendments:

None.

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