

**HOUSE OF REPRESENTATIVES  
FINAL BILL ANALYSIS**

<b>BILL #:</b>	CS/CS/HB 1165	<b>FINAL HOUSE FLOOR ACTION:</b>		
<b>SUBJECT/SHORT TITLE</b>	Trauma Services	110	Y's 0	N's
<b>SPONSOR(S):</b>	Health & Human Services Committee; Health Quality Subcommittee; Trumbull	<b>GOVERNOR'S ACTION:</b>	Approved	
<b>COMPANION BILLS:</b>	CS/CS/CS/SB 1876			

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**SUMMARY ANALYSIS**

CS/CS/HB 1165 passed the House on March 5, 2018, , as amended, and subsequently passed the Senate on March 6, 2018.

The Department of Health (DOH) oversees the statewide trauma system. Currently, DOH designates trauma centers in regional trauma services areas (TSAs) to ensure access to trauma services, but may designate no more than 44 trauma centers in the state. Over the years, there has been extensive litigation related to DOH's apportionment of trauma centers needed in a particular trauma service area, as well as litigation related to the designation of specific hospitals as trauma centers.

CS/CS/HB 1165 redesigns the state's trauma system. The bill limits the number of trauma centers in the state to 35. The bill provides a process for approving trauma centers in excess of the statewide cap based upon current population, trauma caseload, and expected population growth. The bill also requires DOH to analyze the trauma system every three years, beginning August 2020, to determine if additional trauma centers are required. The bill restricts legal challenges to DOH's decisions related to the trauma system to applicants and existing trauma centers in the same TSA or a contiguous TSA.

The bill eliminates the state's trauma registry under DOH and requires trauma centers to participate in the National Trauma Data Bank. Trauma centers and acute care hospitals must still report all transfers and outcomes of trauma patients to DOH.

The bill creates the Florida Trauma System Advisory Council, which is appointed by the Governor. The council must hold its first meeting by June 1, 2018, and is authorized to submit recommendations to DOH on how to maximize existing resources to achieve an inclusive trauma system. The bill requires the advisory council to study the feasibility of using a national certification for pediatric trauma centers. The advisory council must report its findings and recommendations to the Governor and Legislature by December 31, 2018.

The bill grandfathers currently verified and certain provisionally approved trauma centers and provides that if any of the provisions related to the grandfathering are determined to be invalid, then the remaining provisions of the act are deemed to be void.

The bill may have a positive fiscal impact on DOH and has no fiscal impact on local governments.

The bill was approved by the Governor on March 21, 2018, ch. 2018-66, L.O.F., and became effective on that date.

**This document does not reflect the intent or official position of the bill sponsor or House of Representatives.**

**STORAGE NAME:** h1165z1.HQS

**DATE:** March 22, 2018

# I. SUBSTANTIVE INFORMATION

## A. EFFECT OF CHANGES:

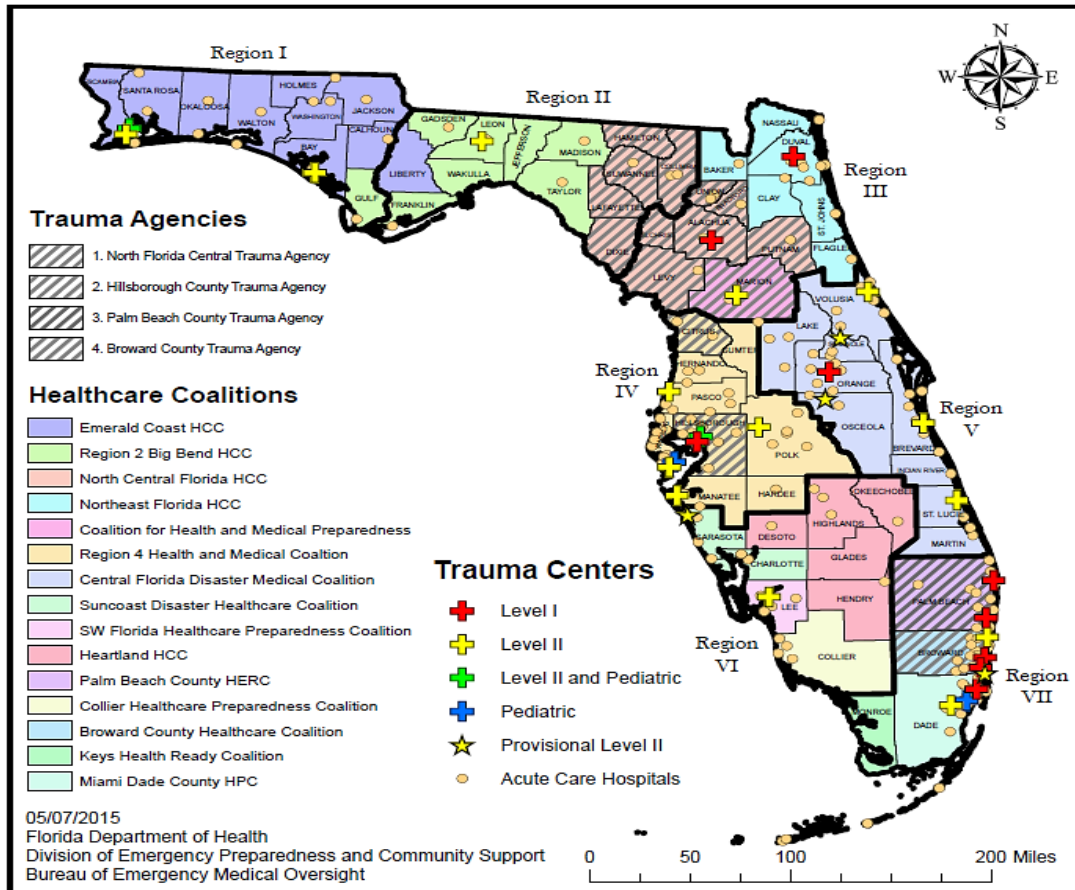
### Current Situation

#### Florida Trauma System

Trauma centers in Florida are governed by Part II of Chapter 395, F.S., and by the Department of Health (DOH) rule in Chapter 64J-2, F.A.C. A trauma center is a type of hospital that provides trauma surgeons, neurosurgeons, and other surgical and non-surgical specialists and medical personnel, equipment, and facilities for immediate or follow-up treatment of severely injured patients who have sustained a single or multisystem injury due to blunt or penetrating means or burns.<sup>1</sup> As part of the state trauma system plan, DOH must establish trauma regions which cover all geographical areas of the state and align with the state's seven Regional Domestic Security Task Force regions established by the Department of Law Enforcement (FDLE).<sup>2</sup> These regions may serve as the basis for the development of DOH-approved local or regional trauma plans.

#### *Florida Trauma Service Areas, Agencies and Regions*

Florida's trauma system has 7 trauma regions and 19 trauma service areas (TSAs). The seven trauma regions are illustrated below.<sup>3</sup>



<sup>1</sup> See generally, American College of Surgeons, *Resources for Optimal Care of the Injured Patient*, (2014), available at <https://www.facs.org/~media/files/quality%20programs/trauma/vrc%20resources/resources%20for%20optimal%20care.aspx> (last visited January 28, 2018).

<sup>2</sup> Section 395.4015, F.S.; s. 943.0312(1), F.S.

<sup>3</sup> Department of Health, *Florida Trauma Agencies & Healthcare Coalitions with Trauma Centers and Acute Care Hospitals*, (May 2015), available at <https://www.hillsboroughcounty.org/library/hillsborough/media-center/documents/trauma/trauma-agencies-trauma-centers-health-care-coalitions-rdtsfs.pdf?la=en> (last visited January 28, 2018).

Florida is divided into nineteen TSAs, detailed below.<sup>4</sup>

TRAUMA SERVICE AREAS (TSAs) IN FLORIDA		
TSA	COUNTIES IN TSA	POPULATION <sup>5</sup>
1	Escambia, Okaloosa, Santa Rosa, Walton	745,006
2	Bay, Gulf, Holmes, Washington	240,314
3	Calhoun, Franklin, Gadsden, Jackson, Jefferson, Leon, Liberty, Madison, Taylor, Wakulla	510,653
4	Alachua, Bradford, Columbia, Dixie, Gilchrist, Hamilton, Lafayette, Levy, Putnam, Suwannee, Union	588,508
5	Baker, Clay, Duval, Nassau, St. Johns	1,482,722
6	Citrus, Hernando, Marion	674,950
7	Flagler, Volusia	628,562
8	Lake, Orange, Osceola, Seminole, Sumter	2,558,683
9	Pasco, Pinellas	1,467,712
10	Hillsborough	1,379,312
11	Hardee, Highlands, Polk	791,220
12	Brevard, Indian River	724,185
13	Desoto, Manatee, Sarasota	811,676
14	Martin, Okeechobee, St. Lucie	491,810
15	Charlotte, Glades, Hendry, Lee	923,347
16	Palm Beach	1,414,160
17	Collier	357,487
18	Broward	1,873,988
19	Dade, Monroe	2,820,003

The TSAs are designed to provide the best and fastest services to the state's population. Each TSA should have at least one Level I or Level II trauma center and there may be no more than 44 trauma centers in the state.<sup>6</sup> Each Level I and Level II trauma center must be capable of annually treating a minimum of 1,000 and 500 patients, respectively, with an injury severity score of 9 or greater.<sup>7</sup> A Level II trauma center in a county with a population of more than 500,000 must have the capacity to care for 1,000 patients per year.<sup>8</sup> Currently, TSA 17 (Collier) is not directly covered by a trauma center.<sup>9</sup>

DOH is required to apportion, by rule, the number of trauma centers needed for each TSA.<sup>10</sup> Additionally, DOH is required to adopt rules based on standards for verification of trauma centers based on national guidelines, to include those established by the American College of Surgeons (ACS) entitled "Hospital and Pre-hospital Resources for Optimal Care of the Injured Patient" and standards specific to pediatric trauma centers are to be developed in conjunction with the DOH Division of Children's Medical Services.<sup>11</sup>

The system also includes local and regional trauma agencies, but at any one time there have been four agencies in existence: the North Central Florida Trauma Agency, Hillsborough County Trauma Agency, Palm Beach Trauma Agency and Broward County Trauma Agency. A trauma agency<sup>12</sup> develops a

<sup>4</sup> Section 395.402(4)(a), F.S.

<sup>5</sup> Office of Economic and Demographic Research, *Florida Population Estimates for Counties and Municipalities April 1, 2017*, (Oct. 17, 2017), available at [http://edr.state.fl.us/Content/population-demographics/data/2017\\_Pop\\_Estimates.pdf](http://edr.state.fl.us/Content/population-demographics/data/2017_Pop_Estimates.pdf) (last visited January 23, 2018).

<sup>6</sup> Section 395.402(4)(b) and (c), F.S.

<sup>7</sup> Section 395.402(1), F.S.

<sup>8</sup> Id.

<sup>9</sup> Florida Department of Health, *Amended Trauma Service Area Assessment*, January 6, 2016, page 23, available at [www.floridahealth.gov/licensing-and-regulation/trauma-system/documents/trauma-area-service-assessment.pdf](http://www.floridahealth.gov/licensing-and-regulation/trauma-system/documents/trauma-area-service-assessment.pdf) (last visited on January 23, 2018).

<sup>10</sup> Section 395.402(4)(b), F.S., and Rule 64J-2.010, F.A.C.

<sup>11</sup> Section 395.401(2), F.S., and Rule 64J-2.011, F.A.C.

<sup>12</sup> A trauma agency is a DOH-approved agency established and operated by one or more counties, or a DOH-approved entity with which one or more counties contract, for the purpose of administering an inclusive regional trauma system. (S. 395.4001(11), F.S.)

plan for its local and regional trauma services system. The plan must be submitted to DOH for approval and must include:

- The organizational structure of the trauma system;
- Prehospital care management guidelines for triage and transportation of trauma cases;
- The flow patterns of trauma cases and transportation system design and resources;
- The number and location of needed trauma centers based on local needs, population, and location and distribution of resources;
- Data collection regarding system operation and patient outcomes;
- Periodic performance evaluation of the trauma system and its components;
- The use of air transport services within the jurisdiction of the trauma agency;
- Public information and education about the trauma system;
- Emergency medical services communication system usage and dispatching;
- The coordination and integration between the trauma center and other acute care hospitals;
- Medical control and accountability; and
- Quality control and system evaluation.

Florida only has one regional trauma agency and three local trauma agencies. Although, by rule,<sup>13</sup> trauma agency boundaries are to be aligned with the Regional Domestic Security Task Force regions, none of regional or local trauma agencies have boundaries that align with these regions.<sup>14</sup>

### *Trauma Centers*

A hospital may receive a designation as a Level I, Level II, pediatric, or provisional trauma center if DOH verifies that the hospital is in substantial compliance with s. 395.4025, F.S., and the relevant trauma center standards.<sup>15</sup> A trauma center may have more than one designation; for example, Sacred Heart Hospital in Pensacola carries both a Level II and a pediatric trauma center designation. As of January 16, 2018, the following hospitals are designated trauma centers:<sup>16</sup>

TRAUMA CENTER	LEVEL	COUNTY (TSA)
Aventura Hospital and Medical Center	Level II	Miami-Dade (19)
Baptist Hospital	Level II	Escambia (1)
Bay Medical Center Sacred Heart	Level II	Bay (2)
Bayfront Medical Center	Level II	Pinellas (9)
Blake Medical Center	Level II	Manatee (13)
Broward Health Medical Center	Level I	Broward (18)
Broward Health North	Level II	Broward (18)
Central Florida Regional Hospital	Level II	Seminole (8)
Delray Medical Center	Level I	Palm Beach (16)
Fort Walton Beach Medical Center	Level II	Okaloosa (1)
Halifax Hospital Medical Center / Halifax Health	Level II	Volusia (7)
Holmes Regional Medical Center, Inc.	Level II	Brevard (12)
Jackson Memorial Hospital / Ryder Trauma Center	Level I	Miami-Dade (19)
Jackson South Community Hospital	Provisional Level II	Miami-Dade (19)
Johns Hopkins All Children's Hospital, Inc.	Pediatric	Pinellas (9)
Kendall Regional Medical Center	Provisional Level I	Miami-Dade (19)
Lakeland Regional Medical Center, Inc.	Level II	Polk (11)
Lawnwood Regional Medical Center & Heart Institute	Level II	St. Lucie (14)
Lee Memorial Health System	Level II	Lee (15)

<sup>13</sup> Rule 64J-2.007, F.A.C.

<sup>14</sup> *Supra* note 9, at pg. 5.

<sup>15</sup> The trauma center standards are provided in DOH Pamphlet 150-9 and codified in Rule 64J-2.011, F.A.C. The standards were last updated in January 2010.

<sup>16</sup> Florida Department of Health, *Florida Trauma Centers*, available at <http://www.floridahealth.gov/%5C/licensing-and-regulation/trauma-system/ documents/traumacenterlisting2018.pdf> (last visited on January 23, 2018).

Memorial Hospital (Jacksonville)	Provisional Level II	Duval (5)
Memorial Regional Hospital	Level I	Broward (18)
Ocala Regional Medical Center	Level II	Marion (6)
Orange Park Medical Center	Provisional Level II	Clay (5)
Orlando Regional Medical Center	Level I	Orange (8)
Osceola Regional Medical Center	Level II	Osceola (8)
Regional Medical Center Bayonet Point	Level II	Pasco (9)
Sacred Heart Health System, Inc.	Level II / Pediatric	Escambia (1)
Sarasota Memorial Hospital	Level II	Sarasota (13)
Shands Jacksonville/ UF Health Jacksonville	Level I	Duval (5)
Shands UF (Gainesville)	Level I	Alachua (4)
Southern Baptist Hospital of Florida / Wolfson Children's Hospital	Provisional Pediatric	Duval (5)
St. Joseph's Hospital, Inc.	Level II / Pediatric	Hillsborough (10)
St. Mary's Medical Center, Inc.	Level I	Palm Beach (16)
Tallahassee Memorial Healthcare, Inc.	Level II	Leon (3)
Tampa General Hospital	Level I	Hillsborough (10)
Variety Children's Hospital, Inc. Nicklaus Children's Hospital	Pediatric	Miami-Dade (19)

A provisional trauma center is a hospital that has been verified to be in substantial compliance with the requirements in s. 395.4025, F.S., is approved by DOH to operate as a provisional Level I, Level II, or pediatric trauma center, and has applied to be a verified trauma center.<sup>17</sup> A hospital that is granted provisional status operates as a provisional trauma center for up to one year while DOH conducts an in-depth review and a provisional onsite survey prior to deciding to approve or deny verification.<sup>18</sup> Currently, there is one provisional Level I trauma center, Kendall Regional Medical Center in Miami; three provisional Level II trauma centers, Jackson South Community Hospital in Miami, Memorial Hospital in Jacksonville, Orange Park Medical Center in Orange Park; and one provisional pediatric trauma center, Wolfson Children's Hospital.

A Level I trauma center serves as a resource facility to Level II trauma centers, pediatric trauma referral-centers, and general hospitals through shared outreach, education, and quality-improvement activities.<sup>19</sup> A Level I trauma center must have:<sup>20</sup>

- A minimum of five qualified trauma surgeons, assigned to the trauma service, with at least two trauma surgeons available to provide in-hospital trauma services and backup trauma coverage 24 hours a day, when summoned.
- Twelve surgical specialties and eleven non-surgical specialties. These specialties must be available to provide in-hospital trauma services and backup trauma coverage 24 hours a day, when summoned.
- Formal research and education programs for the enhancement of both adult and pediatric trauma care.

A Level II trauma center serves as a resource facility to general hospitals through shared outreach, education, and quality improvement activities.<sup>21</sup> A Level II trauma center must have:<sup>22</sup>

- A minimum of five qualified trauma surgeons, assigned to trauma service, with at least two trauma surgeons available to arrive promptly to the trauma center to provide trauma services

<sup>17</sup> Section 395.4001(10), F.S.

<sup>18</sup> Section 395.4025(3), (5), and (6), F.S.

<sup>19</sup> Section 395.4001(6)(b), F.S.

<sup>20</sup> Florida Department of Health, *Trauma Center Standards*, Pamphlet 150-9, January 2010, pages 2.1-2.38, available at <http://www.floridahealth.gov/licensing-and-regulation/trauma-system/documents/traumacntstrandpamphlet150-9-2009rev1-14-10.pdf> (last visited on January 23, 2018).

<sup>21</sup> Section 395.4001(7)(b), F.S.

<sup>22</sup> *Supra* note 20 at pages 3.2-3.33.

within 30 minutes from inside or outside of the hospital, and backup trauma coverage 24 hours a day, when summoned.

- Nine surgical specialties and nine non-surgical specialties available to provide trauma services and arrive promptly to provide trauma coverage 24 hours a day, when summoned.

In contrast to the requirements of a Level I or Level II trauma center, a pediatric trauma center must have:<sup>23</sup>

- A minimum of five qualified trauma surgeons<sup>24</sup>, assigned to the trauma service, with at least two trauma surgeons available to provide trauma services and backup trauma coverage 24-hours a day, when summoned. If the trauma medical director is not a pediatric surgeon, then at least one of the five must be a pediatric surgeon.
- Ten surgical specialties and eight non-surgical specialties available 24 hours a day to arrive promptly when summoned.
- Formal research and education programs for the enhancement of pediatric trauma care.

All trauma centers are required to submit quality indicator data to the Florida Trauma Registry.<sup>25</sup>

### *Florida Trauma System Reforms*

During the 2003-2004 legislative interim, the Florida Senate's Committee on Home Defense, Public Security, and Ports conducted a study to review Florida's hospital response capacity and examine the disparity of available trauma centers across the state.<sup>26</sup> The study recommended adopting the borders of the seven Regional Domestic Security Task Force regions as the state trauma regions and maintaining the nineteen TSAs.<sup>27</sup>

Following the interim study, numerous bills were filed during the 2004 Legislative Session to amend the trauma system. Senate Bill 1762 (2004) was the only law enacted following that Session.<sup>28</sup> The law required the boundaries of the trauma regions to be coterminous with the boundaries of the Regional Domestic Security Task Force regions established within FDLE. The law included a grandfather clause to allow the delivery of trauma services coordinated with a trauma agency pursuant to a public or private agreement established before July 1, 2004. DOH was also directed to complete an assessment of the effectiveness of the trauma system and report its findings to the Governor and Legislature by February 1, 2005. The assessment included:<sup>29</sup>

- Consideration of aligning trauma service areas within the trauma region boundaries as established in July 2004.
- Review of the number and level of trauma centers needed for each TSA to provide a statewide, integrated trauma system.
- Establishment of criteria for determining the number and level of trauma centers needed to serve the population in a defined TSA or region.
- Consideration of a criterion within trauma center verification standards based on the number of trauma victims served within a service area.

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<sup>23</sup> Id. at pages 4.2-4.36

<sup>24</sup> A trauma surgeon is required to be board certified or a trauma surgeon actively participating in the certification process within a specified timeframe may fill the requirement for pediatric surgery if the following conditions are met:

- The trauma medical director attests in writing that the substitute trauma surgeon has competency in the care of pediatric trauma; and
- A hospital grants privileges to the trauma surgeon to provide care to the injured child.

<sup>25</sup> Section 395.404(1)(a), F.S.

<sup>26</sup> The Florida Senate, Committee on Home Defense, Public Security, and Ports, *Hospital Response Capacity*, Report Number 2004-148, available at [http://archive.flsenate.gov/data/Publications/2004/Senate/reports/interim\\_reports/pdf/2004-148hp.pdf](http://archive.flsenate.gov/data/Publications/2004/Senate/reports/interim_reports/pdf/2004-148hp.pdf) (last visited on January 23, 2018).

<sup>27</sup> Id. at page 11.

<sup>28</sup> Chapter 2004-259, Laws of Fla.

<sup>29</sup> Section 395.402(2), F.S.

- Review of the Regional Domestic Security Task Force structure to determine whether integrating the trauma system planning with interagency regional emergency and disaster planning efforts is feasible and to identify any duplication of effort between the two entities.

In conducting the assessment and subsequent annual reviews, the law required DOH to consider the following:<sup>30</sup>

- The recommendations made as a part of the regional trauma system in plans submitted by regional trauma agencies.
- Stakeholder recommendations.
- Geographical composition of an area to ensure rapid access to trauma care.
- Historical patterns of patient referral and transfer in an area.
- Inventories of available trauma care resources, including professional medical staff.
- Population growth characteristics.
- Transportation capabilities, including ground and air transport.
- Medically appropriate ground and air travel times.
- Recommendations of the Regional Domestic Security Task Force.
- The actual number of trauma victims currently being served by each trauma center.
- Other appropriate criteria.

In February 2005, DOH submitted the report to the Legislature, which included the findings of an assessment conducted by a group of researchers from the University of South Florida and the University of Florida. The report made numerous recommendations, including a recommendation to amend the TSAs to align them with the Regional Domestic Security Task Force regions. To date, the Legislature has not amended the structure of the trauma system to incorporate the recommendations of the report.

In 2013, the Legislature passed, and the Governor signed into law, House Bill 1159 which, among other provisions, amended s. 395.4025(14), F.S., to require DOH to designate a hospital in an area with limited access to trauma center services as a Level II trauma center if the hospital provided a valid certificate of trauma center verification from the ACS.<sup>31</sup> An area with limited access to trauma center services is defined by the following criteria:

- The hospital is located in a TSA with a population greater than 600,000 persons but a population density of less than 225 persons per square mile;
- The hospital is located in a county with no verified trauma center; and
- The hospital is located at least 15 miles or 20 minutes travel time by ground transport from the nearest verified trauma center.

#### *Florida Trauma System Administrative Rule Challenge and Associated Litigation*

In 2011, four not-for-profit hospitals<sup>32</sup> challenged DOH approval of new trauma centers in Pasco,<sup>33</sup> Manatee,<sup>34</sup> and Clay<sup>35</sup> counties by initiating a formal challenge to Rule 64J-2.010, F.A.C. (“the Rule”). The Rule sets the number of trauma centers in the state at 42 and apportions to each TSA the number of trauma centers permitted therein.<sup>36</sup> The hospitals argued that, since the Rule was promulgated in 1992, substantial amendments to part II of chapter 395, F.S., effectively repealed and invalidated the

<sup>30</sup> Section 395.402(3), F.S.

<sup>31</sup> Section 3, ch. 2013-153, Laws of Fla.

<sup>32</sup> Bayfront Medical Center in St. Petersburg, Tampa General Hospital, St. Joseph’s Hospital in Tampa, and Shands Jacksonville.

<sup>33</sup> Blake Medical Center in Bradenton.

<sup>34</sup> Regional Medical Center Bayonet Point in Hudson.

<sup>35</sup> Orange Park Medical Center in Orange Park.

<sup>36</sup> For example, Rule 64J-2.010(3), F.A.C., limits the number of trauma centers in TSA 9 (Pasco, Pinellas) to 3 and in TSA 16 (Palm Beach) to 2.

Rule. In addition, the hospitals argued that the 2004 amendments to s. 395.4015, F.S., required DOH to establish trauma regions coterminous with the boundaries of the seven Regional Domestic Security Task Force regions established in s. 943.0312, F.S. However, the Rule establishes 19 TSAs that are not coterminous with the seven regions. Lastly, the hospitals argued that the 2005 assessment found that it would be feasible to reduce the TSAs to match the seven regions, yet the Rule was never amended to adopt this recommendation. In July 2011, due to the rule challenge, DOH initiated a special study using national trauma experts and state and local stakeholders to develop evidenced-based guidelines to be used by DOH in the determination of new trauma center locations.

In September 2011, the Division of Administrative Hearings (DOAH) issued an administrative order finding that the Rule was invalid, as alleged. DOH appealed the ruling and the State Surgeon General suspended the special study and the planning efforts of the trauma program until the rule challenge and resulting litigation was resolved. DOH continued the trauma program's application, verification, and quality assurance activities pending the outcome of the appeal.

On November 30, 2012, the First District Court of Appeal held that the Rule was an invalid exercise of delegated legislative authority, finding:<sup>37</sup>

- The trauma statutes were substantially amended in 2004, yet the rule remained unchanged since 1992. As such, the rule continues to implement outdated provisions of the statutes, without implementing any of the enumerated statutes.
- DOH has not updated the rule to conform to the 2004 amendments or the 2005 Assessment.
- The rule does not implement the 2004 amendment to section 395.4015, which governs state regional trauma planning and trauma regions.
- Both the pre-and post-2004 versions of the statute require DOH to establish trauma regions that "cover all geographic areas of the state." However, the 2004 amendment requires that the trauma regions both "cover all geographical areas of the state and have boundaries that are coterminous with the boundaries of the regional domestic security task forces established under s. 943.0312."
- Because the rule continues to set forth nineteen trauma service areas that are not coterminous with the boundaries of the seven regional domestic security taskforces, it does not implement the changes in the 2004 version of section 395.4015, F.S.

Instead of appealing the decision, DOH initiated the rulemaking process to develop an inclusive, sustainable trauma system that distributes trauma centers throughout the state. The rulemaking process is discussed in detail below.

#### Rulemaking Process to Amend the Rule on Apportionment of Trauma Centers

In December 2012, DOH held its first rule development workshop to gather input from the trauma system providers and partners on how the Rule could be amended to ensure an inclusive trauma system in Florida. At least 10 rulemaking workshops were held through 2013 in an effort to reach agreement, but no consensus on rule language was reached.

A negotiated rulemaking proceeding was held on January 23, 2014, to draft a mutually acceptable proposed rule addressing the appropriate distribution of trauma centers in Florida. No consensus on draft rule language was reached at the meeting. Subsequently, DOH published a Notice of Proposed Rule on February 3, 2014, which detailed substantive changes to the Rule governing the allocation of trauma centers in the TSAs. The final rule was adopted on July 29, 2014. Although a number of cases were filed challenging the validity of the rule, an administrative law judge upheld the validity of rule.<sup>38</sup>

In May 2015, DOH sought to amend the trauma system rules and held a workshop on the proposed changes. The workshop included a discussion of the changes, including changes to the allocation of

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<sup>37</sup> See *Dep't of Health v. Bayfront Medical Center*, 2012 WL 5971201 (Fla. App. 1 Dist.).

<sup>38</sup> *Id.*



trauma centers in two TSAs in northeast Florida and two TSAs in south Florida. An additional workshop was held in August 2015, to discuss issues related to guidelines for triage and trauma center standards. In December 2015, DOH withdrew proposed amendments to rule 64J-2.010, F.A.C., which specifically addressed the allocation of the trauma centers.

In February 2016, DOH once again published a proposed rule amendment impacting the allocation of trauma centers among the TSAs. DOH held a rule hearing in March 2016, on the proposed amendment, which again changed the allocation of trauma centers in two TSAs in northeast Florida and two TSAs in south Florida. Challenges to the rule were filed with DOAH by The Public Health Trust of Miami-Dade County, which operates the Jackson Memorial Health System, Broward County, which operates three trauma centers, and Shands Jacksonville Medical Center, Inc., d/b/a UF Health of Jacksonville. On April 12, 2016, DOH withdrew the rule; and with that withdrawal, the plaintiffs' challenges were moot.

In June and July 2016, DOH held a series of workshops in Tallahassee, West Palm Beach, and Orlando to work with stakeholders on proposed amendments to the trauma rules, again addressing the allocation of trauma centers. On September 26, 2016, DOH published proposed amendments to the trauma rule that established a minimum number of trauma centers allocated for each TSA and held a rule hearing.

Several hospitals filed petitions with DOAH to determine the validity of the proposed rules.<sup>39</sup> The primary concern of this litigation, as with previous litigation, is the allocation of trauma centers, as well as the methodology used by DOH to determine the allocation. A hearing on the rule challenge was held January 10 through 13, 2017. On March 28, 2017, a final order was issued in the rule challenge holding that the proposed rules were an invalid exercise of delegated legislative authority.<sup>40</sup> Specifically, the administrative law judge (ALJ) found that the proposed rules conferred DOH with discretion that was articulated in the statute. The ALJ found that the statute, s. 395.402(4)(b), F.S., establishes the minimum number of trauma centers needed in a TSA as one trauma center, and that the intent of the Legislature was for DOH to calculate the maximum (rather than minimum) number of trauma centers needed in the TSAs.<sup>41</sup> Since the proposed rules established a minimum, DOH would have discretion to determine whether it would accept a letter of intent from a trauma center in a TSA in which the proposed minimum need for trauma centers had been met. The case was appealed to the First District Court of Appeals and is awaiting disposition.<sup>42</sup>

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<sup>39</sup> 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 Health – 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.

<sup>40</sup> *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 (DOH Case No. 16-5841RP). Section 120.52(8), F.S., defines "invalid exercise of delegated legislative authority" as an action that goes beyond the powers, functions, and duties delegated by the Legislature.

<sup>41</sup> *Id.*

<sup>42</sup> *Dep't of Health, et al. v. Shands Jacksonville Medical Center, Inc., et al.*, Case No. 1D17-1713. Oral arguments were held on January 23, 2018. The case consolidates the following cases: 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 Health – 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).

## Litigation Related to Trauma Center Designation

In May 2016, Shands Jacksonville Medical Center, Inc., d/b/a UF Health Jacksonville, challenged DOH's approval of Orange Park Medical Center, Inc., as a provisional Level II trauma center.<sup>43</sup> At the time of submission of its intent to establish a Level II trauma center in October 2015 and throughout the application and review process, TSA 5, where Orange Park Medical Center is located, was allocated one trauma center for the area.<sup>44</sup> In 2015, DOH proposed an amendment to the rule governing the allocation of trauma centers that would have increased the number of trauma centers in TSA 5 to two, but the proposed rule was challenged and eventually withdrawn by DOH.<sup>45</sup> The rule had not been adopted at the time DOH approved Orange Park Medical Center to operate as a provisional Level II trauma center. In the court's proposed order, it found that the provisional Level II trauma center designation was awarded in error because there was not a slot available in TSA 5, and DOH relied on an unadopted rule that permitted DOH to accept a letter of intent regardless of whether there was a slot available in the affected TSA.<sup>46</sup> DOH rejected the recommended order and issued a final order upholding the approval of Orange Park Medical Center to operate as a Level II provisional center.<sup>47</sup> The case was appealed to the First District Court of Appeals and is awaiting disposition.<sup>48</sup>

In June 2016, the Public Health Trust of Miami-Dade County, Florida d/b/a Jackson Memorial Hospital, Jackson North Medical Center, and Jackson South Community Hospital, and Variety Children's Hospital d/b/a Nicklaus Children's Hospital challenged DOH's approval of Kendall Regional Medical Center as a provisional Level I Trauma Center.<sup>49</sup> A hearing in the matter is scheduled for May 7-11, 2018.

In May 2017, Galencare, Inc. d/b/a Northside Hospital filed an administrative challenge to DOH's denial of Northside Hospital's application to operate as a provisional Level II trauma center.<sup>50</sup> DOH based its denial on Northside Hospital's failure to meet certain standards relating to the emergency department, physician qualifications, and quality management. In the recommended order, the ALJ found that Northside Hospital was in compliance with all the critical elements, as required by statute and rule and should be awarded provisional status. DOH has not yet entered a final order in the case.

In June 2017, Shands Jacksonville Medical Center, Inc. d/b/a UF Health Jacksonville filed an administrative challenge to DOH's preliminary decision to approve Memorial Healthcare Group, Inc. d/b/a Memorial Hospital Jacksonville as a provisional Level II trauma center.<sup>51</sup> A hearing was held on November 16, 2017. The parties submitted proposed recommended orders on February 14, 2018, and the ALJ has not yet issued a recommended order.<sup>52</sup>

In October 2017, the Public Health Trust of Miami-Dade County, Florida d/b/a Jackson Memorial Hospital and d/b/a South Community Hospital filed an administrative challenge to DOH's approval of

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<sup>43</sup> *Shands Jacksonville Medical Center, Inc., d/b/a UF Health Jacksonville v. Dep't of Health*, DOAH Case No. 16-3369 (Jan. 27, 2017).

<sup>44</sup> Rule 64J-2.010, F.A.C. TSA 5 includes Baker, Clay, Duval, Nassau, and St. John's County.

<sup>45</sup> See below for further discussion of the rulemaking process.

<sup>46</sup> *Supra* note 43.

<sup>47</sup> *Shands Jacksonville Medical Center, Inc., d/b/a UF Health Jacksonville v. Dep't of Health*, DOAH Case No. 16-3369 (Jan. 27, 2017); DOH Rendition No.: DOH-17-0752-FOF-HSEM (Apr. 27, 2017).

<sup>48</sup> *Shands Jacksonville Medical Center, Inc., et al. v. Dep't of Health*, Case No. 1D17-2215. Oral arguments were held on February 12, 2018.

<sup>49</sup> *The Public Health Trust of Miami-Dade County, Florida, d/b/a Jackson Memorial Hospital, Jackson North Medical Center, and Jackson South Community Hospital v. Dep't of Health*, DOAH Case No. 16-3370, and *Variety Children's Hospital d/b/a Nicklaus Children's Hospital v. Dep't of Health*, DOAH Case No. 16-3372.

<sup>50</sup> *Galencare, Inc. d/b/a Northside Hospital v. Dep't of Health*, DOAH Case 17-2754 (Dec. 20, 2017). The ALJ allowed Bayfront HMA Medical Center, LLC, d/b/a Bayfront Health-St. Petersburg; and St. Joseph's Hospital, Inc. d/b/a St. Joseph's Hospital to intervene on a limited basis.

<sup>51</sup> *Shands Jacksonville Medical Center, Inc. d/b/a UF Health Jacksonville v. Dep't of Health*, DOAH Case No. 17-3265.

<sup>52</sup> *Id.*

Aventura Hospital and Medical Center to operate as a verified Level II trauma center on July 1, 2016.<sup>53</sup> A hearing in the case has been scheduled for June 18-20, 2018.

DOH has also been subject to litigation objecting to the submission of applications and letters of intent. In those cases, the plaintiffs requests the court to issue injunctions to prevent DOH from considering applications if there was not an available slot in the TSA.<sup>54</sup>

### American College of Surgeons (ACS)

The ACS is a scientific and educational association of surgeons established in 1913.<sup>55</sup> ACS works to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. ACS does not designate trauma centers; instead, it verifies the presence of the resources listed in a book, "Resources for Optimal Care of the Injured Patient,"<sup>56</sup> which is recognized as a guide to develop trauma centers in the United States. ACS site surveyors use the book to review trauma centers. Currently, ACS is the only national trauma accreditation body to offer verification services.

According to ACS, the consultation and verification process helps hospitals to evaluate and improve trauma care by providing an objective, external review of a trauma center's resources and performance. A team of ACS trauma experts complete an on-site review of a hospital to assess relevant features of a trauma program, including commitment, readiness, resources, policies, patient care, and performance improvement. The fee for the initial verification consultation is \$18,000,<sup>57</sup> and the annual fee ranges from \$17,000 to \$34,000 depending on the level of verification the hospital holds.<sup>58</sup> The certification process is voluntary and only those trauma centers that have successfully completed a verification visit are awarded a certificate.<sup>59</sup> ACS awards Level I through IV verifications:<sup>60</sup>

- A Level I facility is a regional resource trauma center that is a tertiary care facility central to the trauma system. The facility must have the capability of providing leadership and total care for every aspect of injury, from prevention through rehabilitation, and must have the depth of resources and personnel. A Level I center is usually a university-based teaching hospital due to the large number of personnel and resources required for patient care, education, and research.
- A Level II facility may not be able to provide the same comprehensive care as a Level I trauma center and more complex injuries may need to be transferred to a Level I center. The Level II trauma center is required to provide initial definitive trauma care regardless of the severity of the injury. A Level II trauma center may be an academic institution or a public or private community facility located in an urban, suburban, or rural area.
- A Level III facility is required to provide prompt assessment, resuscitation, emergency operations, and stabilization for a patient, arrange for possible transfer to another facility that

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<sup>53</sup> *The Public Health Trust of Miami-Dade Florida, d/b/a Jackson Memorial Hospital and d/b/a Jackson South Community Hospital v. Dep't of Health*, DOAH Case No. 17-5467.

<sup>54</sup> See *Delray Medical Center, Inc., and St. Mary's Medical Center, Inc. v. Dep't of Health*, Case No. 2017-CA-000588 (Fla. 2d Cir. Ct.), (the case was voluntarily dismissed), and *Dep't of Health v. Bayfront HMA Medical Center, LLC, and Glencare, Inc.*, 2018 WL 266986 (Fla. 1st DCA Jan. 2, 2018).

<sup>55</sup> American College of Surgeons, *History of the American College of Surgeons*, available at <https://www.facs.org/about-acs/archives/acshistory> (last visited on January 23, 2018).

<sup>56</sup> A copy of this publication is on file with Health Innovation Subcommittee staff.

<sup>57</sup> If the consultation is for a Level II Pediatric with a Level I or II Adult, the total fee is \$21,500. Additional fees may apply if other visits are needed. The cost of the initial consultation will increase to \$19,000 in July 2018. See ACS, *Fees and Invoices*, available at <https://www.facs.org/quality-programs/trauma/vrc/fees> (last visited on January 23, 2018).

<sup>58</sup> The fees will increase in July 2019, and will range from \$19,000 to \$38,000. See ACS, *Fees and Invoices*, available at <https://www.facs.org/quality-programs/trauma/vrc/fees> (last visited on January 23, 2018).

<sup>59</sup> The hospitals with ACS verification in Florida are Blake Medical Center in Bradenton (Level II trauma center), Fort Walton Beach Medical Center in Fort Walton Beach (Level II trauma center), Jackson Memorial Hospital in Miami (Level I trauma center), Kendall Regional Medical Center in Miami (Level II trauma center), Lawnwood Regional Medical Center in Fort Pierce (Level II trauma center), Memorial Regional in Hollywood (Level I adult and Level II pediatric trauma center), Ocala Regional Medical Center (Level II trauma center), and Tampa General Hospital (Level I adult and Level I pediatric trauma center). See American College of Surgeons, *Searching for Verified Trauma Centers*, available at: <https://www.facs.org/search/trauma-centers> (last visited on January 23, 2018).

<sup>60</sup> American College of Surgeons, *Description of Hospital Levels*, available at <http://www.facs.org/trauma/hospitallevels.pdf> (last visited on February 9, 2018).

can provide definitive care, and maintain transfer agreements and standardized treatment protocols. General surgeons are required in a Level III trauma center. A Level III trauma center is generally not appropriate in urban or suburban areas with adequate Level I or Level II resources.

- A Level IV facility provides advanced trauma life support before a patient is transferred to another facility for additional care. A Level IV trauma center is located in a remote area where no higher level of care is available and the trauma center serves as the de facto primary care provider. Such a facility may be a clinic rather than a hospital and a physician may not be available.

In February 2013, the ACS Committee on Trauma (COT), at the request of the State Surgeon General, conducted a system consultation and review of Florida's trauma system. The final report from ACS was released to the DOH in May 2013. The following are some of the priority recommendations contained in the report:<sup>61</sup>

- Appoint a new Florida Trauma System Advisory Council to provide input to policy development for the trauma system.
- Revise immediately the Florida trauma system plan to address key issues necessary for the further development of the regional and statewide trauma system.<sup>62</sup>
- Use the Regional Domestic Security Task Force regions as the TSA regions, which will enable the integration of trauma centers with emergency medical services, disaster preparedness, and other regional activities.
- Revise the distribution method of the trauma center fund to ensure designated trauma centers receive level-appropriate support for the "cost of readiness."
- Conduct an assessment of the current trauma system to inform decisions regarding the location and level of new trauma center designations.
- Establish a transparent, broadly accepted process for future provisional trauma center designation based upon both capacity and trauma system need.
- Impose a moratorium on any new provisional or verified trauma center designation until new processes are in place.
- Evaluate the content, implementation, and method of enforcement of trauma transport protocols to assure uniformity and efficiency of patient flow both within trauma regions as well as statewide.<sup>63</sup>

## Data Collection

### *Hospital Data Submissions*

Health care facilities must submit the following data to the Agency for Health Care Administration (AHCA):<sup>64</sup>

- Case-mix data;
- Patient admission and discharge data;

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<sup>61</sup> American College of Surgeons Committee on Trauma, Trauma Systems Evaluation and Planning Committee, *Trauma System Consultation Report-State of Florida*, Tallahassee, FL, February 2-5, 2013, available at <http://www.floridahealth.gov/licensing-and-regulation/trauma-system/documents/fl-report-final-5-6-13.pdf> (last viewed on February 9, 2018).

<sup>62</sup> On March 3, 2014 and updated on April 21, 2015, the DOH released the State Trauma System Plan, a document that laid out strategic priorities for the Florida trauma system based, in part, on the priority recommendations from the ACS, and set goals to be achieved by December 31, 2016. The Plan focused on tasks associated with developing Regional Trauma Agencies statewide and establishing benchmarking and ensuring data quality for performance improvement. The Plan is available at <http://www.floridahealth.gov/licensing-and-regulation/trauma-system/documents/state-trauma-system-plan-final.pdf> (last visited on February 9, 2018).

<sup>63</sup> *Supra* note 61 at pages 12-14.

<sup>64</sup> Section 408.061, F.S.

- 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.

### *Florida Trauma Registry*

Every trauma center and acute care hospital must provide DOH certain data related to trauma care provided in its facility.<sup>65</sup> Such data is collected to monitor patient outcomes and ensure compliance with standards.<sup>66</sup> The data in the state trauma registry contains the same data that trauma centers must report to the National Trauma Data Bank (NTDB).<sup>67</sup> The data in the NTDB is not available for analysis for 18 months after the initial reporting and is limited to standardized reports for all participants.<sup>68</sup>

## **Effect of Proposed Changes**

### **Trauma Center Allocation**

CS/CS/HB 1165 repeals current statutory language that requires each Level I and Level II trauma center to be capable of annually treating a minimum number of certain injured patients, as well as the annual trauma system assessment by DOH, which allocates the number of trauma centers for each TSA. The bill also repeals the state wide cap on the number of trauma centers.

The bill revises the composition of the TSAs by:

- Moving Collier County from TSA 17 to TSA 15;
- Moving Broward County from TSA 18 to TSA 17;
- Moving Miami-Dade County from TSA 19 to TSA 18; and
- Eliminating TSA 19.

The bill repeals DOH's authority to allocate the number of trauma centers by TSA and statutorily sets the number of trauma centers allowed in each TSA, for a total of 35:

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

The bill prohibits a TSA from having more than five trauma centers; and no TSA may have more than one stand-alone pediatric trauma center. The bill prohibits DOH from designating a Level II trauma center as a Level I or a pediatric trauma center in a TSA that already has a Level I trauma center or pediatric trauma center.

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<sup>65</sup> Section 395.404, F.S.

<sup>66</sup> Id.

<sup>67</sup> Department of Health, *Agency Legislative Analysis of Senate Bill 1876*, (Jan. 17, 2018), on file with the Health Quality Subcommittee. SB 1876 is substantively similar to CS/CS/HB 1165.

<sup>68</sup> Id.

## Determination of Trauma System Needs

The bill requires DOH to prepare an analysis of the state's trauma center by August 31, 2020, and every 3 years thereafter. DOH's analysis must, at a minimum, include:

- The population growth for the state and for each TSA;
- The number of high-risk patients<sup>69</sup> treated at each trauma center within each TSA, including pediatric trauma centers;
- The total number of high-risk patients treated at acute care hospitals, including non-trauma centers, in each TSA; and
- The percentage of each trauma center's statutory minimum caseload volume, in accordance with the International Classification Injury Severity Score for the trauma center's designation, including the additional caseload volume required for those trauma centers with graduate medical education programs.

For its analysis, the bill requires DOH to use the hospital discharge data submitted to the Agency for Health Care Administration for the most current year and the most recent population data for the state available from the American Community Survey 5-Year Estimates produced by the United States Census Bureau. DOH must make publicly available all data, formulas, methodologies, calculations, and risk adjustment tools used in its analysis.

## Trauma Center Designation Process

The bill redesigns the current trauma center designation process used by DOH.

### *Letter of Intent*

The bill requires DOH to notify each acute care hospital and each local and regional trauma agency in a TSA that it has identified a need for an additional trauma center in that TSA and that it is accepting letter of intent from hospitals interested in becoming trauma centers. The bill prohibits DOH from accepting a letter of intent for a TSA for which it has not identified a need for an additional trauma center. The letter of intent must be postmarked no later than October 1 of the year in which DOH notifies hospitals that it plans to accept letters of intent (**Year 1**).

### *Application*

The bill retains the current requirement that DOH sends all hospitals that submitted a letter of intent an application package by October 15 of that year (**Year 1**). Completed applications must be submitted to DOH by April of the year following submission of the letter of intent (**Year 1**).

### *Initial Review*

The bill requires DOH to conduct an initial review of each application to determine if the hospital's application is complete and whether the hospital is capable of constructing and operating a trauma center. During this review, DOH must determine whether the hospital is prepared to attain and operate all of the following components before April 30 of the following year (**Year 2**):

- Equipment and physical facilities necessary to provide trauma services.
- Personnel in sufficient numbers with proper qualifications to provide trauma services.
- An effective quality assurance process.

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<sup>69</sup> The bill defines "high-risk patient" as trauma patient with an International Classification Injury Severity Score of less than 0.85. According to s. 395.4001(5), F.S., an International Classification Injury Severity Score is the statistical method for computing the severity of injuries sustained by a trauma patient.

The bill repeals a requirement that an applicant submit confirmation by the local or regional trauma agency that the hospital’s application to become a trauma center is consistent with the trauma agency’s plan.

The bill prohibits DOH from approving an application for a trauma center if approval of the application would exceed the limit on trauma centers, indicated above (35). However, DOH must review and may approve an application that exceeds the limit if the applicant demonstrates and DOH determines that:

- Each existing trauma center’s caseload volume of high-risk patient’s is more than double the statutory minimum caseload volume for Level I and Level II trauma centers or more than triple the statutory minimum caseload volume for stand-alone pediatric trauma centers;
- The population growth for the TSA exceeds the statewide population growth by more than 15 percent based on the American Community 5-Year Estimates by the United States Census Bureau for the 5-year period before the date of submission of the letter of intent; and
- A sufficient caseload volume of potential trauma patients exists within the TSA to ensure that each existing trauma center maintain the statutory minimum caseload volume.

Trauma Center Type	TSA Population	Minimum Caseload Volume
Level I	Greater than 1.5 million	<ul style="list-style-type: none"> <li>• 1,200 high-risk patients admitted per year.</li> <li>• Plus an additional 40 cases per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow, if the trauma center has a trauma or critical residency or fellowship program.</li> </ul>
Level I	Less than 1.5 million	<ul style="list-style-type: none"> <li>• 1,000 high-risk patients admitted per year.</li> <li>• Plus an additional 40 cases per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow, if the trauma center has a trauma or critical residency or fellowship program.</li> </ul>
Level II	Greater than 1.25 million	<ul style="list-style-type: none"> <li>• 1,000 high-risk patients admitted per year.</li> <li>• Plus an additional 40 cases per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow, if the trauma center has a trauma or critical residency or fellowship program.</li> </ul>
Level II	Less than 1.25 million	<ul style="list-style-type: none"> <li>• 500 high-risk patients admitted per year.</li> <li>• Plus an additional 40 cases per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow, if the trauma center has a trauma or critical residency or fellowship program.</li> </ul>
Stand-Alone Pediatric	Not applicable	<ul style="list-style-type: none"> <li>• 500 high-risk patients admitted per year.</li> <li>• Plus an additional 40 cases per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow, if the trauma center has a trauma or critical residency or fellowship program.</li> </ul>

For purposes of determining the minimum caseload volume, DOH and the applicant must use the most recent available hospital discharge data collected by AHCA. The bill requires AHCA, in consultation with DOH, to adopt rules for trauma centers and acute care hospitals to submit the data needed by DOH to perform its duties under the law.

By May 1 of the year following DOH's initial review (**Year 2**), DOH must select one or more applicants for approval to prepare to operate as a trauma center. If DOH receives more applications than may be approved based on established need, DOH must select the best applicant(s) based on:

- DOH's determination of the applicant's ability to provide the highest quality patient care using the most recent technological, medical, and staffing resources available; and
- Which applicant is located the farthest away from an existing trauma center in the applicant's TSA.

#### *In-Depth Evaluation and Operation as a Provisional Trauma Center*

The bill requires DOH to conduct an in-depth evaluation of all applications that it finds acceptable after the initial review (**Year 2**). The applicant(s) must be evaluated against the criteria enumerated in the application packet provided to DOH by the applicant(s). The applicant may begin operating as a provisional trauma center if DOH approves the application after the in-depth evaluation.

#### *Final Designation*

DOH must assemble and dispatch a review team of out-of-state experts to make an onsite visit of the provisional trauma center within one year after an applicant begins operation as a provisional trauma center (**Year 3**). The bill retains the current requirement that the onsite review team use an instrument that includes objective criteria and guidelines based on existing trauma standards and has a uniform rating system. Based on the recommendation from the review team, DOH must approve a trauma center for designation if it is in compliance with trauma center standards, as adopted by DOH rule. The bill retains the current 7-year approval period for the trauma center designation.

#### Standing

Under current law, any hospital may protest the designation of a trauma center in any TSA in the state. The bill restricts protests of a DOH decision to approve a trauma center application, or whether a need has been established as required under the bill, to an applicant or an existing trauma center that is in the same TSA or a contiguous TSA.

#### Grandfathering

The bill deems the following trauma centers as having met the trauma center application and operational requirements for designation by DOH.

- A trauma center that was verified by DOH before December 15, 2017, which will resolve the litigation involving Aventura Hospital and Medical Center.
- A trauma center that was not verified by DOH before December 15, 2017, but was provisionally approved by DOH to be in substantial compliance with Level II trauma standards before January 1, 2017, and is operating as a Level II trauma center, which will resolve the litigation involving Orange Park Medical Center.
- A trauma center that was not verified by DOH before December 15, 2017, as a Level I trauma center but that was provisionally approved by DOH to be in substantial compliance with Level I trauma standards before January 1, 2017, and is operating as a Level I trauma center, which will resolve the litigation involving Kendall Regional Center.
- A trauma center that was not verified by DOH before December 15, 2017, as a pediatric trauma center but that was provisionally approved by 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 which will resolve the litigation involving Wolfson Children's Hospital. However, this pediatric trauma center must successfully complete the in-depth and site review process for designation.



- A hospital operating as a Level II trauma center after January 1, 2017, must be designated by DOH as a Level II trauma center if all of the following apply and may resolve litigation related to Memorial Hospital (Jacksonville) and Jackson South Community Hospital:
  - The hospital was provisionally approved after January 1, 2017, to operate as a Level II trauma center;
  - DOH's decision to approve the hospital to operate a provisional Level II trauma center was pending in litigation on or before January 1, 2018;
  - The hospital receives a final recommended order from the Division of Administrative Hearings, a final determination from DOH, 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
  - DOH determines that the hospital is in substantial compliance with the Level II trauma center standards, including the in-depth and site reviews.
- A joint pediatric trauma center involving a Level II trauma center and a specialty licensed children's hospital that was verified by DOH before December 15, 2017, if the joint program is dissolved and the pediatric trauma center meets all requirements for verification by DOH. This addresses the possibility of a future dissolution of the joint program between All Children's Hospital and Bayfront Health St. Petersburg.

The bill will resolve the majority of the ongoing litigation related to trauma center designation. However, the bill authorizes DOH to adopt rules for exceeding the statutory minimum need established in the bill which may give rise to future litigation.

#### Florida Trauma System Advisory Council

The bill requires DOH to establish the Florida Trauma System Advisory Council (FTSAC), by May 1, 2018. The purpose of the FTSAC is to promote an inclusive trauma center and enhance cooperation among stakeholders. The FTSAC is composed of 12 members appointed by the Governor, and must include:

- 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 who actively works in a trauma center of an investor-owned hospital;
- A trauma program manager or trauma medical director who actively works in a trauma center of a nonprofit or public hospital;
- A trauma surgeon who is board-certified in an appropriate trauma or critical care specialty and who actively practices medicine in a Level II trauma center of an investor-owned hospital;
- A trauma surgeon who is board-certified in an appropriate trauma or critical care specialty and who actively practices medicine in a nonprofit or public hospital;
- A trauma surgeon who is board-certified in an appropriate trauma or critical care specialty and actively practicing medicine in a Level I trauma center;
- A representative of the American College of Surgeons Committee on Trauma who has pediatric trauma care experience;
- A representative of the Safety Net Hospital Alliance of Florida;
- A representative of the Florida Hospital Association; and
- A Florida-licensed allopathic or osteopathic physician who is board-certified in emergency medicine and is not affiliated with a trauma center.

Under the bill, each FTSAC member is appointed for 3 years. To provide for staggered terms, the bill requires the initial appointment of 4 members to be for a 1-year term, 4 members to be for a 2-year term, and 4 members to be for a 3-year term. FTSAC must hold its first meeting no later than June 1, 2018, and must meet quarterly thereafter. FTSAC may submit recommendations to 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 center, but are not required to do so.

The bill requires DOH to administer and support the activities of FTSAC within existing resources. The bill requires members to serve without compensation or reimbursement for per diem or travel expenses.

### *Study on National Certification of Pediatric Trauma Services*

The bill requires FTSAC to conduct a study comparing the laws, rules, regulations, standards, and guidelines for designation as a pediatric trauma center in Florida and the requirements, rules, regulations, standards, and guidelines for verification of a pediatric trauma center by a national trauma center accreditation body that certifies compliance with published standards for administration of trauma care and the treatment of injured patients. Currently, ACS is the only accreditation body that meets this requirement.

FTSAC's study must also consider:

- The costs and requirements associated with obtaining and maintaining certification;
- Which pediatric trauma centers and trauma centers providing trauma care have obtained, are in the process of obtaining, or are capable of obtaining certification;
- Barriers to obtaining certification; and
- Policy proposals that address the need and value of certification.

FTSAC must request information and assistance from DOH to perform the study, and DOH must provide such information and assistance. FTSAC must submit a report of its findings and recommendations to the Governor and Legislature by December 31, 2018.

### Trauma Registry

The bill repeals the trauma registry and requires all trauma centers to report data to the National Trauma Data Bank. The bill requires DOH to only use the National Trauma Data Bank for quality and assessment purposes. The bill requires trauma centers and acute care hospitals to report all transfers of trauma patients and the outcomes of such patients to DOH.

### Non-severability Clause

The bill also contains a non-severability clause related to the grandfathering provision. The non-severability clause provides that if any portion of the grandfathering clause is determined to be invalid or inoperable, then remaining provisions of the act are deemed to be void.

The bill provides that the act shall take effect upon becoming law.

## **II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

### **A. FISCAL IMPACT ON STATE GOVERNMENT:**

#### **1. Revenues:**

None.

2. Expenditures:

DOH may have less expenditures related to legal challenges to the allocation of trauma centers since the bill establishes a mandatory minimum number of trauma centers needed in a trauma service area based on population, limits the persons who may bring a challenge to the designation of a trauma center, and deems certain trauma centers that are the subject of ongoing litigation as having met the requirements for designation.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.