

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 1077 Trauma Services  
**SPONSOR(S):** Trumbull  
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 746

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	10 Y, 5 N	Siples	Poche
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

### SUMMARY ANALYSIS

The Department of Health (DOH) is responsible overseeing of the statewide inclusive trauma system which ensures that all injured trauma victims have access to the resources needed for care and treatment. Currently, DOH designates trauma centers in regional trauma services areas, but may designate no more than 44 trauma centers in the state, to ensure access to trauma services. 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.

HB 1077 restructures how trauma centers are designated in the state by:

- Eliminating the statewide limit on the number of trauma centers;
- Eliminating trauma service areas and trauma regions;
- Eliminating DOH's responsibility to set the standards for trauma centers or perform the necessary site surveys to ensure compliance with the standards;
- Authorizing DOH to designate a hospital as a trauma center if it holds a certificate of verification issued by a national trauma accreditation body, completes a DOH-approved application, and provides copies of certain documents submitted to and received from the national trauma accreditation body; and
- Allowing DOH to only deny an application for designation for failure to submit required application materials.

Current provisional and verified trauma centers must obtain the certificate of verification by July 1, 2022, to maintain designations. DOH may take action against a trauma center if it fails to maintain its certification or the standards required to obtain the certificate of verification. DOH may also revoke a trauma center designation if it fails to provide or withholds the information it supplied to the national trauma center accreditation body.

The bill requires DOH to coordinate the development of a state trauma plan to serve as the basis for the statewide inclusive trauma system. The plan must be updated by December 31 of every odd year.

The bill prohibits more than one trauma agency in a county. The bill grandfathers the trauma agencies that exist before July 1, 2018. The bill requires trauma agencies, which serve regional areas or counties, to submit a regional trauma plan biennially rather than every 5 years as required in existing law. The bill requires all emergency medical services providers to submit and obtain approval of their trauma transport protocol, regardless of whether it operates in conjunction with a trauma agency that has DOH-approved trauma transport protocols.

The bill will have a significant, positive indeterminate fiscal impact on DOH and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2017.

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

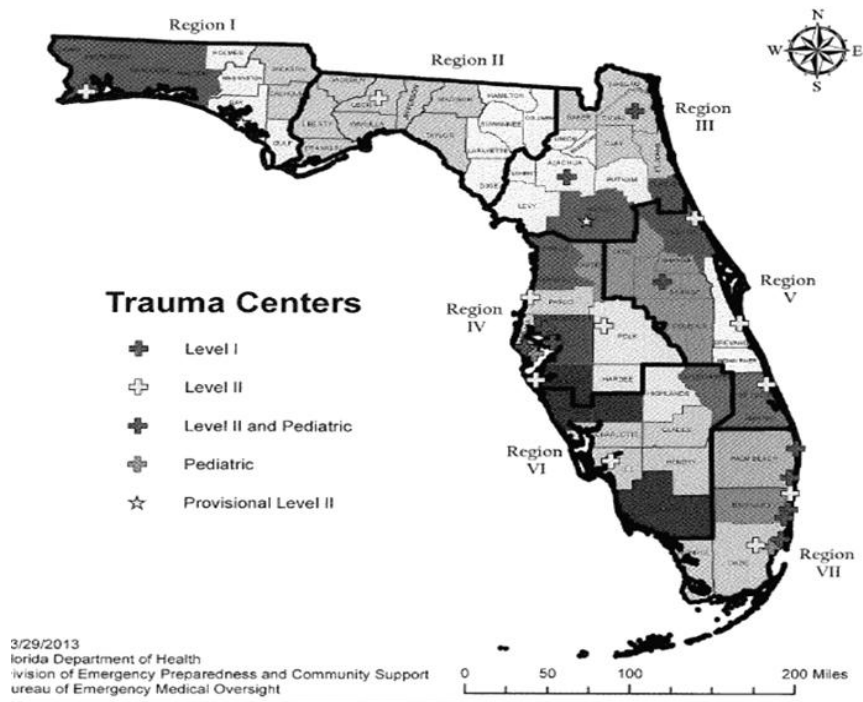
##### Current Situation

##### Florida Trauma System

The regulation of trauma centers in Florida is governed by Part II of Chapter 395, F.S., and administered by the Department of Health (DOH) by 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. As part of the state trauma system plan, DOH is required to establish trauma regions which cover all geographical areas of the state and have boundaries that align with the state's seven Regional Domestic Security Task Force regions.<sup>1</sup> These regions may serve as the basis for the development of department-approved local or regional trauma plans.

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

Florida's trauma system is comprised of seven trauma regions and nineteen trauma service areas (TSAs). The trauma 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. The impact of trauma agencies in the current trauma system is unknown. The seven trauma regions, which match the Regional Domestic Security Task Force regions established by the Department of Law Enforcement (FDLE) pursuant to s. 943.0312(1), F.S., are illustrated below.<sup>2</sup>



<sup>1</sup> S. 395.4015, F.S.,

<sup>2</sup> Florida Department of Health, Division of Emergency Preparedness and Community Support, Bureau of Emergency Medical Oversight, *Trauma Centers*, March 29, 2013 (on file with Health and Human Services Committee staff).

Florida is divided into nineteen TSAs, detailed below:<sup>3</sup>

TRAUMA SERVICE AREAS (TSAs) IN FLORIDA	
TSA	COUNTIES IN TSA
1	Escambia, Okaloosa, Santa Rosa, Walton
2	Bay, Gulf, Holmes, Washington
3	Calhoun, Franklin, Gadsden, Jackson, Jefferson, Leon, Liberty, Madison, Taylor, Wakulla
4	Alachua, Bradford, Columbia, Dixie, Gilchrist, Hamilton, Lafayette, Levy, Putnam, Suwannee, Union
5	Baker, Clay, Duval, Nassau, St. Johns
6	Citrus, Hernando, Marion
7	Flagler, Volusia
8	Lake, Orange, Osceola, Seminole, Sumter
9	Pasco, Pinellas
10	Hillsborough
11	Hardee, Highlands, Polk
12	Brevard, Indian River
13	Desoto, Manatee, Sarasota
14	Martin, Okeechobee, St. Lucie
15	Charlotte, Glades, Hendry, Lee
16	Palm Beach
17	Collier
18	Broward
19	Dade, Monroe

For purposes of medical response times, 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>4</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>5</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>6</sup> Currently, TSA 17 (Collier) is not directly covered by a trauma center.<sup>7</sup>

DOH is required to apportion, by rule, the number of trauma centers needed for each TSA.<sup>8</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>9</sup>

<sup>3</sup> S. 395.402(4)(a), F.S.

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

<sup>5</sup> S. 395.402(1), F.S.

<sup>6</sup> Id.

<sup>7</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 March 7, 2017).

<sup>8</sup> S. 395.402(4)(b), F.S., and Rule 64J-2.010, F.A.C.

<sup>9</sup> S. 395.401(2), F.S., and Rule 64J-2.011, F.A.C.

A trauma agency<sup>10</sup> develops a plan for its local and regional trauma services system. The plan, which must be submitted to DOH for approval, 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>11</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>12</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>13</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 July 29, 2016, the following hospitals are designated trauma centers:<sup>14</sup>

TRAUMA CENTER	LEVEL	COUNTY
Aventura Hospital and Medical Center	Level II	Miami-Dade
Baptist Hospital, Inc.	Level II	Escambia
Bay County Health Systems, LLC Bay Medical Center Sacred Heart Health System	Level II	Bay
Bayfront HMA Medical Center, LLC Bayfront Medical Center	Level II	Pinellas
Central Florida Regional Hospital	Level II	Seminole
Delray Medical Center, Inc.	Level I	Palm Beach
Florida Health Sciences, Inc. Tampa General Hospital	Level I	Hillsborough
Halifax Hospital Medical Center / Halifax Health	Level II	Volusia
HCA Health Services of Florida, Inc. Blake Medical Center	Level II	Manatee
HCA Health Services of Florida, Inc. Regional Medical Center Bayonet Point	Level II	Pasco
Holmes Regional Medical Center, Inc.	Level II	Brevard
Jackson South Community Hospital	Provisional Level II	Miami-Dade
Johns Hopkins All Children's Hospital, Inc.	Pediatric	Pinellas
Kendall Healthcare Group, LTD	Provisional Level I	Miami-Dade

<sup>10</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.)

<sup>11</sup> Rule 64J-2.007, F.A.C.

<sup>12</sup> Supra, FN 7, at pg. 5.

<sup>13</sup> The trauma center standards are provided in DH Pamphlet 150-9 and codified in Rule 64J-2.011, F.A.C. The standards were last updated in January 2010.

<sup>14</sup> Florida Department of Health, *Florida Trauma Centers*, available at <http://www.floridahealth.gov/licensing-and-regulation/trauma-system/documents/traumacenterlisting2016.pdf> (last visited on March 7, 2017).

Kendall Regional Medical Center		
Lakeland Regional Medical Center, Inc.	Level II	Polk
Lawnwood Medical Center, Inc. Lawnwood Regional Medical Center & Heart Institute	Level II	St. Lucie
Lee Memorial Health System	Level II	Lee
Marion Community Hospital, Inc. Ocala Regional Medical Center/ West Marion Community	Level II	Marion
North Broward Hospital District Broward Health Medical Center	Level I	Broward
North Broward Hospital District Broward Health North	Level II	Broward
Orlando Health, Inc.(Orlando Regional Medical Center)	Level I	Orange
Orange Park Medical Center	Provisional Level II	Clay
Osceola Regional Medical Center	Level II	Osceola
Sacred Heart Health System, Inc.	Level II / Pediatric	Escambia
Sarasota Memorial Hospital	Level II	Sarasota
Shands Jacksonville Medical Center, Inc. Shands Jacksonville/ UF Health Jacksonville	Level I	Duval
Shands Teaching Hospital and Clinics, Inc. Shands UF (Gainesville)	Level I	Alachua
South Broward Hospital District Memorial Regional Hospital	Level I	Broward
St. Joseph's Hospital, Inc.	Level II / Pediatric	Hillsborough
St. Mary's Medical Center, Inc.	Level I	Palm Beach
Tallahassee Memorial Healthcare, Inc.	Level II	Leon
The Public Health Trust of Miami-Dade County, Florida Jackson Health System Jackson Memorial Hospital / Ryder Trauma Center	Level I	Miami-Dade
Variety Children's Hospital, Inc. Nicklaus Children's Hospital	Pediatric	Dade

A provisional trauma center is a hospital that has been verified to be in substantial compliance with the requirements in s. 395.4025, 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>15</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>16</sup> Currently, there is one provisional Level I trauma center, Kendal Regional Medical Center in Miami, and two provisional Level II trauma centers, Jackson South Community Hospital in Miami and Orange Park Medical Center in Orange Park.

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>17</sup> A Level I trauma center must have:<sup>18</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, when summoned.

<sup>15</sup> S. 395.4001(10), F.S.

<sup>16</sup> S. 395.4025(3), (5), and (6), F.S.

<sup>17</sup> S. 395.4001(6)(b), F.S.

<sup>18</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/traumacntrstandpamphlet150-9-2009rev1-14-10.pdf](http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/traumacntrstandpamphlet150-9-2009rev1-14-10.pdf) (last visited on March 7, 2017).

- 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>19</sup> A Level II trauma center must have:<sup>20</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 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>21</sup>

- A minimum of five qualified trauma surgeons<sup>22</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>23</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>24</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>25</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>26</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

<sup>19</sup> S. 395.4001(7)(b), F.S.

<sup>20</sup> Supra, FN 18 at pages 3.2-3.33.

<sup>21</sup> Id. at pages 4.2-4.36

<sup>22</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>23</sup> S. 395.404(1)(a), F.S.

<sup>24</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 March 7, 2017).

<sup>25</sup> Id. at page 11.

<sup>26</sup> Ch. 2004-259, Laws of Fla.

of the effectiveness of the trauma system and report its findings to the Governor and Legislature by February 1, 2005. The assessment included:<sup>27</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.
- 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>28</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. 395.402(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>29</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.

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<sup>27</sup> S. 395.402(2), F.S.

<sup>28</sup> S. 395.402(3), F.S.

<sup>29</sup> S. 3, ch. 2013-153, Laws of Fla.

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

In 2011, four not-for-profit hospitals<sup>30</sup> challenged DOH approval of new trauma centers in Pasco,<sup>31</sup> Manatee,<sup>32</sup> and Clay<sup>33</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>34</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 Rule. In addition, the hospitals argued that 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>35</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.

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>36</sup> At the time of submission of its intent to establish a Level II trauma center in October 2015 and throughout the

<sup>30</sup> Bayfront Medical Center in St. Petersburg, Tampa General Hospital, St. Joseph’s Hospital in Tampa, and Shands Jacksonville.

<sup>31</sup> Blake Medical Center in Bradenton.

<sup>32</sup> Regional Medical Center Bayonet Point in Hudson.

<sup>33</sup> Orange Park Medical Center in Orange Park.

<sup>34</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.

<sup>35</sup> See *Department of Health v. Bayfront Medical Center*, 2012 WL 5971201 (Fla.App. 1 Dist.).

<sup>36</sup> *Shands Jacksonville Medical Center, Inc., d/b/a UF Health Jacksonville v. Department of Health*, DOAH Case No. 16-3369 (Jan. 27, 2017).



application and review process, TSA 5, where Orange Park Medical Center is located, was allocated one trauma center for the area.<sup>37</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>38</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. The court ultimately ruled 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>39</sup>

### 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>40</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 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 and held a rule hearing. Several hospitals filed petitions with DOAH to determine the validity of the proposed rules.<sup>41</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

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<sup>37</sup> Rule 64J-2.010, F.A.C. TSA 5 includes Baker, Clay, Duval, Nassau, and St. John's County.

<sup>38</sup> See below for further discussion of the rulemaking process.

<sup>39</sup> Supra, FN 36.

<sup>40</sup> Id.

<sup>41</sup> According to the DOAH's website, there are active rule challenges by St. Joseph's Hospital, Inc., d/b/a St. Joseph's Hospital (Tampa); Bayfront HMA Medical Center, LLC, d/b/a Bayfront Health – St. Petersburg; Lee Memorial Health System, d/b/a Lee Memorial Hospital; Florida Health Sciences Center, Inc., d/b/a Tampa General Hospital; and Shands Jacksonville Medical Center, Inc. d/b/a U.F. Hospital Jacksonville. Intervenor include 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 (last viewed March 25, 2017).

hearing on the rule challenge was held January 10 through 13, 2017, and a recommended order has not yet been issued.

### American College of Surgeons (ACS)

The ACS is a scientific and educational association of surgeons established in 1913.<sup>42</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>43</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>44</sup> and the annual fee ranges from \$17,000 to \$34,000 depending on the level of verification the hospital holds.<sup>45</sup> The certification process is voluntary and only those trauma centers that have successfully completed a verification visit are awarded a certificate.<sup>46</sup> ACS awards Level I through IV verifications:<sup>47</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 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

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<sup>42</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 March 7, 2017).

<sup>43</sup> A copy of this publication is on file with Health Innovation Subcommittee staff.

<sup>44</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 March 9, 2017).

<sup>45</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 March 9, 2017).

<sup>46</sup> As of March 28, 2014, ACS verifies trauma centers in 47 states. The hospitals with ACS verification in Florida are Blake Medical Center in Bradenton (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), Ocala Regional Medical Center (Level II trauma center), Tampa General Hospital (Level I trauma center), and Tampa General Hospital Children’s Medical Center (Level I and 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 March 7, 2017).

<sup>47</sup> American College of Surgeons, *Description of Hospital Levels*, available at: <http://www.facs.org/trauma/hospitallevels.pdf> (last visited on March 7, 2017).

provider. Such a facility may be a clinic rather than a hospital and a physician may not be available.

According to DOH, several of the trauma centers in this state have started or completed ACS verification.<sup>48</sup> Three trauma centers have scheduled on-site visits and seven have scheduled consultation visits for 2017.<sup>49</sup>

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>50</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>51</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>52</sup>

### Trauma Transport Protocols

Emergency medical service (EMS) providers must transport trauma alert victims<sup>53</sup> to approved trauma centers, except as provided for in either a DOH-approved trauma transport protocol<sup>54</sup> of the local or regional trauma agency, or if none exists, the DOH-approved trauma transport protocol of the EMS provider. A local or regional trauma agency<sup>55</sup> may develop a uniform trauma transport protocol that is applicable to all licensed EMS providers operating within its geographical area.

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<sup>48</sup> Department of Health, *2017 Agency Bill Analysis for HB 1077*, (February 14, 2017), on file with the Health Innovation Subcommittee.

<sup>49</sup> Id.

<sup>50</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 March 7, 2017).

<sup>51</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 March 7, 2017).

<sup>52</sup> Supra, FN 50 at pages 12-14.

<sup>53</sup> A trauma alert victim is a person who has incurred a single or multiple injury due to blunt or penetrating means or burns, who requires immediate medical intervention or treatment, and who meets one or more of the adult or pediatric scorecard criteria established by DOH by rule. S. 395.4001(12), F.S.

<sup>54</sup> A trauma transport protocol is a document that describes the policies, processes, and procedures governing the dispatch of vehicles, triage, prehospital transport, and interfacility trauma transfer of trauma victims.

<sup>55</sup> A trauma agency is a DOH-approved agency established or operated by one or more counties, or a DOH-approved entity with which one or more counties contract to administer an inclusive regional trauma center.

In a TSA in which air ambulance services are available, the trauma transport protocol may not permit an EMS provider to transport outside the TSA. However, if there is no air ambulance service available and there is no agreement between adjacent local or regional trauma agencies, an EMS provider must transport a patient with life-threatening injuries to the most appropriate trauma center as defined by DOH-approved trauma transport protocols.

### **Effect of Proposed Changes**

HB 1077 redesigns the process by which trauma centers are designated by repealing the statewide limitation on the number of trauma centers, eliminating the regional trauma service areas, repealing DOH's duty to set standards for designation, and requiring trauma centers seeking designation to meet standards established by a national trauma accreditation body. Under the bill, DOH is responsible for planning, coordinating, and overseeing the statewide trauma system. Those duties include:

- Designating trauma centers;
- Publishing and maintaining a state trauma plan;
- Establishing and maintaining a statewide trauma registry to monitor, evaluate, and enforce the requirements of the state trauma plan;
- Soliciting input from stakeholders and subject matter experts for the enhancement of a coordinated approach to the care of trauma victims, including the movement of a trauma victim through the system of care and the defined role of acute care hospitals; and
- Actively fostering provision of trauma care and serving as a catalyst for improvements in the outcomes and treatment of trauma patients in an inclusive trauma system.

The bill repeals a requirement that DOH coordinate with the Agency for Health Care Administration, the Board of Medicine, and the Board of Nursing to develop guidelines, standards, and rules related to an inclusive trauma system. The bill also repeals the designation of TSAs.

### **Designation of Trauma Centers**

The bill eliminates the statewide limit on the number of trauma centers, as well as the limit on the number of trauma centers that may be located in each of the 19 TSAs.

The bill repeals the current system of designating trauma centers and establishes a new procedure. The verification process for which DOH is currently responsible will shift from DOH to a national trauma center accreditation body. A hospital seeking verification must pay for any fees associated with obtaining such verification.

Any hospital may apply for designation as a trauma center if it submits an application to DOH which includes:

- The name and physical address of the hospital;
- The name, telephone number, and e-mail address of the hospital's chief executive officer, trauma medical director, and trauma program manager. Level I trauma center applicants must include information for both adult and pediatric services;
- A list of all trauma victim-related interfacility transfer agreements with other designated trauma centers, acute care hospitals, burn centers, and rehabilitation facilities;
- A description of the hospital's trauma surge capacity in the event of a natural disaster or mass casualty event;
- A copy of the application materials submitted to the national trauma center accreditation body<sup>56</sup> for verification as a trauma center;

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<sup>56</sup> The bill defines "national trauma center accreditation body" as an organization with optimal trauma center accreditation standards, approved by DOH, that publishes national guidelines for trauma center verification, has an active national trauma center verification program that has verified trauma centers in at least 25 states, and is not affiliated with any entity that is engaged in the delivery of

- A copy of reports and evaluations issued to the hospital by the national trauma center accreditation body relating to verification as a trauma center; and
- The certificate of trauma center verification.<sup>57</sup>

DOH will designate a hospital as a trauma center upon receipt of a completed application for designation as a trauma center and a valid certificate of trauma center verification. Currently, ACS is the only entity qualified under the provisions of the bill to issue a certificate of trauma center verification. The ACS verification program is used in at least 20 states, including Texas, New York, and Georgia.<sup>58</sup> The designation as a Level I, Level II, or pediatric trauma center must correspond to the certificate of trauma center verification. DOH may only deny an application if it is missing any of the required information listed above.

If a hospital has received provisional or verified status as a trauma center before July 1, 2016, it may continue its current operation as such, but must obtain a certificate of trauma center verification by July 1, 2022, to maintain its designation as a trauma center by DOH.

DOH may take corrective action against a trauma center, including revocation of the designation, if the trauma center fails to maintain its certification or the standards required to obtain verification from the national trauma center accreditation body as determined by DOH, its subcontractor, or the national trauma center accreditation body. A trauma center's designation is not valid if it does not hold a certificate of trauma center verification or the standards required to obtain verification from the national trauma center verification. DOH may also revoke a trauma center's designation if it fails to provide or withholds the information it supplied to any national trauma center accreditation body, at any time.

The bill abolishes DOH's responsibility to determine the number of trauma centers needed, to conduct a review of an applicant for designation as a trauma center to determine if the hospital has the critical elements required for a trauma center, to have a review team of out of state experts<sup>59</sup> perform onsite visits of provisional trauma centers, to grant provisional status to a trauma center awaiting full approval, and adopt rules for the procedure and process by which it will select trauma centers.

The bill retains but relocates provisions that require a designated trauma center to accept all trauma victims regardless of race, sex, creed, or ability to pay, and prohibits a hospital or other facility from representing itself as a trauma center unless it has been designated as such by DOH.

### Trauma Funding

The bill retains the eligibility of designated trauma centers to receive state funds, in equal amounts, when such funds are appropriated. However, the bill repeals a requirement that the trauma center comply with all DOH rules that ensure high quality trauma services.

### State Trauma Plan

The bill requires DOH to coordinate the development of the state trauma plan, which serves as the basis for the statewide inclusive trauma system. The bill repeals requirements for the establishment of trauma regions based on the regions established by FDLE for the Regional Domestic Security Task

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health care services. The accreditation body must have standards relating to facilities, trauma system integration, equipment, staffing, physician response requirements, interfacility transfer, education, and performance improvement. Currently, only the American College of Surgeons meets these criteria.

<sup>57</sup> The bill defines "certificate of trauma center verification" as the documentation issued by a national trauma center accreditation body that certifies a hospital's compliance with published standards for the administration of trauma care and the treatment of injured patients.

<sup>58</sup> Supra, FN 48 at pg. 5.

<sup>59</sup> Under s. 395.402(5), F.S., these out of state experts are considered agents of DOH and are exempt from civil liability for actions taken within the scope of the authority and responsibility assigned by DOH.

Force. DOH is responsible for updating the state trauma system plan by December 31 of each odd numbered year.

### Trauma Agency Plans

To operate as a trauma agency, DOH must approve a trauma agency plan submitted by the entity. The bill retains many of the requirements for the trauma agency plan that exist under current law for a local and regional trauma agency plan. However, the trauma agency plan required under the bill does not require the number and location of needed trauma centers based on local needs, population, and location and distribution of resources. In addition to the requirements in current law, the trauma agency plan must include:

- An annual performance evaluation of the trauma system, rather than the nonspecific periodic evaluations are required in current law;
- A uniform trauma transport protocol or approved trauma transport protocols from each emergency medical services provider in the geographic area served by the trauma agency, that incorporates all trauma centers and resources required to implement an inclusive trauma system; and
- A list of all participating healthcare facilities, organizations, and emergency medical services providers.

DOH must approve the trauma agency application within 120 days after notifying the developer of the trauma agency plan that the plan is complete. Under the bill, a trauma agency plan is not subject to the provisions of law that govern the approval or denial of applications. Under s. 120.60, F.S., an agency must approve or deny an application for a license<sup>60</sup> within 90 days of receipt of a completed application; and if it is not acted on within the 90 days, the license application is approved. Since the trauma agency plan is not a license, the trauma agency plan is not considered approved without department approval.

After the initial submission of a trauma system plan, a trauma agency must submit an updated plan by July 1 of each even-numbered year, which is more often than every five years as mandated under current law. The trauma agency plan must be consistent with the state trauma plan and must coordinate trauma care on a county level.

The bill allows a coordinated delivery of trauma services established before July 1, 2018, to continue in accordance with the public and private agreements and operational procedures previously established and in accordance with law.

The bill prohibits DOH from designating more than one trauma agency per county.

### Trauma Transport Protocols

The bill requires each EMS provider license applicant to submit and obtain approval of its trauma transport protocol, regardless of whether the applicable trauma agency has DOH-approved trauma transport protocols. A trauma patient must be transported to the most appropriate trauma center as defined by DOH-approved trauma transport protocols. The trauma transport protocols are no longer limited by whether there is an air ambulance available, as they are under current law.

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<sup>60</sup> A "license" is defined as a franchise, permit, certification, registration, charter, or similar form of authorization required by law, but does not include a license required primarily for revenue purposes when issuance of the license is merely a ministerial act. S. 120.52(10), F.S.

## Public records

Under current law, DOH has a public records exemption for all patient care, transport, or treatment records or reports, or patient care quality assurance proceedings, records, or reports obtained or made pursuant to its responsibility to plan, coordinate, and oversee the trauma system in this state.<sup>61</sup> The bill clarifies that emergency medical service transport and treatment records obtained by DOH are exempt, but does not expand the existing public records exemption.

## Rulemaking Authority

The bill repeals various grants of DOH's rulemaking authority located in the statutes relating to the trauma system. Currently, DOH has authority under s. 395.405, F.S., to adopt rules related to trauma care and therefore, the elimination of these individual, specific grants of rulemaking authority does not affect DOH's ability to adopt any necessary rules.

The bill provides an effective date of July 1, 2017.

### B. SECTION DIRECTORY:

**Section 1:** Amends s. 395.40, F.S., relating to legislative findings and intent.

**Section 2:** Amends s. 395.4001, F.S., relating to definitions.

**Section 3:** Amends s. 395.401, F.S., relating to trauma services system plans; approval of trauma centers and pediatric trauma centers; procedures; renewal.

**Section 4:** Amends s. 395.4015, F.S., relating to state regional trauma planning; trauma regions.

**Section 5:** Repeals s. 395.402, F.S., relating to trauma service areas; number and locations of trauma centers.

**Section 6:** Amends s. 395.4025, F.S., relating to trauma centers; selection; quality assurance; records.

**Section 7:** Amends s. 395.403, F.S., relating to reimbursement of trauma centers.

**Section 8:** Amends s. 395.4036, F.S., relating to trauma payments.

**Section 9:** Amends s. 395.404, F.S., relating to review of trauma registry data; report to central registry; confidentiality and limited release.

**Section 10:** Amends s. 395.4045, F.S., relating to emergency medical service providers; trauma transport protocols; transport of trauma alert victims to trauma centers; interfacility transfer.

**Section 11:** Amends s. 395.405, F.S., relating to rulemaking.

**Section 12:** Amends s. 395.50, F.S., relating to quality assurance activities of trauma agencies.

**Section 13:** Amends s. 320.0801, F.S.; relating to additional tax on certain vehicles.

**Section 14:** Amends s. 408.036, F.S.; relating to projects subject to review; exemptions.

**Section 15:** Amends s. 409.975, F.S.; relating to managed care plan accountability.

**Section 16:** Provides an effective date of July 1, 2017.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

#### 1. Revenues:

None.

#### 2. Expenditures:

DOH projects a reduction in expenditures of \$1,348,641 through fiscal year 2022-2023, under the bill, since it will not be responsible for reviewing applications, performing site reviews, and providing a defense for litigation regarding apportionment and designation of trauma centers.<sup>62</sup>

<sup>61</sup> S. 395.4025(10), F.S. The sections of law covered by this provision include ss. 395.3025(4)(f), 395.401, 395.4015, 395.402, 395.403, 395.404, 395.4045, 395.405, 395.50, and 395.51, F.S.

<sup>62</sup> Supra, FN 48 at pg. 7.

**B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

1. Revenues:

None.

2. Expenditures:

None.

**C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:**

Hospitals that are designated trauma centers, as well as hospitals seeking to be designated as a trauma center, will incur costs associated with obtaining and maintaining the certificate of trauma center verification.

An unlimited number of new trauma centers may result in decreased patient volume and income for existing trauma centers or for trauma centers in close proximity to one another.

Consumers may have more choices on where to seek emergency medical services. Increased competition may affect the cost and quality of care for consumers.

**D. FISCAL COMMENTS:**

None.

**III. COMMENTS**

**A. CONSTITUTIONAL ISSUES:**

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect municipal or county governments.

2. Other:

None.

**B. RULE-MAKING AUTHORITY:**

The bill provides DOH sufficient rulemaking authority to implement its provisions.

**C. DRAFTING ISSUES OR OTHER COMMENTS:**

None.

**IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES**