HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1077 Allocation of Trauma Services
SPONSOR(S): Health & Human Services Committee; 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	10 Y, 5 N	Mielke	Pridgeon
3) Health & Human Services Committee	14 Y, 4 N, As CS	Siples	Calamas

SUMMARY ANALYSIS

The Department of Health (DOH) is responsible for oversight 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 (TSA), as well as litigation related to the designation of specific hospitals as trauma centers.

CS/HB 1077 creates a statutory minimum need for trauma centers within a TSA based on its population. Current law contemplates that each of the 19 TSAs have at least one trauma center. Under the provisions of the bill, a TSA with a population of at least 1.25 million is deemed to need at least two trauma centers. A TSA with a population of more than 2.5 million is deemed to need at least four trauma centers. DOH retains the authority to allocate the number of trauma centers needed in each TSA, and the bill specifically authorizes DOH to allocate additional trauma centers above the minimum need established in the bill.

The bill also provides that any trauma center that has been approved, provisionally approved, or verified counts against the statewide cap of 44 trauma centers.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

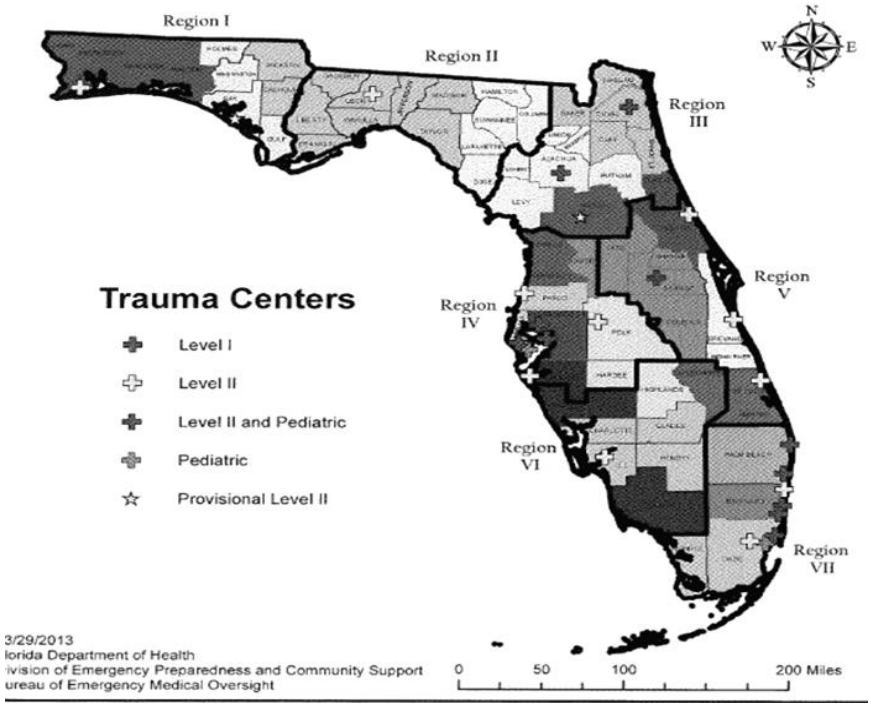
Current Situation

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.[1] 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.[2]



[1] S. 395.4015, F.S.,
[2] 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:[3]

TRAUMA SERVICE AREAS (TSAs) IN FLORIDA		
TSA	COUNTIES IN TSA	POPULATION[4]
1	Escambia, Okaloosa, Santa Rosa, Walton	732,863
2	Bay, Gulf, Holmes, Washington	237,535
3	Calhoun, Franklin, Gadsden, Jackson, Jefferson, Leon, Liberty, Madison, Taylor, Wakulla	509,547
4	Alachua, Bradford, Columbia, Dixie, Gilchrist, Hamilton, Lafayette, Levy, Putnam, Suwannee, Union	583,736
5	Baker, Clay, Duval, Nassau, St. Johns	1,454,031
6	Citrus, Hernando, Marion	668,306
7	Flagler, Volusia	620,506
8	Lake, Orange, Osceola, Seminole, Sumter	2,494,935
9	Pasco, Pinellas	1,450,437
10	Hillsborough	1,352,797
11	Hardee, Highlands, Polk	776,157
12	Brevard, Indian River	715,329
13	Desoto, Manatee, Sarasota	792,270
14	Martin, Okeechobee, St. Lucie	484,502
15	Charlotte, Glades, Hendry, Lee	902,406
16	Palm Beach	1,391,741
17	Collier	350,202
18	Broward	1,854,513
19	Dade, Monroe	2,776,841

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.[5] 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.[6] 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.[7] Currently, TSA 17 (Collier) is not directly covered by a trauma center.[8]

DOH is required to apportion, by rule, the number of trauma centers needed for each TSA.[9] 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

[3] S. 395.402(4)(a), F.S.
[4] Office of Economic and Demographic Research, *Florida Population Estimates for Counties and Municipalities April 1, 2016*, (Oct. 17, 2016), available at http://edr.state.fl.us/Content/population-demographics/data/2016_Pop_Estimates.pdf (last visited April 24, 2017).
[5] S. 395.402(4)(b) and (c), F.S.
[6] S. 395.402(1), F.S.
[7] Id.
[8] 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 (last visited on March 7, 2017).
[9] S. 395.402(4)(b), F.S., and Rule 64J-2.010, F.A.C.

specific to pediatric trauma centers are to be developed in conjunction with the DOH Division of Children's Medical Services.[10]

A trauma agency[11] 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,[12] 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.[13]

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.[14] 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:[15]

TRAUMA CENTER	LEVEL	COUNTY (TSA)
Aventura Hospital and Medical Center	Level II	Miami-Dade (19)
Baptist Hospital, Inc.	Level II	Escambia (1)
Bay County Health Systems, LLC Bay Medical Center Sacred Heart Health System	Level II	Bay (2)
Bayfront HMA Medical Center, LLC Bayfront Medical Center	Level II	Pinellas (9)
Central Florida Regional Hospital	Level II	Seminole (8)
Delray Medical Center, Inc.	Level I	Palm Beach (16)
Florida Health Sciences, Inc. Tampa General Hospital	Level I	Hillsborough (10)
Halifax Hospital Medical Center / Halifax Health	Level II	Volusia (7)
HCA Health Services of Florida, Inc. Blake Medical Center	Level II	Manatee (13)
HCA Health Services of Florida, Inc.	Level II	Pasco (9)

[10] S. 395.401(2), F.S., and Rule 64J-2.011, F.A.C.
[11] 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.)
[12] Rule 64J-2.007, F.A.C.
[13] Supra, FN 8, at pg. 5.
[14] 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.
[15] 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).

Regional Medical Center Bayonet Point		
Holmes Regional Medical Center, Inc.	Level II	Brevard (12)
Jackson South Community Hospital	Provisional Level II	Miami-Dade (19)
Johns Hopkins All Children's Hospital, Inc.	Pediatric	Pinellas (9)
Kendall Healthcare Group, LTD Kendall Regional Medical Center	Provisional Level I	Miami-Dade (19)
Lakeland Regional Medical Center, Inc.	Level II	Polk (11)
Lawnwood Medical Center, Inc. Lawnwood Regional Medical Center & Heart Institute	Level II	St. Lucie (14)
Lee Memorial Health System	Level II	Lee (15)
Marion Community Hospital, Inc. Ocala Regional Medical Center/ West Marion Community	Level II	Marion (6)
North Broward Hospital District Broward Health Medical Center	Level I	Broward (18)
North Broward Hospital District Broward Health North	Level II	Broward (18)
Orlando Health, Inc.(Orlando Regional Medical Center)	Level I	Orange (8)
Orange Park Medical Center	Provisional Level II	Clay (5)
Osceola Regional Medical Center	Level II	Osceola (8)
Sacred Heart Health System, Inc.	Level II / Pediatric	Escambia (1)
Sarasota Memorial Hospital	Level II	Sarasota (13)
Shands Jacksonville Medical Center, Inc. Shands Jacksonville/ UF Health Jacksonville	Level I	Duval (5)
Shands Teaching Hospital and Clinics, Inc. Shands UF (Gainesville)	Level I	Alachua (4)
South Broward Hospital District Memorial Regional Hospital	Level I	Broward (18)
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)
The Public Health Trust of Miami-Dade County, Florida Jackson Health System Jackson Memorial Hospital / Ryder Trauma Center	Level I	Miami-Dade (19)
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, 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.[16] 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.[17] 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.[18] A Level I trauma center must have:[19]

[16] S. 395.4001(10), F.S.
[17] S. 395.4025(3), (5), and (6), F.S.
[18] S. 395.4001(6)(b), F.S.
[19] Florida Department of Health, *Trauma Center Standard*s, 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 (last visited on March 7, 2017).

- 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.
- 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.[20] A Level II trauma center must have:[21]

- 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:[22]

- A minimum of five qualified trauma surgeons[23], 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.[24]

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.[25] 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.[26]

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.[27] The law required the boundaries of the trauma regions to be coterminous with the boundaries of the Regional

[20] S. 395.4001(7)(b), F.S.
[21] Supra, FN 19 at pages 3.2-3.33.
[22] Id. at pages 4.2-4.36
[23] 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.

[24] S. 395.404(1)(a), F.S.
[25] 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 (last visited on March 7, 2017).
[26] Id. at page 11.
[27] Ch. 2004-259, Laws of Fla.

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:[28]

- 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:[29]

- 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.[30] 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

[28] S. 395.402(2), F.S.
[29] S. 395.402(3), F.S.
[30] S. 3, ch. 2013-153, Laws of Fla.

- 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[31] challenged DOH approval of new trauma centers in Pasco,[32] Manatee,[33] and Clay[34] 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.[35] 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:[36]

- 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.

[31] Bayfront Medical Center in St. Petersburg, Tampa General Hospital, St. Joseph's Hospital in Tampa, and Shands Jacksonville.
[32] Blake Medical Center in Bradenton.
[33] Regional Medical Center Bayonet Point in Hudson.
[34] Orange Park Medical Center in Orange Park.
[35] 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.
[36] See *Dep't of Health v. Bayfront Medical Center*, 2012 WL 5971201 (Fla. App. 1 Dist.).

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.[37] 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.[38] 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.[39] 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.[40]

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.[41]

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 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

[37] *Shands Jacksonville Medical Center, Inc., d/b/a UF Health Jacksonville v. Dep't of Health,* DOAH Case No. 16-3369 (Jan. 27, 2017).
[38] Rule 64J-2.010, F.A.C. TSA 5 includes Baker, Clay, Duval, Nassau, and St. John's County.
[39] See below for further discussion of the rulemaking process.
[40] Supra, FN 37.
[41] Id.

rules.[42] 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.[43] Specifically, the court held that the proposed rules conferred DOH with discretion that was articulated in the statute. The court 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.[44] 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.

American College of Surgeons (ACS)

The ACS is a scientific and educational association of surgeons established in 1913.[45] 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,"[46] 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,[47] and the annual fee ranges from $17,000 to $34,000 depending on the level of verification the hospital holds.[48] The certification process is voluntary and only those trauma centers that have successfully completed a verification visit are awarded a certificate.[49] ACS awards Level I through IV verifications:[50]

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[42] 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 Heath – 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. Intervenors 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).

[43] *Shands Jacksonville Medical Center, Inc., d/b/a UF Health Jacksonville v. Dep't of Health,* DOAH Case No. 16-5837RP (Jan. 27, 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.

[44] Id.

[45] 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).

[46] A copy of this publication is on file with Health Innovation Subcommittee staff.

[47] 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).

[48] 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).

[49] 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).

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

- 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 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.[51] Three trauma centers have scheduled on-site visits and seven have scheduled consultation visits for 2017.[52]

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:[53]

- 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.[54]
- 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.

[51] Department of Health, *2017 Agency Bill Analysis for HB 1077*, (February 14, 2017), on file with the Health Innovation Subcommittee.
[52] Id.
[53] 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).
[54] 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).

- 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.[55]

Effect of Proposed Changes

Current law authorizes at least one Level I or Level II trauma center in each TSA, and authorizes DOH to allocate additional trauma centers needed for each TSA, up to a statewide maximum of 44 trauma centers. CS/HB 1077 retains the current statewide cap on trauma centers and establishes the minimum number of trauma centers needed in a TSA area by population.

Under the bill's provisions, a TSA with a population of at least 1,250,000, is deemed to need at least two Level I or Level II adult trauma centers or one of each. If the population of a TSA exceeds 2,500,000, then the bill establishes a statutory need of at least four adult trauma centers, which must be Level I or Level II or a combination of such trauma centers. DOH retains the authority to allocate the number of trauma centers for each TSA, and the bill authorizes DOH to adopt rules exceeding the statutory minimum established in the bill if DOH determines additional trauma centers are needed. Currently, six TSAs have populations that meet the threshold for the need of at least two adult trauma centers and one TSA meets the population threshold for the need of at least four adult trauma centers.

Any trauma centers that DOH has notified of final approval, provisional approval, or verification count against the statewide total of 44 trauma centers.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 395.402, F.S., relating to trauma service areas; number and locations of trauma centers.
Section 2: Amends s. 395.4025, F.S., relating to trauma centers; selection; quality assurance; records.
Section 3: 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:

   Since the bill establishes a mandatory minimum number of trauma centers needed in a trauma service area based on population, DOH may have less expenditures related to legal challenges to the allocation of trauma centers.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

[55] Supra, FN 53 at pages 12-14.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

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:

The Florida Constitution provides that the Legislature shall not enact any special law unless notice is first published.[56] A special law does not apply with geographic uniformity across the state. It operates only upon certain persons or regions, and bears no reasonable relationship to a difference in population or other legitimate criteria.[57] Laws which arbitrarily affect one subdivision of the state, but which fail to encompass other similarly situated subdivisions may be classified as special laws.[58] Even if a bill is enacted as a general law, courts will treat the bill as a special law if the effect is more like a special law.[59] Still other special laws are specifically prohibited by the Florida Constitution, such as laws pertaining to rules of evidence in any court or hunting or fresh water fishing.[60]

However, Florida case law has established that a local law need not apply universally in order to be a general law, and therefore constitutional, as long as "it is one of general import affecting directly or indirectly all the citizens of the state."[61] A general law may apply to a specific area if the classification of the area is permissible and reasonably related to the purpose of the statute, such as the valid exercise of the state's police power.[62] Police power is the sovereign right of the state to enact laws for the protection of lives, health, morals, comfort, and general welfare.[63] Legislative action exercised under the state's police power is valid if confined to acts which may reasonably be construed as expedient for the protection of public safety, public welfare, public morals, or public health. A great deal of discretion is vested in the Legislature to determine public interest and measures for its protection.[64]

B. RULE-MAKING AUTHORITY:

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

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[56] Florida Const. Art. III, s. 10; notice may be avoided if a referendum is conducted among those citizens affected by the law.
[57] *State ex rel. City of Pompano Beach v. Lewis*, 368 So.2d 1298 (Fla. 1979)(statute relating to particular persons or things or other particular subjects of a class is a special law); see also *Housing Auth. v. City of St. Petersburg*, 287 So.2d 307 (Fla. 1973)(defining a special law).
[58] *Dep't. of Bus. Regulation v. Classic Mile, Inc.*, 541 So.2d 1155 (Fla. 1989).
[59] Id.; see also *Anderson v. Board of Pub. Instruction for Hillsborough Cnty.*, 136 So. 334 (Fla. 1931).
[60] Florida Const. Art. III, s. 11.
[61] *State v. Leavins*, 599 So.2d 1326, 1336 (Fla. 1st DCA 1992)(citing *Cantwell v. St. Petersburg Port Authority*, 21 So.2d 139 (Fla. 1945)).
[62] Id. at 1336-37.
[63] *Newman v. Carson*, 280 So.2d 426, 428 (Fla. 1973)(citing *State ex rel. Municipal Bond and Inv. Co., Inc. v. Knott*, 154 So. 143 (1934)); *Holley v. Adams*, 238 So.2d 401 (Fla.1970).
[64] Id. (citing *Scarborough v. Newsome*, 7 So.2d 321 (1942); *Holley,* 238 So.2d at 407).

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On April 24, 2017, the Health and Human Services Committee adopted a strike-all amendment that:

- Deleted the provisions of the bill that eliminated the statewide cap on trauma centers, the trauma service areas, and DOH's responsibility to verify a hospital as a trauma center prior to designating the trauma center;
- Deemed a need for a minimum of two Level I or Level II adult trauma centers in a trauma service area with a population greater than 1,250,000;
- Deemed a need for a minimum of four Level I or Level II adult trauma center in a trauma service area with a population greater than 2,500,000;
- Authorized DOH to allocate, by rule, additional trauma centers above the minimums established; and
- Required all Level I, Level II, and pediatric trauma centers with provisional or final approval or verification from DOH to count against the statewide cap on the total number of trauma centers.
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The bill was reported favorably as a committee substitute. This analysis is drafted to the committee substitute as passed by the Health & Human Services Committee.