HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HIS 14-01 Health Care
SPONSOR(S): Health Innovation Subcommittee; Brodeur
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Innovation Subcommittee	8 Y, 4 N	Poche	Shaw

SUMMARY ANALYSIS

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. Florida's trauma system is comprised of seven trauma regions and nineteen trauma service areas (TSAs). The DOH is required to apportion, by rule, the number of trauma centers needed for each TSA. In Florida, there are Level I, Level II, and pediatric trauma centers, each of which must meet certain standards of care, quality of care requirements, and patient outcomes standards.

PCB HIS 14-01 includes legislative findings that an integrated, comprehensive, and superior quality trauma system is necessary to protect the health, safety and welfare of Floridians and visitors to the state; that each trauma center currently operating as a trauma center is an integral part of the trauma system and fulfills a critical need for trauma care services in the area where it is located; that a disruption in the operation of a trauma center may disrupt the availability of needed trauma services; and that all currently operating trauma centers are contributing to the trauma system and delivering needed trauma services so that optimal trauma care is available and accessible throughout the state.

Legal challenges to the rule established by the DOH to apportion trauma centers in the TSAs and approve provisional and verified trauma centers, and other litigation, threaten the ongoing inclusive trauma system in the state.

The PCB permits a hospital that has operated continuously as a Level I, Level II, or pediatric trauma center for a consecutive 12-month period after enactment of certain laws and submits an application to the American College of Surgeons Committee on Trauma (ACS COT) for a site visit to obtain a consultation report to continue to operate as a trauma center, if it continues to meet the trauma center and patient outcome requirements in s. 395.4025(6), F.S. The new requirement allows all trauma centers currently operating as trauma centers to remain an approved trauma center and ensure the continued operation of a stable, inclusive trauma system.

Any trauma center that obtains a consultation report from the ACS COT must provide a copy to the DOH. The DOH will use the reports in any assessment of the trauma system.

The PCB does not appear to have a fiscal impact on state or local government.

The PCB provides an effective date of upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

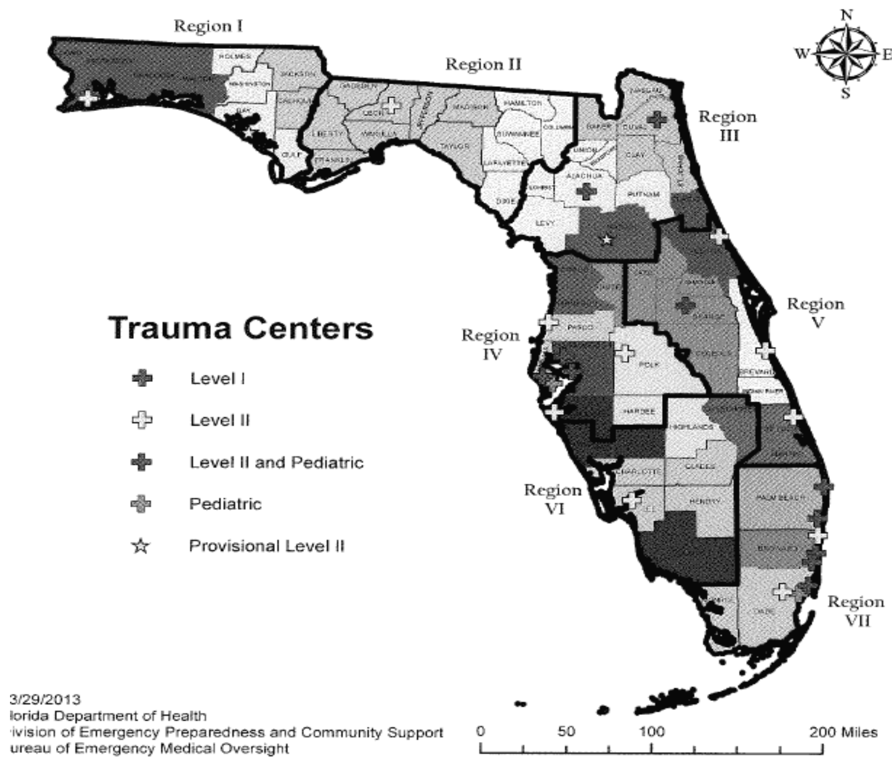
Background

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, the 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 Innovation Subcommittee staff).

Florida is divided into nineteen TSAs, detailed below:[3]

TRAUMA SERVICE AREAS (TSAs) IN FLORIDA	
TSA	COUNTIES IN TSA
1	Escambia, Santa Rosa, Okaloosa, Walton
2	Holmes, Washington, Bay, Gulf
3	Jackson, Calhoun, Gadsden, Liberty, Franklin, Leo, Wakulla, Jefferson, Madison, Taylor
4	Hamilton, Suwannee, Lafayette, Dixie, Columbia, Gilchrist, Levy, Union, Bradford, Alachua, Putnam
5	Baker, Nassau, Duval, Clay, St. Johns
6	Marion, Citrus, Hernando
7	Flagler, Volusia
8	Sumter, Lake, Seminole, Orange, Osceola
9	Pasco, Pinellas
10	Hillsborough
11	Polk, Hardee, Highlands
12	Brevard, Indian River
13	Manatee, Sarasota, Desoto
14	Okeechobee, St. Lucie, Martin
15	Charlotte, Lee, Glades, Hendry
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.[4] 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.[5] 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.[6] Currently, TSA 17 (Collier) is not directly covered by a trauma center.[7]

The DOH is required to apportion, by rule, the number of trauma centers needed for each TSA.[8] Additionally, the 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.[9]

Trauma Centers

A hospital may receive a designation as a Level I, Level II, pediatric, or provisional trauma center if the DOH verifies that the hospital is in substantial compliance with s. 395.4025, F.S., and the relevant

[3] S. 395.402(4)(a), F.S.
[4] S. 395.402(4)(b) and (c), F.S.
[5] S. 395.402(1), F.S.
[6] Id.
[7] Florida Department of Health, Bureau of Emergency Medical Oversight, Health Information and Policy Analysis Program, *Trauma Service Area Assessment*, January 31, 2014, page 23, available at www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/trauma-area-service-assessment.pdf (last viewed on March 9, 2014).
[8] S. 395.402(4)(b), F.S., and Rule 64J-2.010, F.A.C.
[9] S. 395.401(2), F.S., and Rule 64J-2.011, F.A.C.

trauma center standards.[10] 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 March 6, 2014, the following hospitals are designated trauma centers:[11]

TRAUMA CENTER	LEVEL	COUNTY
All Children's Hospital	Pediatric	Pinellas
Baptist Hospital	Level II	Escambia
Bay Medical Center	Level II	Bay
Bayfront Medical Center	Level II	Pinellas
Blake Medical Center	Level II	Manatee
Broward Health Medical Center	Level I	Broward
Broward Health North	Level II	Broward
Delray Medical Center	Level I	Palm Beach
Halifax Medical Center	Level II	Volusia
Holmes Regional Medical Center	Level II	Brevard
Kendall Regional Medical Center	Level II	Miami-Dade
Jackson Memorial Hospital/ Ryder Trauma Center	Level I	Miami-Dade
Lakeland Regional Medical Center	Level II	Polk
Lawnwood Regional Medical Center	Level II	St. Lucie
Lee Memorial Hospital	Level II	Lee
Memorial Regional Hospital	Level I	Broward
Miami Children's Hospital	Pediatric	Miami-Dade
Ocala Regional Medical Center/ Marion Community Hospital	Provisional Level II	Marion
Orlando Regional Medical Center	Level I	Orange
Regional Medical Center Bayonet Point	Level II	Pasco
Sacred Heart Hospital	Level II / Pediatric	Escambia
St. Joseph's Hospital	Level II / Pediatric	Hillsborough
St. Mary's Hospital	Provisional Level I	Palm Beach
Shands Jacksonville	Level I	Duval
Shands at the University of Florida	Level I	Alachua
Tallahassee Memorial Hospital	Level II	Leon
Tampa General	Level I	Hillsborough

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 the DOH to operate as a provisional Level I, Level II or pediatric trauma center, and has applied to be a verified trauma center.[12] A hospital that is granted provisional status operates as a provisional trauma center for up to one year while the DOH conducts an in-depth review and a provisional onsite survey prior to the deciding to approve or deny verification.[13] Currently, there is one provisional Level I trauma center, St. Mary's Medical Center in West Palm Beach, and one provisional Level II trauma center, Ocala Regional Medical Center in Ocala.

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.[14] A Level I trauma center:[15]

- Must have 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.

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[10] 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.

[11] Florida Department of Health, *Florida Trauma Centers*, available at www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/%20traumacenterlisting2014.pdf (last viewed on March 9, 2014).

[12] S. 395.4001(10), F.S.

[13] S. 395.4025(3), (5), and (6), F.S.

[14] S. 395.4001(6)(b), F.S.

[15] Florida Department of Health, *Trauma Center Standards*, Pamphlet 150-9, January 2010, pages 2.1-2.38, available at www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/%20traumacntrstandpamphlet150-9-2009rev1-14-10.pdf (last viewed on March 9, 2014).

- Must have 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.
- Must have 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.[16] A Level II trauma center:[17]

- Must have a minimum of five qualified trauma surgeons, assigned to the 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.
- Must have 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:[18]

- Must have a minimum of five qualified trauma surgeons[19], 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.
- Must have ten surgical specialties and eight non-surgical specialties available 24 hours a day to arrive promptly when summoned.
- Must have 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.[20]

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.[21] 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.[22]

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.[23] 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 the 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. The DOH was also directed to complete an

[16] S. 395.4001(7)(b), F.S.
[17] See supra, FN 15 at pages 3.2-3.33
[18] Id. at pages 4.2-4.36
[19] 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.

[20] S. 395.404(1)(a), F.S.
[21] 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 (on file with the Health Innovation subcommittee staff).
[22] Id. at page 11.
[23] Ch. 2004-259, Laws of Fla.

assessment of the effectiveness of the trauma system and report its findings to the Governor and Legislature by February 1, 2005. The assessment included:[24]

- Consideration of aligning trauma service areas within the trauma region boundaries as established 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 this assessment and subsequent annual reviews, the law required the DOH to consider the following:[25]

- 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, the 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 the 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.[26] 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.

[24] S. 395.402(2), F.S.
[25] S. 395.402(3), F.S.
[26] S. 3, ch. 2013-153, Laws of Fla.

Based on the DOH Trauma Service Area Assessment from January 2014,[27] and applying the criteria in statute, a hospital in the following counties could be designated as a Level II trauma center, if it holds a certificate of trauma center verification from the ACS:

- TSA 1-
  - Santa Rosa
  - Okaloosa
  - Walton
- TSA 11-
  - Hardee
  - Highlands

As of March 9, 2014, no hospital has been designated as a Level II trauma center under this statute.

<u>Florida Trauma System Administrative Rule Challenge and Associated Litigation</u>

In 2011, four not-for-profit hospitals[28] challenged the DOH approval of new trauma centers in Pasco,[29] Manatee,[30] and Clay[31] 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.[32] 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 hospital argued that 2004 amendments to s. 395.4015, F.S., required the 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, the DOH initiated a special study using national trauma experts and state and local stakeholders to develop evidenced-based guidelines to be used by the 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 on both grounds, as alleged. The 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 were resolved. The 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:[33]

- The trauma statutes were substantially amended in 2004, yet the rule remains unchanged since 1992. As such, the rule continues to implement outdated provisions of the statutes, without implementing any of the enumerated statutes.
- The Department 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.

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[27] See supra, FN 7.
[28] Bayfront Medical Center in St. Petersburg, Tampa General Hospital, St. Joseph's Hospital in Tampa, and Shands Jacksonville.
[29] Blake Medical Center in Bradenton.
[30] Regional Medical Center Bayonet Point in Hudson.
[31] Orange Park Medical Center in Orange Park. The trauma center at this facility closed in February 2013 when its provisional license was rescinded after DOH inspectors found standards for approval as a Level II trauma center had not been met. The Medical Center filed for a formal administrative proceeding in May 2013 to challenge the loss of its provisional license. The case was placed in abeyance in November 2013, pending the completion of the rulemaking process described later in this analysis. A status update on the process and whether or not the parties are ready to proceed is due to the court no later than May 15, 2014.
[32] For example, in 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.
[33] See *Department of Health v. Bayfront Medical Center*, 2012 WL 5971201 (Fla.App. 1 Dist.).

- Both the pre-and post-2004 versions of the statute require the Department 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." §395.4015(1), Fla. Stat. (2004).
- 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.

Instead of appealing the decision, the 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.

There are several cases that are in active litigation as a result of the invalidity of the Rule and the DOH approval of Ocala Regional Medical Center as a provisional Level II trauma center and approval of Regional Medical Center Bayonet Point and Blake Medical Center as provisional, then verified Level II trauma centers. The following is a partial list of those cases:

- Shands at the University of Florida is challenging the designation of Ocala Regional Medical Center as a provisional Level II trauma center. The case is set for administrative hearing on April 14, 2014, to April 16, 2014, and April 21, 2014 to April 23, 2014.
- In a case that was consolidated in February 2014 from two separate cases before the DOAH, Tampa General Hospital and Bayfront Medical Center are challenging the designation of Blake Medical Center as a provisional Level II trauma center. The case is set for administrative hearing from June 16, 2014, to June 19, 2014, and from June 23, 2014, to June 27, 2014.
- In a case that was consolidated in February 2014 from three separate cases before the DOAH, Tampa General Hospital, Bayfront Medical Center, and St. Joseph's Hospital are challenging the designation of Regional Medical Center Bayonet Point as a provisional Level II trauma center. The case is set for administrative hearing from July 7, 2014 to July 11, 2014, and from July 28, 2014 to August 1, 2014.
- Several cases have been filed by the same parties to challenge the designations of Ocala Regional Medical Center, Regional Medical Center Bayonet Point, and Blake Medical Center as verified Level II trauma centers. Those cases are in abeyance and status updates are due to the court at various times in April 2014.

Rulemaking Process to Amend the Rule on Apportionment of Trauma Centers

In December 2012, the 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, the DOH published a Notice of Proposed Rule on February 3, 2014, which detailed substantive changes to the Rule governing the apportionment (now called "allocation" in the proposed rule) of trauma centers in the TSAs. A hearing was scheduled to take place of February 25, 2014, to solicit public input on the proposed rule. The DOH is expected to continue finalizing rule language and approve the rule. It is expected that the final allocation rule will be challenged.

American College of Surgeons (ACS)

The ACS is a scientific and educational association of surgeons established in 1913. 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,"[34] which is recognized as a guide to develop trauma centers in the United States. ACS site surveyors use the book to review trauma centers.

According to ACS, the consultation/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 certification process is voluntary and only those trauma centers that have successfully completed a verification visit are awarded a certificate.[35] ACS awards Level I-IV verifications:[36]

- 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 university-based teaching hospitals 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 services as the de facto primary care provider. Such a facility may be a clinic rather than a hospital and a physician may not be available.

In February 2013, the ACS Committee on Trauma (COT), at the request of the State Surgeon General, conducted a system consultation and review of Florida's trauma system. The final report from ACS was released to the DOH in May 2013. The following are some of the priority recommendations contained in the report:[37]

- 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.[38]

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

[35] As of February 19, 2014, ACS verifies trauma centers in 46 states. The hospitals with ACS verification in Florida are Tampa General Hospital (Level I trauma center), and Tampa General Hospital Children's Medical Center (Level I and pediatric trauma center). Verification for both facilities expires on January 29, 2016. See American College of Surgeons, *Verified Trauma Centers*, available at: http://www.facs.org/trauma/verified.html (last viewed on March 8, 2014).

[36] American College of Surgeons, *Description of Hospital Levels*, available at: http://www.facs.org/trauma/hospitallevels.pdf (last viewed on March 8, 2014).

[37] 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://newsroom.doh.state.fl.us/wp-content/uploads/newsroom/2013/05/Report-Final.pdf (last viewed on March 8, 2014).

[38] On March 3, 2014, the DOH released the State Trauma System Plan, a three page document that lays out strategic priorities for the next 36 months for the Florida trauma system based, in part, on the priority recommendations from the ACS. The Plan appears to focus on tasks associated with developing Regional Trauma Agencies statewide and establishing benchmarking and ensuring data

- 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.[39]

Effect of Proposed Changes

The PCB includes legislative findings that an integrated, comprehensive, and superior quality trauma system is necessary to protect the health, safety and welfare of Floridians and visitors to the state; that each trauma center currently operating as a trauma center is an integral part of the trauma system and fulfills a critical need for trauma care services in the area where it is located; that a disruption in the operation of a trauma center may disrupt the availability of needed trauma services; and that all currently operating trauma centers are contributing to the trauma system and are delivering needed trauma services so that optimal trauma care is available and accessible throughout the state.

The PCB permits a hospital that has operated continuously as a Level I, Level II, or pediatric trauma center for a consecutive 12-month period after enactment of ch. 2004-259 and submits an application to the ACS COT for a site visit to obtain a consultation report to continue to operate as a trauma center, if it continues to meet the trauma center and patient outcome requirements in s. 395.4025(6), F.S., until the approval period in statute expires. A hospital that meets the requirements of the PCB is eligible for renewal of its 7-year approval period under s. 395.4025(6).

The PCB allows all trauma centers currently operating in the state as a trauma center to be approved by the DOH as a trauma center, to operate for the initial 7-year approval period, and apply for renewal of the 7-year approval period when the initial period expires.

The PCB requires each hospital that obtains a trauma center consultation report from the ACS COT following a site visit to submit the report to the DOH, which is then required to use those reports in any assessment of the state trauma system.

The PCB is effective upon becoming a law.

B. SECTION DIRECTORY:

Section 1: Provides legislative findings.
Section 2: Creates an unnumbered section of law relating to a hospital operating as a Level I, Level II, or pediatric trauma center.
Section 3: Creates an unnumbered section of law relating to the provision and use of trauma consultation reports to and by the Department of Health.
Section 4: Provides an effective date of upon becoming a law.

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quality for performance improvement. The Plan is available at www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/state-trauma-system-plan-final.pdf.

[39] See supra, FN 37 at pages 12-14.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

A consultation site visit to a trauma center by the ACS COT costs $15,000 for a three person review team and $18,000 for a four person review team.[40] Review teams consist of two trauma surgeons and one nurse supervisor.[41] A four person review team adds a specialist with additional trauma experience.[42] Any additional member of the review team costs $3,000.[43] A consultation site visit to a facility that is a combination trauma center and pediatric trauma center, such as Sacred Heart Hospital in Pensacola, costs $19,500.[44]

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

[40] American College of Surgeons, Trauma Consultation/Verification Packet-Site Visit Application, page 2, available at www.facs.org/trauma/site-visit-app.pdf (last viewed on March 10, 2014).
[41] Telephone conference between Molly Lozada, Verification/Consultation Programs Program Administrator, and Health Innovation Subcommittee staff on January 30, 2014.
[42] Id.
[43] Id.
[44] See supra, FN 40.

The Florida Constitution provides that the Legislature shall not enact any special law unless notice is first published.[45] 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.[46] Laws which arbitrarily affect one subdivision of the state, but which fail to encompass other similarly situated subdivisions may be classified as special laws.[47] 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.[48] 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.[49]

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."[50] 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.[51] Police power is the sovereign right of the state to enact laws for the protection of lives, health, morals, comfort and general welfare.[52] 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.[53]

B. RULE-MAKING AUTHORITY:

No rule-making authority is needed to implement the provisions of the PCB.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 11, 2014, the Health Innovation Subcommittee adopted one amendment to PCB HIS 14-01. The amendment clarified that a Level I, Level II, or pediatric trauma center which meets the criteria in the bill may continue to operate as a Level I, Level II, or pediatric trauma. The amendment clarifies that a trauma center that meets the provisions of the bill continues to operate at its current designated level. The PCB does not allow a trauma center to change its designation level.

The PCB was reported favorably as amended. The analysis reflects the PCB as amended.

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[45] Florida Const. Art. III, s. 10; notice may be avoided if a referendum is conducted among those citizens affected by the law.
[46] See *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).
[47] See *Dept. of Bus. Regulation v. Classic Mile, Inc.*, 541 So.2d 1155 (Fla. 1989).
[48] See id.; see also *Anderson v. Board of Pub. Instruction for Hillsborough Cnty.*, 136 So. 334 (Fla. 1931).
[49] Florida Const. Art. III, s. 11.
[50] See *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)).
[51] Id. at 1336-37.
[52] See *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)).
[53] Id. (citing *Scarborough v. Newsome*, 7 So.2d 321 (1942); *Holley v. Adams*, supra, 238 So.2d at 407).