HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 817 Health Care
SPONSOR(S): Health & Human Services Committee; Health Care Appropriations Subcommittee; Gaetz
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 966

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N	Holt	O'Callaghan
2) Health Care Appropriations Subcommittee	12 Y, 0 N, As CS	Rodriguez	Pridgeon
3) Health & Human Services Committee	12 Y, 5 N, As CS	Holt	Calamas

SUMMARY ANALYSIS

The bill substantially amends Part II of chapter 395, F.S., to streamline the application and review process by the Department of Health (DOH) for Level I and pediatric trauma centers and to deregulate state oversight of Level II trauma centers, such that hospitals must seek a valid certificate as a Level II trauma center from the American College of Surgeons instead of completing the current application and review process performed by DOH.

The bill further stipulates that a hospital is only eligible for Level II trauma center review and verification if the hospital is located in a rural county and not located within 75 miles of an existing Level I trauma center. The bill defines “rural county” to mean a county with boundaries that encompass a population of 300 or fewer persons per square mile. The population densities are to be based on the most recent United States census. The bill repeals s. 395.402, F.S., relating to the requirement for a specific number and location of trauma centers and a set number of trauma service areas.

The bill codifies current authority and standards for DOH to conduct a provisional review of applicants for a Level I or pediatric trauma center to determine whether the application is complete and if a hospital has the critical elements required for trauma care. The bill streamlines the review process by requiring DOH to determine whether the hospital has certain minimum standards and by eliminating certain application processes and timelines.

The bill repeals s. 395.40, F.S., related to legislative findings and intent. The bill makes conforming changes throughout Part II of ch. 395, F.S., and substantially reorganizes, restructures and removes unnecessary words to improve readability.

The bill amends s. 154.11(1)(f) and (p), F.S., to provide an exemption to the lease requirements for office space controlled by any public health trust and provides the board of trustees of a public health trust the sole discretion in its use and employment of legal counsel, subject to the approval by the governing body of the county where the trust is located.

The bill has a significant positive fiscal impact on the Emergency Services Trust Fund within DOH and an insignificant negative fiscal impact to local governments.

The bill provides an effective date of July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

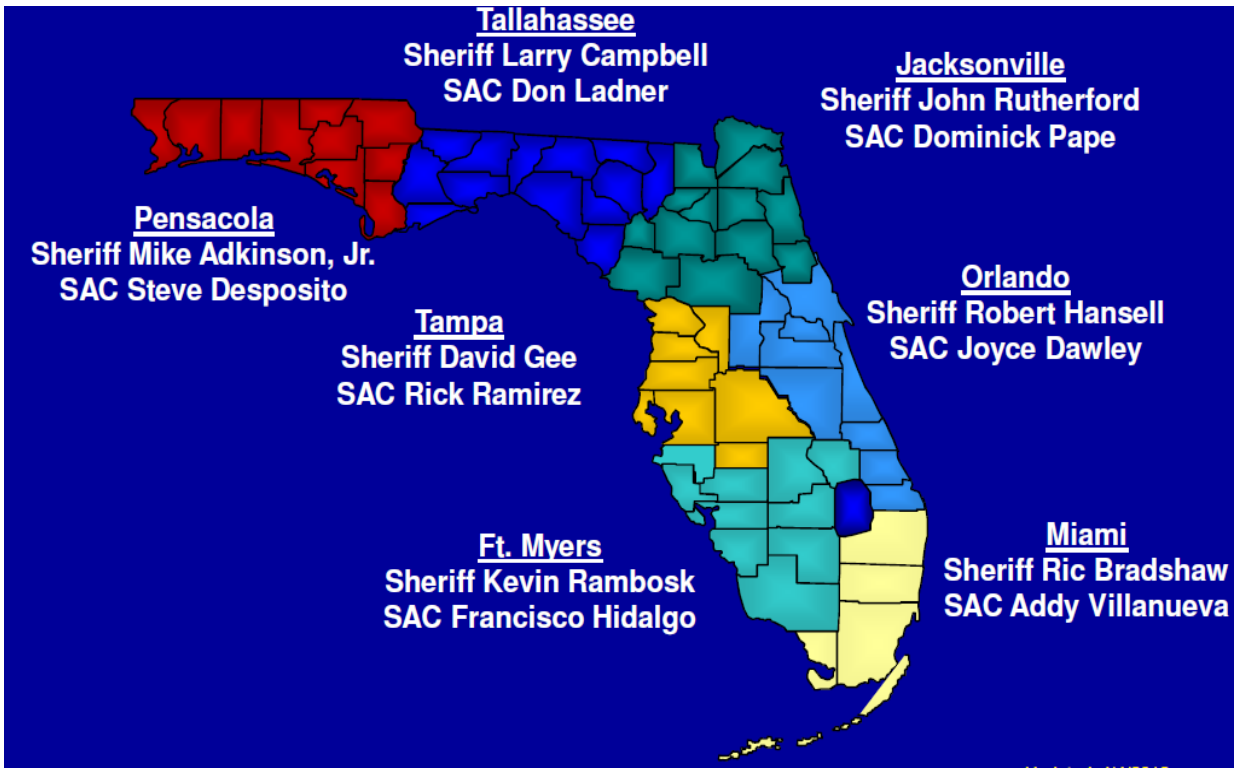
Present Situation

Florida Trauma System

The regulation of trauma centers in Florida is established under Part II of Chapter 395, F.S. Trauma centers treat individuals who have incurred a single or multisystem injury due to blunt or penetrating means or burns and who require immediate medical intervention or treatment. In order to provide timely access to care, trauma standards are based on the "golden hour" principle, which is generally defined by emergency medical personnel as the first 60 minutes of intensive care during which it is possible to save the life of an injured or traumatized person.[1]

As part of the state trauma system plan, s. 395.4015, F.S., requires the Department of Health (DOH) 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 forces. These regions may serve as the basis for the development of department-approved local or regional trauma plans.[2]

Florida Regional Domestic Security Task Forces

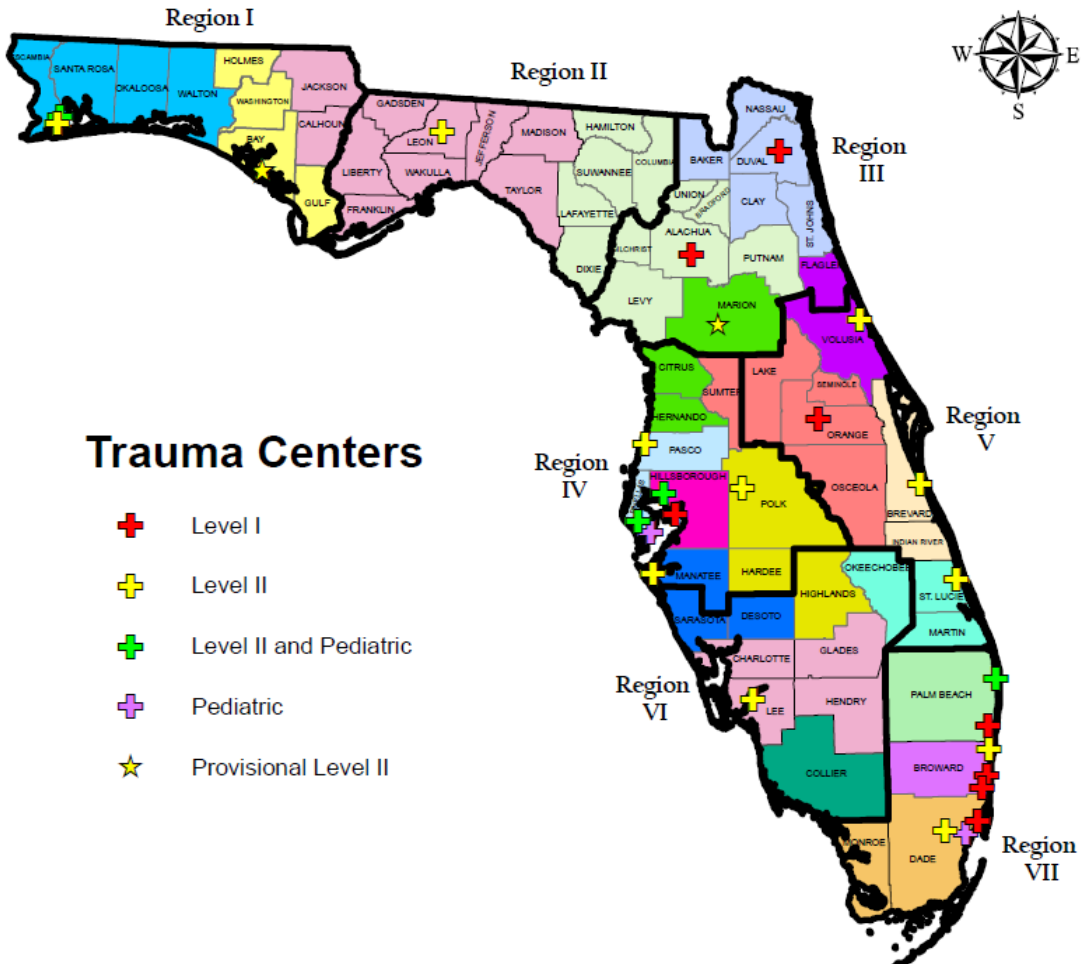


Florida's trauma system is comprised of four trauma agencies, seven trauma regions, and nineteen trauma service areas.

Trauma agencies are responsible for the development of department-approved local or regional trauma plans, administering an inclusive regional trauma system, coordinating arrangements to develop a trauma system, and updating an approved plan.[3] The four trauma agencies are: North Central Florida

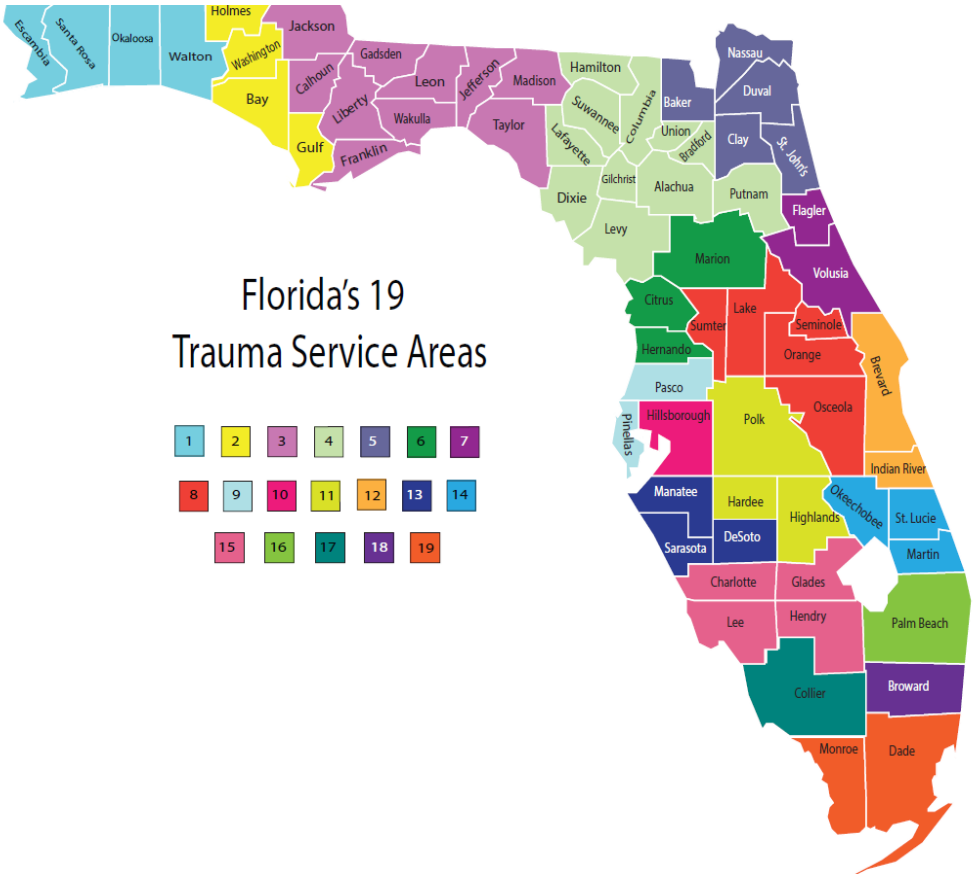
[1] Department of Health, Florida Trauma System: 2010 Annual Report, available at: http://www.doh.state.fl.us/demo/trauma/forms.htm (last viewed on April 22, 2013).
[2] Section 395.4015(1), F.S.
[3] Section 395.401, F.S.

Trauma Agency, Hillsborough County Trauma Agency, Palm Beach Trauma Agency and Broward County Trauma Agency. The seven trauma regions are illustrated below.



Pursuant to s. 395.402, F.S., Florida is statutorily divided into nineteen "trauma service areas." For purposes of medical response times, the trauma service areas are designed to provide the best and fastest services to the state's population. Each trauma service area 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] Moreover, 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. Level II trauma centers in counties with a population of more than 500,000 shall have the capacity to care for 1,000 patients per year.[5]

[4] Section 395.402(4), F.S.
[5] Section 395.402(1), F.S.



DOH is required to allocate, by rule, the number of trauma centers needed for each trauma service area. On October 8, 2008, DOH adopted these allocation requirements in Rule 64J-2.010, F.A.C.[6]

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 DOH's, Division of Children's Medical Services.[7]

Trauma Centers

Currently, 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.[8] A trauma center may have more than one designation; for example, St. Mary's Medical Center in Delray Beach carries both a Level I and a pediatric trauma center designation. As of April 22, 2013, the following hospitals are designated trauma centers:[9]

[6] Rule 64J-2.0101, F.A.C., which allocates a total of 42 trauma centers throughout the 19 trauma service areas, has been the subject of recent litigation. *See infra* fn 20 and the comments under the header "Trauma System Administrative Rule Challenge."
[7] Section 395.401(2), F.S. and Rule 64J-2.011, F.A.C.
[8] 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.
[9] Per email correspondence with DOH staff dated April 15, 2013, on file with the Health and Human Services Committee staff.

TRAUMA CENTER	LEVEL	DATE OF VERIFICATION OR PROVISIONAL	COUNTY	TRAUMA SERVICE AREA
Bayfront Medical Center and All Children's Bayfront	Joint Pediatric	1999	Pinellas	9
Baptist Hospital	Level II	1996	Escambia	1
Bay Medical Center	Provisional Level II	2012	Bay	2
Bayfront Medical Center	Level II	1984	Pinellas	9
Blake Medical Center	Level II	2013	Manatee	13
Broward General Medical Center	Level I	1998	Broward	18
Delray Medical Center	Level I	2012	Palm Beach	16
Halifax Medical Center	Level II	1985	Volusia	7
Holmes Regional Medical Center	Level II	2000	Brevard	12
Kendall Regional Medical Center	Level II	2013	Miami-Dade	19
Jackson Memorial Hospital/Ryder Trauma Center	Level I	1984	Miami-Dade	19
Lakeland Regional Medical Center	Level II	1998	Polk	11
Lawnwood Regional Medical Center	Level II	2010	St. Lucie	14
Lee Memorial Hospital	Level II	1994	Lee	15
Memorial Regional Hospital	Level I	1998	Broward	18
Miami Children's Hospital	Stand Alone Pediatric	1989	Miami-Dade	19
North Broward Medical Center	Level II	1993	Broward	18
Ocala Regional Medical Center/Marion Community Hospital	Provisional Level II	2012	Marion	6
Orlando Regional Medical Center	Level I	1982	Orange	8
Regional Medical Center Bayonet Point	Level II	2013	Pasco	9
Sacred Heart Hospital	Pediatric Level II	1996 2002	Escambia	1
St. Joseph's Hospital	Pediatric Level II	1997 1983	Hillsborough	10
St. Mary's Hospital	Pediatric Level I	1996 1992	Palm Beach	16
Shands Jacksonville	Level I	1982	Jacksonville	5
Shands at the University of Florida	Level I	2005	Gainesville	4
Tampa General	Level I	1984	Hillsborough	10
Tallahassee Memorial Hospital	Level II	2009	Leon	3

A provisional trauma center is an acute care hospital that has applied to become a Level I, Level II or pediatric verified trauma center.[10] Hospitals granted provisional status must operate as a provisional trauma center for a period of up to a year, while DOH conducts an in-depth review and a provisional onsite survey prior to DOH's determination to approve verification or deny a verification. Currently, there are two provisional Level II trauma centers: Bay Medical Center, Panama City, and Ocala Regional Medical Center, Ocala.[11]

Level I trauma centers serve as resource facilities to Level II trauma centers, pediatric trauma referral-centers, and general hospitals through shared outreach, education, and quality-improvement activities. Compared to other types of trauma centers, Level I trauma centers:[12]

- 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 at the trauma center when summoned.
- Must have twelve surgical specialties and eleven non-surgical specialties (*see* the chart on page 8). These specialties must be available to provide in-hospital trauma services and backup trauma coverage 24-hours a day at the trauma center when summoned.
- Must have formal research and education programs for the enhancement of both adult and pediatric trauma care.

[10] Section 395.4001(10), F.S.
[11] Bay Medical Center received provisional status on May 2, 2012. Likewise, Ocala Regional Medical Center received provisional status on December 8, 2012. Per email correspondence with DOH staff dated April 9, 2013, on file with Health and Human Services Committee staff.
[12] Section 395.4025, F.S., and Rules 64J-2.011 - 64J-2.016, F.A.C.

Level II trauma centers serve as resource facilities to general hospitals through shared outreach, education, and quality improvement activities. Specific differences in the Level II standards and other verifications are that they:[13]

- 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 at the trauma center when summoned.
- Must have nine surgical specialties and nine non-surgical specialties (*see* the chart below) available to provide trauma services and arrive promptly to provide trauma coverage 24 -hours a day at the trauma center when summoned.

Pediatric trauma centers serve as resource facilities to general hospitals through shared outreach, education, and quality improvement activities. Specific differences in the standards of a pediatric trauma center and other verifications are that they:[14]

- Must have a minimum of five qualified trauma surgeons, assigned to the trauma service, with at least two trauma surgeons available to provide trauma services and backup trauma coverage 24-hours a day at the trauma center 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 (*see* the chart below) available 24-hours a day to arrive promptly at the trauma center when summoned.
- Must have formal research and education programs for the enhancement of pediatric trauma care.

Trauma Center Specialties by Trauma Center Type			
Surgical Specialties	**Level I**	**Level II**	**Pediatric**
Cardiac Surgery	×		×
Hand Surgery	×		×
Microsurgery capabilities	×		
Obstetric/gynecologic Surgery	×	×	
Ophthalmic Surgery	×	×	×
Oral/maxillofacial Surgery	×	×	×
Orthopedic Surgery	×	×	×
Otorhinolaryngologic Surgery	×	×	×
Pediatric Surgery	×	X***	×
Plastic surgery	×	×	×
Thoracic surgery	×	×	×
Urologic surgery	×	×	×
Non-Surgical Specialties	**Level I**	**Level II**	**Pediatric**
Cardiology	×	×	×
Gastroenterology	×		
Hematology	×	×	×
Infectious Disease	×	×	×
Internal Medicine	×	×	
Nephrology	×	×	×
Pathology	×	×	×
Pediatric	×	×	×
Psychiatry	×		
Pulmonary Medicine	×	×	×
Radiology	×	×	×

***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.

All trauma centers are required to submit quality indicator data to the Florida Trauma Registry.[15]

[13] *Id.*
[14] *Id.*
[15] Section 395.404, F.S. and Rule 64J-2.006, F.A.C.

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 which reviewed Florida's hospital response capacity and examined the disparity of available trauma centers across the state.[16] The study recommended adopting the borders of the seven regional domestic security task forces as the state trauma regions and maintaining the nineteen trauma service areas.

In response to the interim study, numerous bills were filed during the 2004 Legislative Session to amend Florida's trauma system. Only one, Senate Bill 1762 (2004), was ultimately enacted.[17] The new law required the boundaries of the trauma regions to be coterminous with the boundaries of the regional domestic security task forces established within the Florida Department of Law Enforcement. The law provided a grandfather clause to allow the continuation of the delivery of trauma services coordinated with a trauma agency pursuant to a public or private agreement established before July 1, 2004. Moreover, DOH was directed to complete an assessment of the effectiveness of the existing trauma system and report its findings to the Governor and Legislature by February 1, 2005. The assessment was to include:[18]

- 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 trauma service area 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 trauma service area 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 Taskforce 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 DOH to consider the following:[19]

- The recommendations made as a part of the regional trauma system 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 Taskforce.
- The actual number of trauma victims currently being served by each trauma center.
- Other appropriate criteria.

In February 2005, DOH submitted to the Legislature a report, 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 2005 report made numerous recommendations, including a recommendation to transform the Florida trauma service areas to align them with the boundaries utilized by the regional domestic security task forces.

[16] Hospital Response Capacity, Report Number 2004-148, Senate Committee on Home Defense, Public Security, and Ports, on file with the Health and Human Services Committee staff.
[17] Senate Bill 1762, Chapter 2004-259, L.O.F.
[18] Section 395.402(2), F.S.
[19] Section 395.402(3), F.S.

To date, the Legislature has not amended the structure of the Florida trauma system to incorporate the recommendations of the 2005 report.

Trauma System Administrative Rule Challenge

The DOH trauma program is tasked with overseeing the development, implementation and monitoring of various patient care guidelines, criteria and protocols for trauma centers and emergency medical services. In 2008, DOH adopted Rule 64J-2.010, F.A.C., which allocates the number of trauma centers needed within each trauma service area. The trauma program held a series of rule development workshops and hearings on Rule 64J-2.010, F.A.C., from 2008 to 2009. These meetings generated no consensus on rule revisions.

In May 2011, DOH received a challenge to Rule 64J-2.010, F.A.C., from five of the existing 22 verified trauma centers. The rule challenge alleged that DOH's rule was invalid for it constituted an invalid exercise of delegated legislative authority and was arbitrary and capricious. 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 that DOH's Rule 64J-2.010, F.A.C., was invalid on both grounds. DOH appealed the administrative hearing officer's ruling. The 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, First District Court of Appeal held that Rule 64J-2.010, F.A.C., is an invalid exercise of delegated legislative authority:[20]

> 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 these 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. 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.

The dissent, stated, in part:

> The order below [DOAH order] and the majority opinion find that because the Legislature, under section 395.4015(1), Florida Statutes, required the Department to change the boundaries of trauma *regions* to be "coterminous with the boundaries of the regional domestic security taskforces established under s. 943.0312," the rule allocating trauma centers within *trauma service areas* is invalid. The flaw with this conclusion is that a trauma service area is not a trauma region; thus, the rule's allocation of trauma centers to trauma service areas cannot be invalid on this basis.

[20] *Department of Health v. Bayfront Medical Center*, 37 Fla. L. Weekly D2754 (Fla. 1st DCA November 30, 2012). The court did not uphold DOAH's finding, however, that the rule was arbitrary and capricious.

On December 21, 2012, DOH held its first rule development workshop to gather input from the trauma system providers and partners on how Rule 64J-2.010, F.A.C., could be amended to ensure an inclusive trauma system in Florida. A series of rule workshops have been held since then. No consensus on rule language has been reached.

In February 2013, the Surgeon General requested the American College of Surgeons (ACS) to conduct a systems consultation of Florida's trauma system. The final report from ACS is expected to be released to DOH in May.[21]

American College of Surgeons

ACS is a scientific and educational association of surgeons that began 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 called the "Resources for Optimal Care of the Injured Patient." ACS site surveyors use this book to review trauma centers and it is recognized as a guide to develop trauma centers in the United States.[22]

According to the 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 to include: 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.[23] ACS awards Level I-IV verifications:[24]

- A *Level I* facility is a regional resource trauma center that is a tertiary care facility central to the trauma system. This type of 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. Level I centers are usually university-based teaching hospitals due to the large personnel and resources required for patient care, education (to include residency programs), 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, but the trauma center is required to provide initial definitive trauma care regardless of the severity of the injury. Level II centers 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 and also arrange for possible transfer to another facility that can provide definitive care and requires transfer agreements and standardized treatment protocols. General surgeons are required in a Level III facility. Level III trauma centers are generally not appropriate in urban or suburban areas with adequate Level I or Level II resources.

[21] Per telephone conversation with DOH staff on April 23, 2013.
[22] American College of Surgeons, About the ACS, available at: http://www.facs.org/about/corppro.html (last viewed April 22, 2013).
[23] ACS currently verifies trauma centers in the following states: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, Nevada, North Carolina, North Dakota, South Carolina, Ohio, Oklahoma, Oregon, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming. 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). *See* American College of Surgeons, available at: http://www.facs.org/trauma/verified.html (last viewed April 22, 2013).
[24] American College of Surgeons, Description of Hospital Levels, available at: http://www.facs.org/trauma/sitepacket.html (last viewed April 22, 2013).

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

The ACS has a multistep application and review process for certification. The costs are delineated by the number of members of the review team.

ACS Fee Structure[25]			
	Two-person review team:	Three-person review team:	Four-person review team:
Verification	$13,000	$16,000	$19,000
Re-verification	$12,000	$15,000	$18,000
Consultation	---	$15,000	$18,000

The fees include ACS administrative fee, reviewers' honoraria, travel expenses and subsistence. The cost for each additional site reviewer is $3,000 (e.g. alternate pathway, trauma program manager, emergency physician, orthopedic surgeon, or neurosurgeon.)[26]

Public Health Trusts

Section 154.07, F.S., grants each of the counties of the state the authority to create a public health trust. To create the trust, a governing body of a county must declare, through proper resolution, that there is a need for such a trust and appoint members to a board to govern the trust (the board of trustees).[27] The board of trustees is then authorized to become the operator of, and governing body for, any county-owned or county-operated facility used in connection with the delivery of health care, which has been designated by the governing body of the county for transfer to the public health trust, referred to as a "designated facility".[28] However, the board of trustees' authority to operate and govern the designated facility is subject to limitation by the governing body of the county.[29] The governing body of the county can transfer to the public health trust any or all of the ownership, operation, governance or maintenance of any designated facility.[30]

The boards of trustees' powers include, but are not limited to, the following:

- To sue and be sued; however, this provision shall not be construed to affect in any way the laws relating to governmental immunity;
- To have a seal and alter the same;
- To make and adopt bylaws and rules and regulations for the board's guidance and for the operation, governance, and maintenance of designated facilities not inconsistent with ordinances of the county;
- To make and execute contracts and other instruments necessary to exercise the powers of the board;
- To acquire by purchase or otherwise, and to hold title to, any property, real or personal, useful to the purposes of the board;
- To lease, either as lessee or lessor, or rent for any number of years and upon any terms and conditions real property, except that the board shall not lease or rent, as lessor, any real property except in accordance with the requirements of s. 125.35, F.S. (1973);
- To appoint a chief executive officer of the trust and to remove such an appointee;

[25] American College of Surgeons, Application for a Site Visit, available at: http://www.facs.org/trauma/sitepacket.html (last viewed April 22, 2013).
[26] *Id.*
[27] Section 154.07, F.S.
[28] Section 154.08, F.S. Designated facilities may include, but shall not be limited to, the following: sanatoriums, clinics, ambulatory care centers, primary care centers, hospitals, rehabilitation centers, health training facilities, nursing homes, nurses' residence buildings, infirmaries, outpatient clinics, mental health facilities, residences for the aged, rest homes, health care administration buildings, and parking facilities and areas serving health care facilities.
[29] Section 154.11, F.S.
[30] Section 154.10, F.S.

- To establish rates and charges for those using the facilities of, or receiving care or assistance from, the board and to collect money pursuant thereto;
- To accept gifts of money, services, or real or personal property;
- To appoint, remove, or suspend employees or agents of the board, fix their compensation, and adopt personnel and management policies;
- To provide for employee benefits, including, but not limited to, the benefits required by s. 154.10(5), F.S., and those benefits provided by s. 154.12(1), F.S.;
- To cooperate with and contract with any governmental agency or instrumentality, federal, state, municipal, or county;
- To adopt and amend rules and regulations for the management and use of any properties under its control;
- To appoint originally the staff of physicians to practice in any designated facility owned or operated by the board and to approve the bylaws and rules to be adopted by the medical staff of any designated facility owned and operated by the board, such governing regulations to be in accordance with the standards of the Joint Commission on the Accreditation of Hospitals which provide, among other things, for the method of appointing additional staff members and for the removal of staff members;
- To employ certified public accountants to audit and analyze the records of the board and to prepare financial or revenue statements of the board; but such authority does not in any way affect any responsibility of the Auditor General pursuant to s. 11.45, F.S.; and
- To employ legal counsel.[31]

Effects of Proposed Changes

Trauma System

The bill amends s. 395.4025, F.S., to require any hospital seeking a Level II trauma center designation after July 1, 2013, to apply to ACS to receive a valid certificate. The bill specifies that a hospital holding a provisional license as a Level II trauma center as of July 1, 2013, may complete the application process to become a verified Level II trauma center and the hospital may maintain the designation for seven years from the date of approval and verification by DOH. After the seven years the trauma center must hold a valid certificate of Level II trauma center verification from ACS.

The bill deletes DOH's authority to review, verify, and approve Level II trauma centers based on state standards. Instead, DOH is required to designate a Level II trauma center based on receiving documentation that the hospital holds a valid certificate of trauma center verification from ACS. Requiring the use of ACS standards for Level II trauma center designation significantly modifies the current trauma center verification process and removes DOH's role in determining the need, number, and location of such trauma centers in the state.[32]

The bill further stipulates that a hospital is only eligible for Level II trauma center review and verification if the hospital is located in a rural county and not located within 75 miles of an existing Level I trauma center. The bill defines "rural county" to mean a county with boundaries that encompass a population of 300 or fewer persons per square mile. The population densities are to be based on the most recent United States census. These provisions prohibit a hospital from establishing a Level II trauma center in a non-rural county and do not take into account any growth in population.[33] Instead of the 7-year renewal period as provided for in current law, the bill provides that a Level II trauma center holding a valid certificate from ACS has a renewal cycle that coincides with ACS' renewal cycle.

The bill streamlines the duties of DOH, such that DOH is authorized to approve applications from hospitals seeking designation, re-designation, or change in status for Level I and pediatric trauma centers. The bill codifies DOH's current authority to oversee the application review and verification, and

[31] *Id.*
[32] Department of Health, Bill Analysis for CS/CS/HB 817 dated April 17, 2013, on file with the Health and Human Services Committee staff.
[33] *Id.*

onsite visits of trauma centers but deletes specific timelines. The bill authorizes DOH to conduct a provisional review of each application for a Level I or pediatric trauma center to determine whether the application is complete and whether the hospital has the critical elements required for trauma care pursuant to standards in s. 395.401(2), F.S. DOH must review whether the hospital has:

- The equipment and physical facilities necessary to provide trauma services;
- The sufficient number of personnel with proper qualifications to provide trauma services;
- An effective quality assurance process; and
- Written confirmation by the local or regional trauma agency that the hospital applying to become a trauma center is consistent with the plan of the local or regional trauma agency, as approved by DOH, if such agency exists.

Currently, there are only four trauma agencies in Florida and these cover only 19 of Florida's 67 counties. Thus, there are counties in trauma service areas that do not have trauma agencies established to provide written confirmation of the hospital's qualifications.[34] The bill clarifies that DOH is authorized to conduct an in-depth evaluation of all applications found acceptable in the provisional review of "clinical" criteria.

Furthermore, the bill repeals s. 395.402, F.S., relating to the requirement for a specific number and location of trauma centers and a set number of trauma service areas. The bill deletes similar language in s. 395.401(1)(b)4., F.S., that requires the trauma service system plan to include the number and location of need trauma centers based on local needs, population, location and distribution of resources. According to DOH, rules would need to be amended to remove the requirement for such specifics within in a trauma system plan.[35]

The bill removes requirements that DOH send letters of intent, application packages, and provide extensions. According to DOH, rules relating to the current trauma center Letter of Intent, application, application extension, site survey, and verification approval process will need to be amended or repealed.[36]

The bill requires local or regional trauma plans to provide for the transportation of trauma patients and the coordination of activities between trauma centers, acute care hospitals, emergency service providers, law enforcement agencies, and local governments. In addition, such plans must recognize trauma service areas that reflect well-established patient flow patterns.

The bill amends the definitions of "Level II trauma center" and "trauma center" to conform to the requirement that a hospital seek a valid certificate from ACS for a Level II trauma center. The definition of "provisional trauma center" is amended to clarify a Level II trauma center may hold the provisional designation if the hospital was verified and approved to operate as a provisional Level II trauma center before July 1, 2013.

The bill repeals s. 395.40, F.S., related to legislative findings and intent. The bill makes conforming changes throughout and substantially reorganizes, restructures and removes unnecessary words to improve readability.

Public Health Trusts

Section 154.11(f), F.S., requires the board of trustees for any public health trust to comply with the requirements of s.125.35, F.S.,[37] for any real property it leases as lessor. The bill amends this subsection to exempt leases of office space controlled by the public health trust from the requirements of s. 125.35, F.S. It is unclear what effect this amendment will have as each county governing body

[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] Section 125.35, F.S. sets forth the requirements for a county to sell and lease real property which included among others, a public notice requirement.

has discretionary authority to grant the board of trustees any or all of the ownership, operation, governance or maintenance of any designated facility.

Section 154.11(p), F.S., allows the board of trustees for any public health trust to employ legal counsel. However, any decision by the board of trustees as to the legal counsel it wishes to retain must be approved by the governing body of the county in which the board is located.[38] The bill amends this subsection to give the board of trustee's sole discretion in its use and employment of legal counsel. It is unclear what effect, if any, this may have on the governing body of the county where the trust is located. However, irrespective of any counsel the board elects to employ, the governing body of the county retains ultimate decision-making authority.

B. SECTION DIRECTORY:

Section 1. Amends s. 154.11, F.S., relating to powers of the board of trustees.
Section 2. Repeals s. 395.40, F.S., relating to legislative findings and intent.
Section 3. Amends s. 395.4001, F.S., relating to definitions.
Section 4. Amends s. 395.401, F.S., relating to trauma service system plans; approval of trauma centers and pediatric trauma centers; procedures; and renewal.
Section 5. Amends s. 395.4015, F.S., relating to state regional trauma planning; and trauma regions.
Section 6. Repeals s. 395.402, F.S., relating to trauma service areas; number and location of trauma centers.
Section 7. Amends s. 395.4025, F.S., relating to trauma centers; selection; quality assurance; and records.
Section 8. Amends s. 395.405, F.S., relating to rulemaking.
Section 9. Provides an effective date of July 1, 2013.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   See Fiscal Comments.

[38] *Supra* fn 29.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

If a public hospital seeks verification as a Level II trauma center from ACS, the costs for such verification may impact local governments that utilize special tax districts to support that hospital.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Currently, the cost for the application and verification of a Level II trauma center reviewed and approved by DOH is paid for by established state funding. The costs for an ACS verification certificate for a Level II trauma center will be borne by a hospital seeking such designation.[39]

D. FISCAL COMMENTS:

DOH projects an annual savings of $165,000 to the Emergency Medical Services Trust Fund from eliminating the need for DOH to hire out-of-state surveyors and decreasing administrative costs associated with processing Level II applications.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The mandates provision appears to apply because this bill requires a hospital, including a public hospital funded by local governments, with a Level II trauma designation to self-fund the costs associated with the verification by ACS if a hospital wishes to maintain such designation. However, an exemption applies since the potential cost borne by a public hospital is insignificant. In addition, an exception applies because the provision applies equally to all similarly situated persons, both public and private.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On April 2, 2013, the Health Care Appropriations Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all amendment:

- Directs DOH to convene a study group that evaluates the need for a statewide primary source verification repository for the core credentials data of health care practitioners.
- Provides requirements for the needs assessment.
- Requires the study group to submit recommendations by July 1, 2014.
- Provides an effective date of July 1, 2013.

[39] *Supra* fn 32.

On March 16, 2013, the Health and Human Services Committee adopted three amendments and reported the bill favorably as a committee substitute for committee substitute. The strike-all and two amendments to the amendment:

- Remove the content of the bill.
- Exempt the board of trustees of a public health trust from the requirements of s. 125.35, F.S., when it leases, as lessor, office space controlled by the public health trust.
- Provide the board of trustees of a public health trust sole discretion in its determinations to employ legal counsel.
- Replace DOH standards and approval processes for Level II trauma centers with certification by the ACS.
- Permit current Level II trauma centers to maintain their designations until expiration. After that, the hospital must have ACS certification.
- Allow DOH to revoke Level II trauma center designations for current trauma centers, if DOH determines the hospital is no longer in compliance with the clinical standards and capability requirements.
- Maintain current authority for DOH to approve and verify Level I and pediatric trauma centers.
- Remove statutory timelines, trauma service area and trauma center number limitations, procedural requirements, and legislative intent, and narrows DOH rule-making authority, relating to the process of designating trauma centers.
- Provide that a hospital is only eligible for Level II trauma center review and verification if the hospital is located in a rural county and provides a definition of "rural county."
- Specify after July 1, 2013, a hospital may not receive a Level II trauma center approval and verification if the hospital is located within 75 miles of an existing Level I trauma center.
- Delete the grandfather clause provided for in the strike-all for provisional Level II trauma centers.
- Make conforming changes throughout and substantially reorganizes the statute to improve readability.

The analysis reflects the committee substitute for committee substitute.