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A bill to be entitled An act relating to health care; amending s. 154.11, F.S.; revising powers of the boards of trustees of the public health trusts; authorizing the lease of certain office space for use by public health trusts; providing discretion to the public health trust to employ legal counsel; repealing s. 395.40, F.S., relating to legislative findings and intent with respect to trauma care; amending s. 395.4001, F.S.; revising definitions with respect to trauma services; amending s. 395.401, F.S.; deleting certain requirements for trauma plan components; limiting the department's authority to adopt verification standards for trauma centers; conforming a cross-reference; amending s. 395.4015, F.S.; revising the criteria for state regional trauma plans; repealing s. 395.402, F.S., relating to trauma service areas and the number and location of trauma centers; amending s. 395.4025, F.S.; deleting requirements for trauma center selection; specifying designation requirements for Level II trauma centers; deleting obsolete provisions; deleting provisions for extension of provisional status; providing for renewals for Level II trauma center designations; revising the renewal process for Level I, Level II, pediatric, and provisional trauma centers; authorizing the department to adopt rules to designate Level I and pediatric trauma centers; amending s. 395.405, F.S.; conforming a cross-

Page 1 of 16

reference; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraphs (f) and (p) of subsection (1) of section 154.11, Florida Statutes, are amended to read:

154.11 Powers of board of trustees.-

- (1) The board of trustees of each public health trust shall be deemed to exercise a public and essential governmental function of both the state and the county and in furtherance thereof it shall, subject to limitation by the governing body of the county in which such board is located, have all of the powers necessary or convenient to carry out the operation and governance of designated health care facilities, including, but without limiting the generality of, the foregoing:
- (f) 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, Florida Statutes [F. S. 1973], or unless the lease is for office space for use by the public health trust.
- (p) To employ legal counsel, as the public health trust sees fit, and in its sole discretion.
- Section 2. <u>Section 395.40, Florida Statutes, is repealed.</u>
 Section 3. Subsections (7), (10), and (14) of section
 395.4001, Florida Statutes, are amended to read:
 - 395.4001 Definitions.—As used in this part, the term:
 - (7) "Level II trauma center" means a trauma center that:

Page 2 of 16

verification from the American College of Surgeons, except as otherwise provided in s. 395.4025 Is verified by the department to be in substantial compliance with Level II trauma center standards and has been approved by the department to operate as a Level II trauma center.

- (b) Serves as a resource facility to general hospitals through shared outreach, education, and quality improvement activities.
 - (c) Participates in an inclusive system of trauma care.
- (10) "Provisional trauma center" means a hospital that has been verified by the department to be in substantial compliance with the requirements in s. 395.4025 and has been approved by the department to operate as a provisional Level I trauma center, been trauma center, or pediatric trauma center, or provisional Level II trauma center verified and approved before July 1, 2013.
- verified by the department to be in substantial compliance with the requirements in s. 395.4025 and has been approved by the department to operate as a Level I trauma center, Level II trauma center, or pediatric trauma center, or designated Level II trauma center that holds a valid certificate of trauma center verification from the American College of Surgeons or as otherwise provided in s. 395.4025.
- Section 4. Paragraph (b) of subsection (1) and subsections (2) and (3) of section 395.401, Florida Statutes, are amended to read:

395.401 Trauma services system plans; approval of trauma centers and pediatric trauma centers; procedures; renewal.—

(1)

- (b) The local and regional trauma agencies shall develop and submit to the department plans for local and regional trauma services systems. The plans must include, at a minimum, the following components:
 - 1. The organizational structure of the trauma system.
- 2. Prehospital care management guidelines for triage and transportation of trauma cases.
- 3. Flow patterns of trauma cases and transportation system design and resources, including air transportation services, provision for interfacility trauma transfer, and the prehospital transportation of trauma victims. The trauma agency shall plan for the development of a system of transportation of trauma alert victims to trauma centers where the distance or time to a trauma center or transportation resources diminish access by trauma alert victims.
- 4. The number and location of needed trauma centers based on local needs, population, and location and distribution of resources.
- $\underline{4.5.}$ Data collection regarding system operation and patient outcome.
- $\underline{5.6.}$ Periodic performance evaluation of the trauma system and its components.
- $\underline{6.7.}$ The use of air transport services within the jurisdiction of the local trauma agency.
 - 7.8. Public information and education about the trauma

Page 4 of 16

113 system.

- $\underline{8.9.}$ Emergency medical services communication system usage and dispatching.
- 9.10. The coordination and integration between the trauma center and other acute care hospitals.
 - 10.11. Medical control and accountability.
 - 11.12. Quality control and system evaluation.
- verification of Level I and pediatric trauma centers based on national guidelines, including those established by the American College of Surgeons entitled "Hospital and Prehospital Resources for Optimal Care of the Injured Patient" and published appendices thereto. Standards specific to pediatric trauma referral centers shall be developed in conjunction with Children's Medical Services and adopted by rule of the department.
- (3) The department may withdraw local or regional agency authority, prescribe corrective actions, or use the administrative remedies as provided in s. 395.1065 for the violation of any provision of this section and ss. 395.4015, 395.402, 395.4025, 395.403, 395.404, and 395.4045 or rules adopted thereunder. All amounts collected pursuant to this subsection shall be deposited into the Emergency Medical Services Trust Fund provided in s. 401.34.
- Section 5. Subsection (1) of section 395.4015, Florida Statutes, is amended, and subsections (4) and (5) are added to that section, to read:
 - 395.4015 State regional trauma planning; trauma regions.-

Page 5 of 16

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The department shall establish a state trauma system (1)plan. As part of the state trauma system plan, the department shall establish trauma regions that 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. These regions may serve as the basis for the development of department-approved local or regional trauma plans 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. Such regional plans shall recognize trauma service areas that reflect well established patient flow patterns. However, The delivery of trauma services by or in coordination with a trauma agency established before July 1, 2004, may continue in accordance with public and private agreements and operational procedures entered into as provided in s. 395.401.

- (4) A hospital is only eligible for Level II trauma center approval and verification if the hospital is located in a rural county. For purposes of this subsection, the term "rural county" means a county with boundaries that encompass a population of 300 or fewer persons per square mile. Population densities used in this subsection must be based upon the most recent United States census.
- (5) After July 1, 2013, a hospital seeking Level II trauma center approval and verification may not receive such approval and verification if the hospital is located within 75 miles of an existing Level I trauma center.

Section 6. Section 395.402, Florida Statutes, is repealed.

Section 7. Section 395.4025, Florida Statutes, is amended

to read:

395.4025 Trauma centers; <u>designation</u> selection; quality assurance; records.—

- (1) (a) Applicants for a Level I or pediatric trauma center designation shall submit an application developed by the department and documentation sufficient to demonstrate compliance with the standards adopted by the department pursuant to subsection (2) and s. 395.401(2).
- (b) A Level II trauma center holding a provisional license as of July 1, 2013, may complete the application process to become a verified Level II trauma center pursuant to subsection (2), and, if designated as such, may maintain the designation of a Level II trauma center for 7 years from the date of approval and verification by the department. Thereafter, the trauma center must hold a valid certificate of trauma center verification from the American College of Surgeons.
- (c) Any hospital seeking a Level II trauma center

 designation after July 1, 2013, shall be designated by the

 department when the department receives documentation of the

 hospital holding a valid certificate of trauma center

 verification from the American College of Surgeons For purposes

 of developing a system of trauma centers, the department shall

 use the 19 trauma service areas established in s. 395.402.

 Within each service area and based on the state trauma system

 plan, the local or regional trauma services system plan, and

 recommendations of the local or regional trauma agency, the

department shall establish the approximate number of trauma centers needed to ensure reasonable access to high-quality trauma services. The department shall select those hospitals that are to be recognized as trauma centers.

- (2) The department shall approve applications from hospitals seeking designation as trauma centers, including current verified trauma centers that seek a change or redesignation in approval status as a trauma center. The department shall conduct a provisional review of each application for the purpose of determining whether the hospital's application is complete and whether the hospital has the critical elements required for a trauma center. This critical review shall be based on trauma center standards pursuant to s. 395.401(2) and shall include, but not be limited to, a review of whether the hospital has:
- trauma services The department shall annually notify each acute care general hospital and each local and each regional trauma agency in the state that the department is accepting letters of intent from hospitals that are interested in becoming trauma centers. In order to be considered by the department, a hospital that operates within the geographic area of a local or regional trauma agency must certify that its intent to operate as a trauma center is consistent with the trauma services plan of the local or regional trauma agency, as approved by the department, if such agency exists. Letters of intent must be postmarked no later than midnight October 1.
 - (b) A sufficient number of personnel with proper

Page 8 of 16

qualifications to provide trauma services By October 15, the department shall send to all hospitals that submitted a letter of intent an application package that will provide the hospitals with instructions for submitting information to the department for selection as a trauma center. The standards for trauma centers provided for in s. 395.401(2), as adopted by rule of the department, shall serve as the basis for these instructions.

- (c) An effective quality assurance process In order to be considered by the department, applications from those hospitals seeking selection as trauma centers, including those current verified trauma centers that seek a change or redesignation in approval status as a trauma center, must be received by the department no later than the close of business on April 1. The department shall conduct a provisional review of each application for the purpose of determining that the hospital's application is complete and that the hospital has the critical elements required for a trauma center. This critical review will be based on trauma center standards and shall include, but not be limited to, a review of whether the hospital has:
- 1. Equipment and physical facilities necessary to provide trauma services.
- 2. Personnel in sufficient numbers and with proper qualifications to provide trauma services.
 - 3. An effective quality assurance process.
- 4. Submitted 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 the department, if such agency

Page 9 of 16

CODING: Words stricken are deletions; words underlined are additions.

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(d) 1. Submitted 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 the department, if such agency exists Notwithstanding other provisions in this section, the department may grant up to an additional 18 months to a hospital applicant that is unable to meet all requirements as provided in paragraph (c) at the time of application if the number of applicants in the service area in which the applicant is located is equal to or less than the service area allocation, as provided by rule of the department. An applicant that is granted additional time pursuant to this paragraph shall submit a plan for departmental approval which includes timelines and activities that the applicant proposes to complete in order to meet application requirements. Any applicant that demonstrates an ongoing effort to complete the activities within the timelines outlined in the plan shall be included in the number of trauma centers at such time that the department has conducted a provisional review of the application and has determined that the application is complete and that the hospital has the critical elements required for a trauma center. 2. Timeframes provided in subsections (1) - (8) shall be

- 2. Timeframes provided in subsections (1) (8) shall be stayed until the department determines that the application is complete and that the hospital has the critical elements required for a trauma center.
- (3) Any hospital that submitted an application found acceptable by the department based on provisional review shall

Page 10 of 16

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be eligible to operate as a provisional trauma center After April 30, Any hospital that submitted an application found acceptable by the department based on provisional review shall be eligible to operate as a provisional trauma center.

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- (4) Between May 1 and October 1 of each year, The department shall conduct an in-depth evaluation of all applications found acceptable in the provisional review. The applications shall be evaluated against clinical criteria enumerated in the application packages as provided to the hospitals by the department.
- Beginning October 1 of each year and ending no later than June 1 of the following year, A review team of out-of-state experts assembled by the department shall make onsite visits to all provisional trauma centers. The department shall develop a survey instrument to be used by the expert team of reviewers. The instrument shall include objective criteria and guidelines for reviewers based on existing trauma center standards pursuant to subsection (2) and s. 395.401(2) such that all trauma centers are assessed equally. The survey instrument shall also include a uniform rating system that will be used by reviewers to indicate the degree of compliance of each trauma center with specific standards, and to indicate the quality of care provided by each trauma center as determined through an audit of patient charts. In addition, Hospitals being considered as provisional trauma centers shall meet all the requirements of a trauma center and shall be located in a trauma service area that has a need for such a trauma center.
 - (6) Based on recommendations from the review team, the

Page 11 of 16

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department shall approve hospitals for designation as select trauma centers by July 1. An applicant for designation as a trauma center may request an extension of its provisional status if it submits a corrective action plan to the department. The corrective action plan must demonstrate the ability of the applicant to correct deficiencies noted during the applicant's onsite review conducted by the department between the previous October 1 and June 1. The department may extend the provisional status of an applicant for designation as a trauma center through December 31 if the applicant provides a corrective action plan acceptable to the department. The department or a team of out-of-state experts assembled by the department shall conduct an onsite visit on or before November 1 to confirm that the deficiencies have been corrected. The provisional trauma center is responsible for all costs associated with the onsite visit in a manner prescribed by rule of the department. By January 1, the department must approve or deny the application of any provisional applicant granted an extension. Each Level I or pediatric trauma center shall be granted a 7-year approval period during which time it must continue to maintain trauma center standards and acceptable patient outcomes as determined by department rule. An approval for a Level I or pediatric trauma center designation, unless sooner suspended or revoked, automatically expires 7 years after the date of issuance and is renewable upon application for renewal as prescribed by rule of the department. Renewals for Level II trauma center designations are dependent upon the American College of Surgeons' renewal cycle.

(7) Any hospital that wishes to protest a decision made by the department based on the department's preliminary or in-depth review of applications or on the recommendations of the site visit review team pursuant to this section shall proceed as provided in chapter 120. Hearings held under this subsection shall be conducted in the same manner as provided in ss. 120.569 and 120.57. Cases filed under chapter 120 may combine all disputes between parties.

- (8) Notwithstanding any provision of chapter 381, a hospital licensed under ss. 395.001-395.3025 that operates a trauma center may not terminate or substantially reduce the availability of trauma service without providing at least 180 days' notice of its intent to terminate such service. Such notice shall be given to the department, to all affected local or regional trauma agencies, and to all trauma centers, hospitals, and emergency medical service providers in the trauma service area. The department shall adopt by rule the procedures and process for notification, duration, and explanation of the termination of trauma services.
- (9) Except as otherwise provided in this subsection, the department or its agent may collect trauma care and registry data, as prescribed by rule of the department, from trauma centers, hospitals, emergency medical service providers, local or regional trauma agencies, or medical examiners for the purposes of evaluating trauma system effectiveness, ensuring compliance with the standards, and monitoring patient outcomes. A trauma center, hospital, emergency medical service provider, medical examiner, or local trauma agency or regional trauma

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agency, or a panel or committee assembled by such an agency under s. 395.50(1) may, but is not required to, disclose to the department patient care quality assurance proceedings, records, or reports. However, the department may require a local trauma agency or a regional trauma agency, or a panel or committee assembled by such an agency to disclose to the department patient care quality assurance proceedings, records, or reports that the department needs solely to conduct quality assurance activities under s. 395.4015, or to ensure compliance with the quality assurance component of the trauma agency's plan approved under s. 395.401. The patient care quality assurance proceedings, records, or reports that the department may require for these purposes include, but are not limited to, the structure, processes, and procedures of the agency's quality assurance activities, and any recommendation for improving or modifying the overall trauma system, if the identity of a trauma center, hospital, emergency medical service provider, medical examiner, or an individual who provides trauma services is not disclosed.

- (10) Out-of-state experts assembled by the department to conduct onsite visits are agents of the department for the purposes of s. 395.3025. An out-of-state expert who acts as an agent of the department under this subsection is not liable for any civil damages as a result of actions taken by him or her, unless he or she is found to be operating outside the scope of the authority and responsibility assigned by the department.
- (11) Onsite visits by the department or its agent may be conducted at any reasonable time and may include but not be

Page 14 of 16

limited to a review of records in the possession of trauma centers, hospitals, emergency medical service providers, local or regional trauma agencies, or medical examiners regarding the care, transport, treatment, or examination of trauma patients.

- (12) Patient care, transport, or treatment records or reports, or patient care quality assurance proceedings, records, or reports obtained or made pursuant to this section, s. 395.3025(4)(f), s. 395.401, s. 395.4015, s. 395.402, s. 395.403, s. 395.404, s. 395.4045, s. 395.405, s. 395.50, or s. 395.51 must be held confidential by the department or its agent and are exempt from the provisions of s. 119.07(1). Patient care quality assurance proceedings, records, or reports obtained or made pursuant to these sections are not subject to discovery or introduction into evidence in any civil or administrative action.
- (13) The department may adopt, by rule, the procedures and process by which it will designate Level I and pediatric select trauma centers. Such procedures and process must be used in designating annually selecting trauma centers and must be consistent with subsections (1)-(8) except in those situations in which it is in the best interest of, and mutually agreed to by, all applicants within a service area and the department to reduce the timeframes.
- (14) Notwithstanding any other provisions of this section and rules adopted pursuant to this section, until the department has conducted the review provided under s. 395.402, only hospitals located in trauma services areas where there is no existing trauma center may apply.

Page 15 of 16

CODING: Words stricken are deletions; words underlined are additions.

421	Section 8. Section 395.405, Florida Statutes, is amended
422	to read:
423	395.405 Rulemaking.—The department shall adopt and enforce
424	all rules necessary to administer ss. 395.401, 395.4015,
425	395.402, 395.4025, 395.403, 395.404, and 395.4045.
426	Section 9. This act shall take effect July 1, 2013.