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A bill to be entitled

2 An act relating to health care; amending s. 154.11, 3 F.S.; revising powers of the boards of trustees of the 4 public health trusts; authorizing the lease of certain 5 office space for use by public health trusts; 6 providing discretion to the public health trust to 7 employ legal counsel; repealing s. 395.40, F.S., 8 relating to legislative findings and intent with 9 respect to trauma care; amending s. 395.4001, F.S.; revising definitions with respect to trauma services; 10 11 amending s. 395.401, F.S.; deleting certain 12 requirements for trauma plan components; limiting the 13 department's authority to adopt verification standards 14 for trauma centers; conforming a cross-reference; 15 amending s. 395.4015, F.S.; revising the criteria for 16 state regional trauma plans; repealing s. 395.402, 17 F.S., relating to trauma service areas and the number 18 and location of trauma centers; amending s. 395.4025, 19 F.S.; deleting requirements for trauma center 20 selection; specifying designation requirements for Level II trauma centers; deleting obsolete provisions; 21 22 deleting provisions for extension of provisional 23 status; providing for renewals for Level II trauma 24 center designations; revising the renewal process for 25 Level I, Level II, pediatric, and provisional trauma 26 centers; authorizing the department to adopt rules to 27 designate Level I and pediatric trauma centers; amending s. 395.405, F.S.; conforming a cross-28

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29 reference; providing an effective date. 30 31 Be It Enacted by the Legislature of the State of Florida: 32 33 Section 1. Paragraphs (f) and (p) of subsection (1) of 34 section 154.11, Florida Statutes, are amended to read: 154.11 Powers of board of trustees.-35 36 (1)The board of trustees of each public health trust 37 shall be deemed to exercise a public and essential governmental function of both the state and the county and in furtherance 38 thereof it shall, subject to limitation by the governing body of 39 40 the county in which such board is located, have all of the powers necessary or convenient to carry out the operation and 41 42 governance of designated health care facilities, including, but 43 without limiting the generality of, the foregoing: 44 To lease, either as lessee or lessor, or rent for any (f) 45 number of years and upon any terms and conditions real property, 46 except that the board shall not lease or rent, as lessor, any 47 real property except in accordance with the requirements of s. 125.35, Florida Statutes [F. S. 1973], or unless the lease is 48 49 for office space for use by the public health trust. To employ legal counsel, as the public health trust 50 (p) 51 sees fit, and in its sole discretion. 52 Section 2. Section 395.40, Florida Statutes, is repealed. 53 Section 3. Subsections (7), (10), and (14) of section 395.4001, Florida Statutes, are amended to read: 54 55 395.4001 Definitions.-As used in this part, the term: 56 "Level II trauma center" means a trauma center that: (7)

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(a) <u>Holds a valid certificate of trauma center</u>
<u>verification from the American College of Surgeons, except as</u>
<u>otherwise provided in s. 395.4025</u> 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
<u>a Level II trauma center</u>.

(b) Serves as a resource facility to general hospitals
through shared outreach, education, and quality improvement
activities.

66

(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, Level II trauma center, or pediatric trauma center, or provisional Level II trauma center verified and approved before July 1, 2013.

74 "Trauma center" means a hospital that has been (14)75 verified by the department to be in substantial compliance with 76 the requirements in s. 395.4025 and has been approved by the 77 department to operate as a Level I trauma center, Level II 78 trauma center, or pediatric trauma center, or designated Level II trauma center that holds a valid certificate of trauma center 79 80 verification from the American College of Surgeons or as 81 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:

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(1)

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

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(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:

92

1. The organizational structure of the trauma system.

93 2. Prehospital care management guidelines for triage and94 transportation of trauma cases.

95 3. Flow patterns of trauma cases and transportation system 96 design and resources, including air transportation services, 97 provision for interfacility trauma transfer, and the prehospital 98 transportation of trauma victims. The trauma agency shall plan 99 for the development of a system of transportation of trauma 100 alert victims to trauma centers where the distance or time to a trauma center or transportation resources diminish access by 101 trauma alert victims. 102

103 4. The number and location of needed trauma centers based 104 on local needs, population, and location and distribution of 105 resources.

106 <u>4.5.</u> Data collection regarding system operation and 107 patient outcome.

108 <u>5.6.</u> Periodic performance evaluation of the trauma system 109 and its components.

110 <u>6.7</u>. The use of air transport services within the 111 jurisdiction of the local trauma agency.

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7.8. Public information and education about the trauma

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113 system.

114 <u>8.9.</u> Emergency medical services communication system usage 115 and dispatching.

116 <u>9.10.</u> The coordination and integration between the trauma 117 center and other acute care hospitals.

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119

<u>10.11.</u> Medical control and accountability.

11.12. Quality control and system evaluation.

120 (2) The department shall adopt, by rule, standards for 121 verification of Level I and pediatric trauma centers based on 122 national guidelines, including those established by the American 123 College of Surgeons entitled "Hospital and Prehospital Resources 124 for Optimal Care of the Injured Patient" and published 125 appendices thereto. Standards specific to pediatric trauma 126 referral centers shall be developed in conjunction with 127 Children's Medical Services and adopted by rule of the 128 department.

129 The department may withdraw local or regional agency (3) 130 authority, prescribe corrective actions, or use the administrative remedies as provided in s. 395.1065 for the 131 132 violation of any provision of this section and ss. 395.4015, 133 395.402, 395.4025, 395.403, 395.404, and 395.4045 or rules 134 adopted thereunder. All amounts collected pursuant to this 135 subsection shall be deposited into the Emergency Medical Services Trust Fund provided in s. 401.34. 136

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.-

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141 The department shall establish a state trauma system (1)142 plan. As part of the state trauma system plan, the department 143 shall establish trauma regions that cover all geographical areas 144 of the state and have boundaries that are coterminous with the 145 boundaries of the regional domestic security task forces 146 established under s. 943.0312. These regions may serve as the basis for the development of department-approved local or 147 regional trauma plans for the transportation of trauma patients 148 149 and the coordination of activities between trauma centers, acute 150 care hospitals, emergency service providers, law enforcement 151 agencies, and local governments. Such regional plans shall 152 recognize trauma service areas that reflect well established 153 patient flow patterns. However, The delivery of trauma services 154 by or in coordination with a trauma agency established before 155 July 1, 2004, may continue in accordance with public and private 156 agreements and operational procedures entered into as provided 157 in s. 395.401. 158 (4) A hospital is only eligible for Level II trauma center

159 approval and verification if the hospital is located in a rural 160 county. For purposes of this subsection, the term "rural county" 161 means a county with boundaries that encompass a population of 162 300 or fewer persons per square mile. Population densities used 163 in this subsection must be based upon the most recent United 164 States census. 165 (5) After July 1, 2013, a hospital seeking Level II trauma 166 center approval and verification may not receive such approval 167 and verification if the hospital is located within 75 miles of an existing Level I trauma center.

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169	Section 6. <u>Section 395.402, Florida Statutes, is repealed.</u>
170	Section 7. Section 395.4025, Florida Statutes, is amended
171	to read:
172	395.4025 Trauma centers; <u>designation</u> selection; quality
173	assurance; records
174	(1) (a) Applicants for a Level I or pediatric trauma center
175	designation shall submit an application developed by the
176	department and documentation sufficient to demonstrate
177	compliance with the standards adopted by the department pursuant
178	to subsection (2) and s. 395.401(2).
179	(b) A Level II trauma center holding a provisional license
180	as of July 1, 2013, may complete the application process to
181	become a verified Level II trauma center pursuant to subsection
182	(2), and, if designated as such, may maintain the designation of
183	a Level II trauma center for 7 years from the date of approval
184	and verification by the department. Thereafter, the trauma
185	center must hold a valid certificate of trauma center
186	verification from the American College of Surgeons.
187	(c) Any hospital seeking a Level II trauma center
188	designation after July 1, 2013, shall be designated by the
189	department when the department receives documentation of the
190	hospital holding a valid certificate of trauma center
191	verification from the American College of Surgeons For purposes
192	of developing a system of trauma centers, the department shall
193	use the 19 trauma service areas established in s. 395.402.
194	Within each service area and based on the state trauma system
195	plan, the local or regional trauma services system plan, and
196	recommendations of the local or regional trauma agency, the

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197 department shall establish the approximate number of trauma 198 centers needed to ensure reasonable access to high-quality 199 trauma services. The department shall select those hospitals 200 that are to be recognized as trauma centers. 201 (2) The department shall approve applications from 202 hospitals seeking designation as trauma centers, including 203 current verified trauma centers that seek a change or 204 redesignation in approval status as a trauma center. The 205 department shall conduct a provisional review of each 206 application for the purpose of determining whether the 207 hospital's application is complete and whether the hospital has 208 the critical elements required for a trauma center. This 209 critical review shall be based on trauma center standards 210 pursuant to s. 395.401(2) and shall include, but not be limited 211 to, a review of whether the hospital has: 212 Equipment and physical facilities necessary to provide (a)

213 trauma services The department shall annually notify each acute 214 care general hospital and each local and each regional trauma 215 agency in the state that the department is accepting letters of 216 intent from hospitals that are interested in becoming trauma 217 centers. In order to be considered by the department, a hospital 218 that operates within the geographic area of a local or regional 219 trauma agency must certify that its intent to operate as a trauma center is consistent with the trauma services plan of the 220 221 local or regional trauma agency, as approved by the department, if such agency exists. Letters of intent must be postmarked no 222 223 later than midnight October 1.

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(b) <u>A sufficient number of personnel with proper</u>

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225 qualifications to provide trauma services By October 15, the 226 department shall send to all hospitals that submitted a letter 227 of intent an application package that will provide the hospitals 228 with instructions for submitting information to the department for selection as a trauma center. The standards for trauma 229 230 centers provided for in s. 395.401(2), as adopted by rule of the 231 department, shall serve as the basis for these instructions. 232 (C) An effective quality assurance process In order to be considered by the department, applications from those hospitals 233 234 seeking selection as trauma centers, including those current 235 verified trauma centers that seek a change or redesignation in 236 approval status as a trauma center, must be received by the 237 department no later than the close of business on April 1. The 238 department shall conduct a provisional review of each 239 application for the purpose of determining that the hospital's 240 application is complete and that the hospital has the critical 241 elements required for a trauma center. This critical review will 242 be based on trauma center standards and shall include, but not 243 be limited to, a review of whether the hospital has: 244 1. Equipment and physical facilities necessary to provide 245 trauma services. 246 2. Personnel in sufficient numbers and with proper 247 qualifications to provide trauma services. 248 3. An effective quality assurance process. 249 4. Submitted written confirmation by the local or regional 250 trauma agency that the hospital applying to become a trauma 251 center is consistent with the plan of the local or regional 252 trauma agency, as approved by the department, if such agency Page 9 of 16

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253 exists.

254 (d) 1. Submitted written confirmation by the local or 255 regional trauma agency that the hospital applying to become a 256 trauma center is consistent with the plan of the local or 257 regional trauma agency, as approved by the department, if such 258 agency exists Notwithstanding other provisions in this section, 259 the department may grant up to an additional 18 months to a 260 hospital applicant that is unable to meet all requirements as 261 provided in paragraph (c) at the time of application if the 262 number of applicants in the service area in which the applicant 263 is located is equal to or less than the service area allocation, 264 as provided by rule of the department. An applicant that is 265 granted additional time pursuant to this paragraph shall submit 266 a plan for departmental approval which includes timelines and 267 activities that the applicant proposes to complete in order to 268 meet application requirements. Any applicant that demonstrates 269 an ongoing effort to complete the activities within the 270 timelines outlined in the plan shall be included in the number 271 of trauma centers at such time that the department has conducted 272 a provisional review of the application and has determined that 273 the application is complete and that the hospital has the 274 critical elements required for a trauma center. 275 2. Timeframes provided in subsections (1) - (8) shall be 276 stayed until the department determines that the application is 277 complete and that the hospital has the critical elements 278 required for a trauma center. 279 Any hospital that submitted an application found (3)280 acceptable by the department based on provisional review shall

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281 be eligible to operate as a provisional trauma center After 282 April 30, Any hospital that submitted an application found 283 acceptable by the department based on provisional review shall 284 be eligible to operate as a provisional trauma center. 285 Between May 1 and October 1 of each year, The (4) 286 department shall conduct an in-depth evaluation of all 287 applications found acceptable in the provisional review. The 288 applications shall be evaluated against clinical criteria

enumerated in the application packages as provided to the hospitals by the department.

291 (5)Beginning October 1 of each year and ending no later 292 than June 1 of the following year, A review team of out-of-state 293 experts assembled by the department shall make onsite visits to 294 all provisional trauma centers. The department shall develop a 295 survey instrument to be used by the expert team of reviewers. 296 The instrument shall include objective criteria and guidelines 297 for reviewers based on existing trauma center standards pursuant 298 to subsection (2) and s. 395.401(2) such that all trauma centers 299 are assessed equally. The survey instrument shall also include a 300 uniform rating system that will be used by reviewers to indicate 301 the degree of compliance of each trauma center with specific 302 standards, and to indicate the quality of care provided by each 303 trauma center as determined through an audit of patient charts. 304 In addition, Hospitals being considered as provisional trauma 305 centers shall meet all the requirements of a trauma center and 306 shall be located in a trauma service area that has a need for 307 such a trauma center.

308

(6) Based on recommendations from the review team, the

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309 department shall approve hospitals for designation as select 310 trauma centers by July 1. An applicant for designation as a 311 trauma center may request an extension of its provisional status 312 if it submits a corrective action plan to the department. The 313 corrective action plan must demonstrate the ability of the 314 applicant to correct deficiencies noted during the applicant's 315 onsite review conducted by the department between the previous 316 October 1 and June 1. The department may extend the provisional 317 status of an applicant for designation as a trauma center 318 through December 31 if the applicant provides a corrective 319 action plan acceptable to the department. The department or a 320 team of out-of-state experts assembled by the department shall 321 conduct an onsite visit on or before November 1 to confirm that 322 the deficiencies have been corrected. The provisional trauma 323 center is responsible for all costs associated with the onsite 324 visit in a manner prescribed by rule of the department. By 325 January 1, the department must approve or deny the application 326 of any provisional applicant granted an extension. Each Level I 327 or pediatric trauma center shall be granted a 7-year approval 328 period during which time it must continue to maintain trauma 329 center standards and acceptable patient outcomes as determined 330 by department rule. An approval for a Level I or pediatric 331 trauma center designation, unless sooner suspended or revoked, 332 automatically expires 7 years after the date of issuance and is 333 renewable upon application for renewal as prescribed by rule of the department. Renewals for Level II trauma center designations 334 335 are dependent upon the American College of Surgeons' renewal 336 cycle.

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337 Any hospital that wishes to protest a decision made by (7)338 the department based on the department's preliminary or in-depth 339 review of applications or on the recommendations of the site 340 visit review team pursuant to this section shall proceed as 341 provided in chapter 120. Hearings held under this subsection 342 shall be conducted in the same manner as provided in ss. 120.569 343 and 120.57. Cases filed under chapter 120 may combine all 344 disputes between parties.

345 Notwithstanding any provision of chapter 381, a (8) 346 hospital licensed under ss. 395.001-395.3025 that operates a 347 trauma center may not terminate or substantially reduce the 348 availability of trauma service without providing at least 180 349 days' notice of its intent to terminate such service. Such 350 notice shall be given to the department, to all affected local 351 or regional trauma agencies, and to all trauma centers, 352 hospitals, and emergency medical service providers in the trauma 353 service area. The department shall adopt by rule the procedures 354 and process for notification, duration, and explanation of the 355 termination of trauma services.

356 (9) Except as otherwise provided in this subsection, the 357 department or its agent may collect trauma care and registry 358 data, as prescribed by rule of the department, from trauma 359 centers, hospitals, emergency medical service providers, local 360 or regional trauma agencies, or medical examiners for the 361 purposes of evaluating trauma system effectiveness, ensuring 362 compliance with the standards, and monitoring patient outcomes. 363 A trauma center, hospital, emergency medical service provider, 364 medical examiner, or local trauma agency or regional trauma

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365 agency, or a panel or committee assembled by such an agency 366 under s. 395.50(1) may, but is not required to, disclose to the 367 department patient care quality assurance proceedings, records, 368 or reports. However, the department may require a local trauma 369 agency or a regional trauma agency, or a panel or committee 370 assembled by such an agency to disclose to the department 371 patient care quality assurance proceedings, records, or reports 372 that the department needs solely to conduct quality assurance 373 activities under s. 395.4015, or to ensure compliance with the 374 quality assurance component of the trauma agency's plan approved 375 under s. 395.401. The patient care quality assurance 376 proceedings, records, or reports that the department may require 377 for these purposes include, but are not limited to, the 378 structure, processes, and procedures of the agency's quality 379 assurance activities, and any recommendation for improving or 380 modifying the overall trauma system, if the identity of a trauma 381 center, hospital, emergency medical service provider, medical 382 examiner, or an individual who provides trauma services is not 383 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 beconducted at any reasonable time and may include but not be

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393 limited to a review of records in the possession of trauma 394 centers, hospitals, emergency medical service providers, local 395 or regional trauma agencies, or medical examiners regarding the 396 care, transport, treatment, or examination of trauma patients.

397 (12)Patient care, transport, or treatment records or 398 reports, or patient care quality assurance proceedings, records, 399 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, 400 401 s. 395.404, s. 395.4045, s. 395.405, s. 395.50, or s. 395.51 402 must be held confidential by the department or its agent and are 403 exempt from the provisions of s. 119.07(1). Patient care quality 404 assurance proceedings, records, or reports obtained or made 405 pursuant to these sections are not subject to discovery or 406 introduction into evidence in any civil or administrative 407 action.

408 The department may adopt, by rule, the procedures and (13)409 process by which it will designate Level I and pediatric select trauma centers. Such procedures and process must be used in 410 411 designating annually selecting trauma centers and must be 412 consistent with subsections (1) - (8) except in those situations 413 in which it is in the best interest of, and mutually agreed to 414 by, all applicants within a service area and the department to 415 reduce the timeframes.

416 (14) Notwithstanding any other provisions of this section 417 and rules adopted pursuant to this section, until the department 418 has conducted the review provided under s. 395.402, only 419 hospitals located in trauma services areas where there is no 420 existing trauma center may apply.

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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.

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Section 9. This act shall take effect July 1, 2013.

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