Bill No. CS/HB 817 (2013)

Amendment No.

COMMITTEE/SUBCOMMITTE	E ACTION
ADOPTED	(Y/N)
ADOPTED AS AMENDED	(Y/N)
ADOPTED W/O OBJECTION	(Y/N)
FAILED TO ADOPT	(Y/N)
WITHDRAWN	(Y/N)
OTHER	

Committee/Subcommittee hearing bill: Health & Human Services

Committee

1 2

3

4

5

6

7

8

9

Representative Gaetz offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert: 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.-

10 (1)The board of trustees of each public health trust shall be deemed to exercise a public and essential governmental 11 12 function of both the state and the county and in furtherance 13 thereof it shall, subject to limitation by the governing body of 14 the county in which such board is located, have all of the powers necessary or convenient to carry out the operation and 15 governance of designated health care facilities, including, but 16 without limiting the generality of, the foregoing: 17

(f) To lease, either as lessee or lessor, or rent for anynumber of years and upon any terms and conditions real property,

651199 - h0817-strike.docx Published On: 4/15/2013 7:52:50 PM Page 1 of 16

Bill No. CS/HB 817 (2013)

Amendment No. 20 except that the board shall not lease or rent, as lessor, any 21 real property except in accordance with the requirements of s. 22 125.35 [F. S. 1973] or unless for the lease of office space 23 controlled by the public health trust. 24 To employ legal counsel, as the trust may see fit, and (p) 25 in its sole discretion. 26 Section 2. Section 395.40, Florida Statutes, is repealed. 27 Section 3. Subsections(7), (10), and (14) of section 395.4001, Florida Statutes, are amended to read: 28 29 395.4001 Definitions.-As used in this part, the term: 30 "Level II trauma center" means a trauma center that: (7) 31 (a) Is verified by the department to be in substantial 32 compliance with Level II trauma center standards and has been 33 approved by the department to operate as a Level II trauma 34 centerHolds a valid certificate of trauma center verification 35 from the American College of Surgeons except as otherwise provided in s. 395.4025. 36 37 (b) Serves as a resource facility to general hospitals 38 through shared outreach, education, and quality improvement 39 activities. 40 (c) Participates in an inclusive system of trauma care. 41 (10) "Provisional trauma center" means a hospital that has 42 been verified by the department to be in substantial compliance with the requirements in s. 395.4025 and has been approved by 43 44 the department to operate as a provisional Level I trauma 45 center, Level II trauma center, or pediatric trauma center or 46 for a provisional Level II trauma center verified and approved 47 prior to July 1, 2013. 651199 - h0817-strike.docx

Published On: 4/15/2013 7:52:50 PM Page 2 of 16

Bill No. CS/HB 817 (2013)

	Diri NO: CO/HD Or/ (2013)
48	Amendment No. (14) "Trauma center" means a hospital that has been
	-
49	verified by the department to be in substantial compliance with
50	the requirements in s. 395.4025 and has been approved by the
51	department to operate as a Level I trauma center , Level II
52	trauma center, or pediatric trauma center <u>, or is designated as a</u>
53	Level II trauma center based on documentation of a valid
54	certificate of trauma center verification from the American
55	College of Surgeons or as otherwise provided in s. 395.4025.
56	Section 4. Paragraph (b) of subsection (1) and (2) of
57	section 395.401, Florida Statutes, are amended to read:
58	395.401 Trauma services system plans; approval of trauma
59	centers and pediatric trauma centers; procedures; renewal
60	(1)
61	(b) The local and regional trauma agencies shall develop
62	and submit to the department plans for local and regional trauma
63	services systems. The plans must include, at a minimum, the
64	following components:
65	1. The organizational structure of the trauma system.
66	2. Prehospital care management guidelines for triage and
67	transportation of trauma cases.
68	3. Flow patterns of trauma cases and transportation system
69	design and resources, including air transportation services,
70	provision for interfacility trauma transfer, and the prehospital
71	transportation of trauma victims. The trauma agency shall plan
72	for the development of a system of transportation of trauma
73	alert victims to trauma centers where the distance or time to a
74	trauma center or transportation resources diminish access by
75	trauma alert victims.
6	551199 - h0817-strike.docx

Published On: 4/15/2013 7:52:50 PM Page 3 of 16

Bill No. CS/HB 817 (2013)

77 on local needs, population, and location and distribution of 78 resources. 79 4.5. Data collection regarding system operation and 80 patient outcome. 81 5.6. Periodic performance evaluation of the trauma system 82 and its components. 83 6.7. The use of air transport services within the 84 jurisdiction of the local trauma agency. 85 7.8. Public information and education about the trauma 86 system. 87 8.9. Emergency medical services communication system usage 88 and dispatching. 89 9.10. The coordination and integration between the trauma 90 center and other acute care hospitals. 91 10.11. Medical control and accountability. 92 11.12. Quality control and system evaluation. 93 The department shall adopt, by rule, standards for (2) 94 verification of Level I and pediatric trauma centers based on national guidelines, including those established by the American 95 96 College of Surgeons entitled "Hospital and Prehospital Resources 97 for Optimal Care of the Injured Patient" and published 98 appendices thereto. Standards specific to pediatric trauma referral centers shall be developed in conjunction with 99 Children's Medical Services and adopted by rule of the 100 department. 101 Section 5. Subsection (1) of section 395.4015, Florida 102 103 Statutes, is amended to read: 651199 - h0817-strike.docx Published On: 4/15/2013 7:52:50 PM

4. The number and location of needed trauma centers based

Amendment No.

76

Page 4 of 16

Bill No. CS/HB 817 (2013)

Amendment No. 104 395.4015 State regional trauma planning; trauma regions.-105 The department shall establish a state trauma system (1)106 plan. As part of the state trauma system plan, the department 107 shall establish trauma regions that cover all geographical areas 108 of the state and have boundaries that are coterminous with the 109 boundaries of the regional domestic security task forces 110 established under s. 943.0312. These regions may serve as the 111 basis for the development of department-approved local or regional trauma plans for the transportation of trauma patients 112 and the coordination of activities between trauma centers, acute 113 care hospitals, emergency service providers, law enforcement 114 115 agencies, and local governments. However, Such regional plans 116 shall recognize trauma service areas that reflect well 117 established patient flow patterns. the The delivery of trauma services by or in coordination with a trauma agency established 118 119 before July 1, 2004, may continue in accordance with public and 120 private agreements and operational procedures entered into as 121 provided in s. 395.401. Section 6. Section 395.402, Florida Statutes, is repealed. 122 123 Section 7. Section 395.4025, Florida Statutes, is amended 124 to read: 395.4025 Trauma centers; selection designation; quality 125 126 assurance; records.-127 For purposes of developing a system of trauma centers, (1) the department shall use the 19 trauma service areas established 128 129 in s. 395.402. Within each service area and based on the state 130 trauma system plan, the local or regional trauma services system 131 plan, and recommendations of the local or regional trauma 651199 - h0817-strike.docx Published On: 4/15/2013 7:52:50 PM

Page 5 of 16

Bill No. CS/HB 817 (2013)

132 agency, the department shall establish the approximate number of 133 trauma centers needed to ensure reasonable access to high-134 quality trauma services. The department shall select those 135 hospitals that are to be recognized as trauma centers.

Amendment No.

136 (2) (a) — The department shall annually notify each acute 137 care general hospital and each local and each regional trauma 138 agency in the state that the department is accepting letters of 139 intent from hospitals that are interested in becoming trauma 140 centers. In order to be considered by the department, a hospital that operates within the geographic area of a local or regional 141 trauma agency must certify that its intent to operate as a 142 143 trauma center is consistent with the trauma services plan of the 144 local or regional trauma agency, as approved by the department, 145 if such agency exists. Letters of intent must be postmarked no 146 later than midnight October 1.

(b) By October 15, the department shall send to all 147 148 hospitals that submitted a letter of intent an application 149 package that will provide the hospitals with instructions for 150 submitting information to the department for selection as a 151 trauma center. The standards for trauma centers provided for in 152 s. 395.401(2), as adopted by rule of the department, shall serve as the basis for these instructions. Applicants for a Level I or 153 154 pediatric trauma center designation shall submit an application 155 developed by the department and documentation sufficient to 156 demonstrate compliance with the standards adopted by the 157 department pursuant to s. 395.401(2) and subsection (2). 158 (c) (b) In order to be considered by the department, 159 applications from those hospitals seeking selection as trauma

651199 - h0817-strike.docx Published On: 4/15/2013 7:52:50 PM Page 6 of 16

Bill No. CS/HB 817 (2013)

Amendment No. 160 centers, including those current verified trauma centers that 161 seek a change or redesignation in approval status as a trauma 162 center, must be received by the department no later than the 163 close of business on April 1. The department shall conduct a 164 provisional review of each application for the purpose of 165 determining that the hospital's application is complete and that 166 the hospital has the critical elements required for a trauma 167 center. This critical review will be based on trauma center standards and shall include, but not be limited to, a review of 168 169 whether the hospital has: 1. Equipment and physical facilities necessary to provide 170 171 trauma services. 2. Personnel in sufficient numbers and with proper 172 173 qualifications to provide trauma services. 174 3. An effective quality assurance process. 4. Submitted written confirmation by the local or regional 175 176 trauma agency that the hospital applying to become a trauma 177 center is consistent with the plan of the local or regional 178 trauma agency, as approved by the department, if such agency 179 exists. 180 (d) 1. Notwithstanding other provisions in this section, the department may grant up to an additional 18 months to a 181 hospital applicant that is unable to meet all requirements as 182 183 provided in paragraph (c) at the time of application if the number of applicants in the service area in which the applicant 184 is located is equal to or less than the service area allocation, 185 as provided by rule of the department. An applicant that is 186 187 granted additional time pursuant to this paragraph shall submit 651199 - h0817-strike.docx Published On: 4/15/2013 7:52:50 PM

Page 7 of 16

Bill No. CS/HB 817 (2013)

188 a plan for departmental approval which includes timelines and 189 activities that the applicant proposes to complete in order to 190 meet application requirements. Any applicant that demonstrates 191 an ongoing effort to complete the activities within the 192 timelines outlined in the plan shall be included in the number 193 of trauma centers at such time that the department has conducted 194 a provisional review of the application and has determined that 195 the application is complete and that the hospital has the 196 critical elements required for a trauma center. 2. Timeframes provided in subsections (1)-(8) shall be 197 198 stayed until the department determines that the application is 199 complete and that the hospital has the critical elements 200 required for a trauma center. 201 (3) After April 30, Any hospital that submitted an 202 application found acceptable by the department based on provisional review shall be eligible to operate as a provisional 203 204 trauma center. A trauma center designated as a Level II trauma 205 center by the department as of July 1, 2013, shall retain such 206 designation unless the department determines the hospital is no 207 longer able to comply with the clinical standards and 208 capabilities for such centers or the designation expires. After 209 the designation pursuant to s. 395.401(2) and subsection (2) 210 expires, the Level II trauma center shall be re-designated when 211 the department receives documentation of the hospital holding a 212 valid certificate of trauma center verification from the 213 American College of Surgeons. 214 (c) A Level II trauma center holding a provisional license 215 as of July 1, 2013, may complete the application process to

651199 - h0817-strike.docx Published On: 4/15/2013 7:52:50 PM

Amendment No.

Page 8 of 16

Bill No. CS/HB 817 (2013)

216	Amendment No. become a verified Level II trauma center pursuant to subsection
217	(2), and if designated as such, may maintain the designation of
218	a Level II trauma center for 7 years from the date of approval
219	and verification by the department. Thereafter, the trauma
220	center must hold a valid certificate of trauma center
221	verification from the American College of Surgeons.
222	(d) Any hospital seeking a Level II trauma center
223	designation after July 1, 2013, shall be designated by the
224	department when the department receives documentation of the
225	hospital holding a valid certificate of trauma center
226	verification from the American College of Surgeons.
227	(4) (2) The department, shall approve applications from
228	hospitals seeking designation as trauma centers, including
229	current verified trauma centers that seek a change or
230	redesignation in approval status as a trauma center. The
231	department shall conduct a provisional review of each
232	application for the purpose of determining that the hospital's
233	application is complete and that the hospital has the critical
234	elements required for a trauma center. This critical review will
235	be based on trauma center standards pursuant to s. 395.401(2)
236	and shall include, but not be limited to, a review of whether
237	the hospital has:
238	1. Equipment and physical facilities necessary to provide
239	trauma services.
240	2. Personnel in sufficient numbers and with proper
241	qualifications to provide trauma services.
242	3. An effective quality assurance process.

651199 - h0817-strike.docx Published On: 4/15/2013 7:52:50 PM

Page 9 of 16

Bill No. CS/HB 817 (2013)

Amendment No. 243 <u>4. Submitted written confirmation by the local or regional</u> 244 <u>trauma agency that the hospital applying to become a trauma</u> 245 <u>center is consistent with the plan of the local or regional</u> 246 <u>trauma agency, as approved by the department, if such agency</u> 247 exists.

248 (3) Any hospital that submitted an application found
249 acceptable by the department based on provisional review shall
250 be eligible to operate as a provisional trauma center.

251 <u>(4)</u> Between May 1 and October 1 of each year, The 252 department shall conduct an in-depth evaluation of all 253 applications found acceptable in the provisional review. The 254 applications shall be evaluated against <u>clinical</u> criteria 255 enumerated in the application packages as provided to the 256 hospitals by the department.

257 Beginning October 1 of each year and ending no later (5) 258 than June 1 of the following year, A review team of out-of-state 259 experts assembled by the department shall make onsite visits to 260 all provisional trauma centers. The department shall develop a 261 survey instrument to be used by the expert team of reviewers. 262 The instrument shall include objective criteria and guidelines 263 for reviewers based on existing trauma center standards pursuant 264 to s. 395.401(2) and subsection (2) such that all trauma centers 265 are assessed equally. The survey instrument shall also include a 266 uniform rating system that will be used by reviewers to indicate the degree of compliance of each trauma center with specific 267 standards, and to indicate the quality of care provided by each 268 trauma center as determined through an audit of patient charts. 269 270 In addition, Hospitals being considered as provisional trauma

651199 - h0817-strike.docx Published On: 4/15/2013 7:52:50 PM

Page 10 of 16

Bill No. CS/HB 817 (2013)

271 centers shall meet all the requirements of a trauma center and 272 shall be located in a trauma service area that has a need for 273 such a trauma center.

Amendment No.

274 Based on recommendations from the review team, the (6) 275 department shall approve hospitals for designation as select trauma centers by July 1. An applicant for designation as a 276 277 trauma center may request an extension of its provisional status if it submits a corrective action plan to the department. The 278 corrective action plan must demonstrate the ability of the 279 280 applicant to correct deficiencies noted during the applicant's onsite review conducted by the department between the previous 281 282 October 1 and June 1. The department may extend the provisional 283 status of an applicant for designation as a trauma center 284 through December 31 if the applicant provides a corrective 285 action plan acceptable to the department. The department or a 286 team of out-of-state experts assembled by the department shall 287 conduct an onsite visit on or before November 1 to confirm that 288 the deficiencies have been corrected. The provisional trauma 289 center is responsible for all costs associated with the onsite 290 visit in a manner prescribed by rule of the department. By 291 January 1, the department must approve or deny the application 292 of any provisional applicant granted an extension. Each Level I 293 or pediatric trauma center shall be granted a 7-year approval 294 period during which time it must continue to maintain trauma center standards and acceptable patient outcomes as determined 295 296 by department rule. An approval for a Level I or pediatric trauma center designation, unless sooner suspended or revoked, 297 298 automatically expires 7 years after the date of issuance and is

651199 - h0817-strike.docx Published On: 4/15/2013 7:52:50 PM

Page 11 of 16

Bill No. CS/HB 817 (2013)

299 renewable upon application for renewal as prescribed by rule of 300 the department. <u>Renewals for Level II designations are</u> 301 <u>dependent upon the American College of Surgeons renewal cycle.</u>

Amendment No.

302 Any hospital that wishes to protest a decision made by (7)303 the department based on the department's preliminary or in-depth 304 review of applications or on the recommendations of the site 305 visit review team pursuant to this section shall proceed as provided in chapter 120. Hearings held under this subsection 306 shall be conducted in the same manner as provided in ss. 120.569 307 308 and 120.57. Cases filed under chapter 120 may combine all 309 disputes between parties.

310 (8) Notwithstanding any provision of chapter 381, a 311 hospital licensed under ss. 395.001-395.3025 that operates a 312 trauma center may not terminate or substantially reduce the availability of trauma service without providing at least 180 313 314 days' notice of its intent to terminate such service. Such 315 notice shall be given to the department, to all affected local or regional trauma agencies, and to all trauma centers, 316 317 hospitals, and emergency medical service providers in the trauma service area. The department shall adopt by rule the procedures 318 319 and process for notification, duration, and explanation of the 320 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

651199 - h0817-strike.docx Published On: 4/15/2013 7:52:50 PM Page 12 of 16

Bill No. CS/HB 817 (2013)

327 compliance with the standards, and monitoring patient outcomes. 328 A trauma center, hospital, emergency medical service provider, 329 medical examiner, or local trauma agency or regional trauma agency, or a panel or committee assembled by such an agency 330 331 under s. 395.50(1) may, but is not required to, disclose to the 332 department patient care quality assurance proceedings, records, 333 or reports. However, the department may require a local trauma 334 agency or a regional trauma agency, or a panel or committee assembled by such an agency to disclose to the department 335 336 patient care quality assurance proceedings, records, or reports that the department needs solely to conduct quality assurance 337 activities under s. 395.4015, or to ensure compliance with the 338 339 quality assurance component of the trauma agency's plan approved 340 under s. 395.401. The patient care quality assurance 341 proceedings, records, or reports that the department may require 342 for these purposes include, but are not limited to, the 343 structure, processes, and procedures of the agency's quality assurance activities, and any recommendation for improving or 344 345 modifying the overall trauma system, if the identity of a trauma 346 center, hospital, emergency medical service provider, medical 347 examiner, or an individual who provides trauma services is not 348 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,

651199 - h0817-strike.docx Published On: 4/15/2013 7:52:50 PM Page 13 of 16

Amendment No.

Bill No. CS/HB 817 (2013)

354 unless he or she is found to be operating outside the scope of 355 the authority and responsibility assigned by the department.

Amendment No.

(11) Onsite visits by the department or its agent may be conducted at any reasonable time and may include but not be 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.

362 (12) Patient care, transport, or treatment records or 363 reports, or patient care quality assurance proceedings, records, 364 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, 365 366 s. 395.404, s. 395.4045, s. 395.405, s. 395.50, or s. 395.51 367 must be held confidential by the department or its agent and are exempt from the provisions of s. 119.07(1). Patient care quality 368 369 assurance proceedings, records, or reports obtained or made 370 pursuant to these sections are not subject to discovery or 371 introduction into evidence in any civil or administrative 372 action.

373 (13)The department may adopt, by rule, the procedures and 374 process by which it will select designate Level I and pediatric trauma centers. Such procedures and process must be used in 375 376 annually selecting designating trauma centers and must be 377 consistent with subsections (1) - (8) except in those situations 378 in which it is in the best interest of, and mutually agreed to by, all applicants within a service area and the department to 379 reduce the timeframes. 380

651199 - h0817-strike.docx Published On: 4/15/2013 7:52:50 PM Page 14 of 16

Bill No. CS/HB 817 (2013)

	Amendment No.
381	(14) Notwithstanding any other provisions of this section
382	and rules adopted pursuant to this section, until the department
383	has conducted the review provided under s. 395.402, only
384	hospitals located in trauma services areas where there is no
385	existing trauma center may apply.
386	Section 8. This act shall take effect July 1, 2013.
387	
388	TITLE AMENDMENT
389	Remove everything before the enacting clause and insert:
390	Act relating to healthcare; amending s. 154.11, F.S.;
391	providing an exception for leases of office space
392	controlled by the public health trust; providing an
393	discretion to the trust to employ legal counsel; repealing
394	s. 395.40, F.S.; relating to legislative findings and
395	intent; amending s. 395.4001; F.S., revising definitions;
396	amending s. 395.401, F.S.; deleting requirements for trauma
397	plan components; limiting the department's rule-making
398	authority to Level I and pediatric trauma centers; amending
399	s. 395.4015, F.S.; revising the criteria for state regional
400	trauma plans; repealing s. 395.402; F.S.; amending s.
401	395.4025, F.S.; deleting the trauma center selection
402	requirements; clarifying duties of the department to
403	approve trauma centers; specifying designation requirements
404	for Level II trauma centers; deleting specific dates;
405	specifying documentation requirements for designation;
406	deleting extensions for applicants with provisional status;
407	providing an exemption for trauma centers granted
408	provisional Level II status; revising the renewal process

651199 - h0817-strike.docx

Published On: 4/15/2013 7:52:50 PM Page 15 of 16

Bill No. CS/HB 817 (2013)

	Amendment No.
409	for Level I, Level II, pediatric and provisional trauma
410	centers; providing the department authority to adopt rules
411	to designate Level I and pediatric trauma centers;
412	providing an effective date.

651199 - h0817-strike.docx Published On: 4/15/2013 7:52:50 PM Page 16 of 16