

Amendment No. 2

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	—	(Y/N)
ADOPTED AS AMENDED	—	(Y/N)
ADOPTED W/O OBJECTION	—	(Y/N)
FAILED TO ADOPT	—	(Y/N)
WITHDRAWN	—	(Y/N)
OTHER	—	

1 Committee/Subcommittee hearing bill: Health & Human Services
 2 Committee

3 Representative Trujillo offered the following:

4
 5 **Amendment to Amendment (787231) by Representative Brodeur**
 6 **(with title amendment)**

7 Between lines 539 and 540 of the amendment, insert:
 8 Section 21. Paragraph (b) of subsection (1) of section 395.401,
 9 Florida Statutes, is amended to read:

10 395.401 Trauma services system plans; approval of trauma
 11 centers and pediatric trauma centers; procedures; renewal.-

12 (1)

13 (b) The local and regional trauma agencies shall develop
 14 and submit to the department plans for local and regional trauma
 15 services systems. The plans must include, at a minimum, the
 16 following components:

17 1. The organizational structure of the trauma system.

18 2. Prehospital care management guidelines for triage and
 19 transportation of trauma cases.

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20 3. Flow patterns of trauma cases and transportation system
21 design and resources, including air transportation services,
22 provision for interfacility trauma transfer, and the prehospital
23 transportation of trauma victims. The trauma agency shall plan
24 for the development of a system of transportation of trauma
25 alert victims to trauma centers where the distance or time to a
26 trauma center or transportation resources diminish access by
27 trauma alert victims.

28 ~~4. The number and location of needed trauma centers based~~
29 ~~on local needs, population, and location and distribution of~~
30 ~~resources.~~

31 ~~4.5.~~ Data collection regarding system operation and
32 patient outcome.

33 ~~5.6.~~ Periodic performance evaluation of the trauma system
34 and its components.

35 ~~6.7.~~ The use of air transport services within the
36 jurisdiction of the local trauma agency.

37 ~~7.8.~~ Public information and education about the trauma
38 system.

39 ~~8.9.~~ Emergency medical services communication system usage
40 and dispatching.

41 ~~9.10.~~ The coordination and integration between the trauma
42 center and other acute care hospitals.

43 ~~10.11.~~ Medical control and accountability.

44 ~~11.12.~~ Quality control and system evaluation.

45 Section 22. Paragraphs (b) and (c) of subsection (4) of
46 section 395.402, Florida Statutes, are amended to read:

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47 395.402 Trauma service areas; number and location of
48 trauma centers.—

49 (4) Annually thereafter, the department shall review the
50 assignment of the 67 counties to trauma service areas, in
51 addition to the requirements of paragraphs (2)(b)-(g) and
52 subsection (3). County assignments are made for the purpose of
53 developing a system of trauma centers. Revisions made by the
54 department shall take into consideration the recommendations
55 made as part of the regional trauma system plans approved by the
56 department and the recommendations made as part of the state
57 trauma system plan. In cases where a trauma service area is
58 located within the boundaries of more than one trauma region,
59 the trauma service area's needs, response capability, and system
60 requirements shall be considered by each trauma region served by
61 that trauma service area in its regional system plan. Until the
62 department completes the February 2005 assessment, the
63 assignment of counties shall remain as established in this
64 section.

65 (b) Each trauma service area should have at least one
66 Level I or Level II trauma center. ~~The department shall~~
67 ~~allocate, by rule, the number of trauma centers needed for each~~
68 ~~trauma service area.~~

69 ~~(c) There shall be no more than a total of 44 trauma~~
70 ~~centers in the state.~~

71 Section 23. Section 395.4025, Florida Statutes, is amended
72 to read:

73 395.4025 Trauma centers; selection; quality assurance;
74 records.—

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75 (1) For purposes of developing a system of trauma centers,
76 the department shall use the 19 trauma service areas established
77 in s. 395.402. Within each service area and based on the state
78 trauma system plan, the local or regional trauma services system
79 plan, and recommendations of the local or regional trauma
80 agency, the department shall establish the approximate number of
81 trauma centers needed to ensure reasonable access to high-
82 quality trauma services. The department shall select those
83 hospitals that are to be recognized as trauma centers.

84 (2) (a) The department shall ~~annually~~ notify each acute
85 care general hospital and each local and each regional trauma
86 agency in the state that the department is accepting letters of
87 intent from hospitals that are interested in becoming trauma
88 centers. ~~In order to be considered by the department, a hospital
89 that operates within the geographic area of a local or regional
90 trauma agency must certify that its intent to operate as a
91 trauma center is consistent with the trauma services plan of the
92 local or regional trauma agency, as approved by the department,
93 if such agency exists. Letters of intent must be postmarked no
94 later than midnight October 1.~~

95 (b) ~~By October 15,~~ The department shall send to all
96 hospitals that ~~submitted~~ submit a letter of intent an
97 application package that will provide the hospitals with
98 instructions for submitting information to the department for
99 selection approval as a trauma center. ~~The standards for trauma
100 centers provided for in s. 395.401(2), as adopted by rule of the
101 department, shall serve as the basis for~~ These instructions
102 shall explain the specific documentation necessary for the

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103 department to determine hospital's compliance with the clinical
104 standards and capabilities of a trauma center.

105 (c) ~~In order to be considered by~~ The department, shall
106 approve applications from those hospitals seeking ~~selection~~
107 designation as trauma centers, including those current verified
108 trauma centers that seek a change or redesignation in approval
109 status as a trauma center, ~~must be received by the department no~~
110 ~~later than the close of business on April 1~~ provided the
111 hospital documents compliance with the clinical standards and
112 capabilities of a trauma center. The department shall conduct a
113 provisional review of each application for the purpose of
114 determining that the hospital's application is complete and that
115 the hospital has the critical elements required for a trauma
116 center. This critical review will be based on trauma center
117 standards and shall include, but not be limited to, a review of
118 whether the hospital has:

119 1. Equipment and physical facilities necessary to provide
120 trauma services.

121 2. Personnel in sufficient numbers and with proper
122 qualifications to provide trauma services.

123 3. An effective quality assurance process.

124 4. Submitted written confirmation by the local or regional
125 trauma agency that the hospital applying to become a trauma
126 center is consistent with the plan of the local or regional
127 trauma agency, as approved by the department, if such agency
128 exists.

129 ~~(d)1. Notwithstanding other provisions in this section,~~
130 ~~the department may grant up to an additional 18 months to a~~

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131 ~~hospital applicant that is unable to meet all requirements as~~
132 ~~provided in paragraph (c) at the time of application if the~~
133 ~~number of applicants in the service area in which the applicant~~
134 ~~is located is equal to or less than the service area allocation,~~
135 ~~as provided by rule of the department. An applicant that is~~
136 ~~granted additional time pursuant to this paragraph shall submit~~
137 ~~a plan for departmental approval which includes timelines and~~
138 ~~activities that the applicant proposes to complete in order to~~
139 ~~meet application requirements. Any applicant that demonstrates~~
140 ~~an ongoing effort to complete the activities within the~~
141 ~~timelines outlined in the plan shall be included in the number~~
142 ~~of trauma centers at such time that the department has conducted~~
143 ~~a provisional review of the application and has determined that~~
144 ~~the application is complete and that the hospital has the~~
145 ~~critical elements required for a trauma center.~~

146 ~~2. Timeframes provided in subsections (1)-(8) shall be~~
147 ~~stayed until the department determines that the application is~~
148 ~~complete and that the hospital has the critical elements~~
149 ~~required for a trauma center.~~

150 ~~(3) After April 30,~~ Any hospital that submitted an
151 application found acceptable by the department based on
152 provisional review shall be eligible to operate as a provisional
153 trauma center.

154 ~~(4) Between May 1 and October 1 of each year,~~ The
155 department shall conduct an in-depth evaluation of all
156 applications found acceptable in the provisional review. The
157 applications shall be evaluated against clinical criteria

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

160 (5) ~~Beginning October 1 of each year and ending no later~~
161 ~~than June 1 of the following year,~~ A review team of out-of-state
162 experts assembled by the department shall make onsite visits to
163 all provisional trauma centers. The department shall develop a
164 survey instrument to be used by the expert team of reviewers.
165 The instrument shall include objective criteria and guidelines
166 for reviewers based on existing trauma center standards such
167 that all trauma centers are assessed equally. The survey
168 instrument shall also include a uniform rating system that will
169 be used by reviewers to indicate the degree of compliance of
170 each trauma center with specific standards, and to indicate the
171 quality of care provided by each trauma center as determined
172 through an audit of patient charts. ~~In addition,~~ Hospitals being
173 considered as provisional trauma centers shall meet all the
174 requirements of a trauma center. ~~and shall be located in a~~
175 ~~trauma service area that has a need for such a trauma center.~~

176 (6) Based on recommendations from the review team, the
177 department shall ~~select~~ approve hospitals for designation as
178 trauma centers by July 1. An applicant for designation as a
179 trauma center may request an extension of its provisional status
180 if it submits a corrective action plan to the department. The
181 corrective action plan must demonstrate the ability of the
182 applicant to correct deficiencies noted during the applicant's
183 onsite review ~~conducted by the department between the previous~~
184 ~~October 1 and June 1.~~ The department may extend the provisional
185 ~~status of an applicant for designation as a trauma center~~

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186 ~~through December 31 if the applicant provides a corrective~~
187 ~~action plan acceptable to the department.~~ The department or a
188 team of out-of-state experts assembled by the department shall
189 conduct an onsite visit ~~on or before November 1~~ to confirm that
190 the deficiencies have been corrected. The provisional trauma
191 center is responsible for all costs associated with the onsite
192 visit in a manner prescribed by rule of the department. ~~By~~
193 ~~January 1, the department must approve or deny the application~~
194 ~~of any provisional applicant granted an extension.~~ Each trauma
195 center shall be granted a 7-year approval period during which
196 time it must continue to maintain trauma center standards and
197 acceptable patient outcomes as determined by department rule. An
198 approval, unless sooner suspended or revoked, automatically
199 expires 7 years after the date of issuance and is renewable upon
200 application for renewal as prescribed by rule of the department.

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

209 (8) Notwithstanding any provision of chapter 381, a
210 hospital licensed under ss. 395.001-395.3025 that operates a
211 trauma center may not terminate or substantially reduce the
212 availability of trauma service without providing at least 180
213 days' notice of its intent to terminate such service. Such

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214 notice shall be given to the department, to all affected local
215 or regional trauma agencies, and to all trauma centers,
216 hospitals, and emergency medical service providers in the trauma
217 service area. The department shall adopt by rule the procedures
218 and process for notification, duration, and explanation of the
219 termination of trauma services.

220 (9) Except as otherwise provided in this subsection, the
221 department or its agent may collect trauma care and registry
222 data, as prescribed by rule of the department, from trauma
223 centers, hospitals, emergency medical service providers, local
224 or regional trauma agencies, or medical examiners for the
225 purposes of evaluating trauma system effectiveness, ensuring
226 compliance with the standards, and monitoring patient outcomes.
227 A trauma center, hospital, emergency medical service provider,
228 medical examiner, or local trauma agency or regional trauma
229 agency, or a panel or committee assembled by such an agency
230 under s. 395.50(1) may, but is not required to, disclose to the
231 department patient care quality assurance proceedings, records,
232 or reports. However, the department may require a local trauma
233 agency or a regional trauma agency, or a panel or committee
234 assembled by such an agency to disclose to the department
235 patient care quality assurance proceedings, records, or reports
236 that the department needs solely to conduct quality assurance
237 activities under s. 395.4015, or to ensure compliance with the
238 quality assurance component of the trauma agency's plan approved
239 under s. 395.401. The patient care quality assurance
240 proceedings, records, or reports that the department may require
241 for these purposes include, but are not limited to, the

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242 structure, processes, and procedures of the agency's quality
243 assurance activities, and any recommendation for improving or
244 modifying the overall trauma system, if the identity of a trauma
245 center, hospital, emergency medical service provider, medical
246 examiner, or an individual who provides trauma services is not
247 disclosed.

248 (10) Out-of-state experts assembled by the department to
249 conduct onsite visits are agents of the department for the
250 purposes of s. 395.3025. An out-of-state expert who acts as an
251 agent of the department under this subsection is not liable for
252 any civil damages as a result of actions taken by him or her,
253 unless he or she is found to be operating outside the scope of
254 the authority and responsibility assigned by the department.

255 (11) Onsite visits by the department or its agent may be
256 conducted at any reasonable time and may include but not be
257 limited to a review of records in the possession of trauma
258 centers, hospitals, emergency medical service providers, local
259 or regional trauma agencies, or medical examiners regarding the
260 care, transport, treatment, or examination of trauma patients.

261 (12) Patient care, transport, or treatment records or
262 reports, or patient care quality assurance proceedings, records,
263 or reports obtained or made pursuant to this section, s.
264 395.3025(4)(f), s. 395.401, s. 395.4015, s. 395.402, s. 395.403,
265 s. 395.404, s. 395.4045, s. 395.405, s. 395.50, or s. 395.51
266 must be held confidential by the department or its agent and are
267 exempt from the provisions of s. 119.07(1). Patient care quality
268 assurance proceedings, records, or reports obtained or made
269 pursuant to these sections are not subject to discovery or

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270 introduction into evidence in any civil or administrative
271 action.

272 ~~(13) The department may adopt, by rule, the procedures and~~
273 ~~process by which it will select trauma centers. Such procedures~~
274 ~~and process must be used in annually selecting trauma centers~~
275 ~~and must be consistent with subsections (1)-(8) except in those~~
276 ~~situations in which it is in the best interest of, and mutually~~
277 ~~agreed to by, all applicants within a service area and the~~
278 ~~department to reduce the timeframes.~~

279 ~~(14) Notwithstanding any other provisions of this section~~
280 ~~and rules adopted pursuant to this section, until the department~~
281 ~~has conducted the review provided under s. 395.402, only~~
282 ~~hospitals located in trauma services areas where there is no~~
283 ~~existing trauma center may apply.~~

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T I T L E A M E N D M E N T

290

Remove line 3693 of the amendment and insert:

291

Health Care Administration; amending s. 395.401, F.S.; deleting

292

local need assessment for trauma center; amending s. 395.402,

293

F.S.; deleting rule-making authority to allocate trauma centers;

294

deleting maximum number of trauma centers; amending s. 395.4025,

295

F.S., deleting department authority to select trauma centers;

296

deleting timelines for application; amending ss. 154.11,

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394.741,

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