

By Senator Grimsley

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20161518\_\_

1                   A bill to be entitled  
2           An act relating to adult cardiovascular services;  
3           amending s. 408.0361, F.S.; expanding rulemaking  
4           criteria for the Agency for Health Care Administration  
5           for licensure of hospitals performing percutaneous  
6           coronary intervention; deleting provisions relating to  
7           newly licensed hospitals seeking a specified program  
8           status; repealing s. 408.036(3)(m) and (n), F.S.,  
9           relating to exemptions for certificate of need  
10          projects subject to review relating to adult open-  
11          heart services in a hospital and percutaneous coronary  
12          intervention; providing an effective date.

13  
14 Be It Enacted by the Legislature of the State of Florida:

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16           Section 1. Section 408.0361, Florida Statutes, is amended  
17 to read:

18           408.0361 Cardiovascular services and burn unit licensure.—

19           (1) Each provider of diagnostic cardiac catheterization  
20 services shall comply with rules adopted by the agency that  
21 establish licensure standards governing the operation of adult  
22 inpatient diagnostic cardiac catheterization programs. The rules  
23 shall ensure that such programs:

24           (a) Comply with the most recent guidelines of the American  
25 College of Cardiology and American Heart Association Guidelines  
26 for Cardiac Catheterization and Cardiac Catheterization  
27 Laboratories.

28           (b) Perform only adult inpatient diagnostic cardiac  
29 catheterization services and will not provide therapeutic  
30 cardiac catheterization or any other cardiology services.

31           (c) Maintain sufficient appropriate equipment and health  
32 care personnel to ensure quality and safety.

21-01207-16

20161518\_\_

33 (d) Maintain appropriate times of operation and protocols  
34 to ensure availability and appropriate referrals in the event of  
35 emergencies.

36 (e) Demonstrate a plan to provide services to Medicaid and  
37 charity care patients.

38 (2) Each provider of adult cardiovascular services or  
39 operator of a burn unit shall comply with rules adopted by the  
40 agency that establish licensure standards that govern the  
41 provision of adult cardiovascular services or the operation of a  
42 burn unit. Such rules shall consider, at a minimum, staffing,  
43 equipment, physical plant, operating protocols, the provision of  
44 services to Medicaid and charity care patients, accreditation,  
45 licensure period and fees, and enforcement of minimum standards.  
46 ~~The certificate of need rules for adult cardiovascular services~~  
47 ~~and burn units in effect on June 30, 2004, are authorized~~  
48 ~~pursuant to this subsection and shall remain in effect and shall~~  
49 ~~be enforceable by the agency until the licensure rules are~~  
50 ~~adopted. Existing providers and any provider with a notice of~~  
51 ~~intent to grant a certificate of need or a final order of the~~  
52 ~~agency granting a certificate of need for adult cardiovascular~~  
53 ~~services or burn units shall be considered grandfathered and~~  
54 ~~receive a license for their programs effective on the effective~~  
55 ~~date of this act. The grandfathered licensure shall be for at~~  
56 ~~least 3 years or until July 1, 2008, whichever is longer, but~~  
57 ~~shall be required to meet licensure standards applicable to~~  
58 ~~existing programs for every subsequent licensure period.~~

59 (3) In establishing rules for adult cardiovascular  
60 services, the agency shall include provisions that allow for:

61 (a) Establishment of two hospital program licensure levels:

21-01207-16

20161518\_\_

62 a Level I program authorizing the performance of adult  
63 percutaneous cardiac intervention without onsite cardiac surgery  
64 and a Level II program authorizing the performance of  
65 percutaneous cardiac intervention with onsite cardiac surgery.

66 (b) For a hospital seeking a Level I program, demonstration  
67 that, for the most recent 12-month period as reported to the  
68 agency, it has provided a minimum of 300 adult inpatient and  
69 outpatient diagnostic cardiac catheterizations or, for the most  
70 recent 12-month period, has discharged or transferred at least  
71 300 inpatients with the principal diagnosis of ischemic heart  
72 disease and that it has a formalized, written transfer agreement  
73 with a hospital that has a Level II program, including written  
74 transport protocols to ensure safe and efficient transfer of a  
75 patient within 60 minutes. However, a hospital located more than  
76 100 road miles from the closest Level II adult cardiovascular  
77 services program does not need to meet the 60-minute transfer  
78 time protocol if the hospital demonstrates that it has a  
79 formalized, written transfer agreement with a hospital that has  
80 a Level II program. The agreement must include written transport  
81 protocols to ensure the safe and efficient transfer of a  
82 patient, taking into consideration the patient's clinical and  
83 physical characteristics, road and weather conditions, and  
84 viability of ground and air ambulance service to transfer the  
85 patient. At a minimum, the rules must require the following:

86 1. Cardiologists must be experienced interventionalists who  
87 have performed a minimum of 50 interventions annually, averaged  
88 over 2 years, that were performed in institutions performing  
89 more than 200 total intervention procedures annually and more  
90 than 36 primary intervention procedures annually.

21-01207-16

20161518\_\_

91       2. The hospital must provide a minimum of 36 primary  
92 interventions annually in order to continue to provide the  
93 service.

94       3. The hospital must offer sufficient physician, nursing,  
95 and laboratory staff to provide the services 24 hours a day, 7  
96 days a week.

97       4. Nursing and technical staff must have demonstrated  
98 experience in handling acutely ill patients requiring  
99 intervention based on the staff members' previous experience in  
100 dedicated interventional laboratories or surgical centers. In  
101 order for experience acquired at a dedicated interventional  
102 laboratory at a hospital without an approved adult open-heart-  
103 surgery program to qualify, the cardiac interventional  
104 laboratory must have, throughout the training period:

105       a. Had an annual volume of 200 or more percutaneous  
106 coronary intervention procedures;

107       b. Achieved a demonstrated success rate of 95 percent or  
108 greater for percutaneous coronary intervention procedures;

109       c. Experienced a complication rate of less than 5 percent  
110 for percutaneous coronary intervention procedures;

111       d. Experienced required emergent coronary artery bypass  
112 grafting on less than 2 percent of the patients undergoing a  
113 percutaneous coronary intervention procedure; and

114       e. Performed diverse cardiac procedures, including, but not  
115 limited to, balloon angioplasty and stenting, rotational  
116 atherectomy, cutting balloon atheroma remodeling, and procedures  
117 relating to left ventricular support capability.

118       5. Cardiac care nursing staff must be adept in hemodynamic  
119 monitoring, operation of temporary pacemakers, intra-aortic

21-01207-16

20161518\_\_

120 balloon pump management, management of indwelling arterial and  
121 venous sheaths, and identifying potential complications.

122 6. Hospitals implementing the service must first undertake  
123 a training program of 3 to 6 months' duration, which includes  
124 establishing standards and testing logistics, creating quality  
125 assessment and error management practices, and formalizing  
126 patient-selection criteria.

127 7. The applicant must certify that the hospital will use at  
128 all times the patient-selection criteria for the performance of  
129 primary angioplasty at hospitals without adult open-heart-  
130 surgery programs issued by the American College of Cardiology  
131 and the American Heart Association.

132 8. The hospital must agree to submit a quarterly report to  
133 the agency detailing patient characteristics, treatment, and  
134 outcomes for all patients receiving emergency percutaneous  
135 coronary interventions pursuant to this paragraph. This report  
136 must be submitted within 15 days after the close of each  
137 calendar quarter.

138 (c) For a hospital seeking a Level II program,  
139 demonstration that, for the most recent 12-month period as  
140 reported to the agency, it has performed a minimum of 1,100  
141 adult inpatient and outpatient cardiac catheterizations, of  
142 which at least 400 must be therapeutic catheterizations, or, for  
143 the most recent 12-month period, has discharged at least 800  
144 patients with the principal diagnosis of ischemic heart disease.

145 (d) Compliance with the most recent guidelines of the  
146 American College of Cardiology and American Heart Association  
147 guidelines for staffing, physician training and experience,  
148 operating procedures, equipment, physical plant, and patient

21-01207-16

20161518\_\_

149 selection criteria to ensure patient quality and safety.

150 (e) Establishment of appropriate hours of operation and  
151 protocols to ensure availability and timely referral in the  
152 event of emergencies.

153 (f) Demonstration of a plan to provide services to Medicaid  
154 and charity care patients.

155 ~~(4) In order to ensure continuity of available services,~~  
156 ~~the holder of a certificate of need for a newly licensed~~  
157 ~~hospital that meets the requirements of this subsection may~~  
158 ~~apply for and shall be granted Level I program status regardless~~  
159 ~~of whether rules relating to Level I programs have been adopted.~~  
160 ~~To qualify for a Level I program under this subsection, a~~  
161 ~~hospital seeking a Level I program must be a newly licensed~~  
162 ~~hospital established pursuant to a certificate of need in a~~  
163 ~~physical location previously licensed and operated as a~~  
164 ~~hospital, the former hospital must have provided a minimum of~~  
165 ~~300 adult inpatient and outpatient diagnostic cardiac~~  
166 ~~catheterizations for the most recent 12-month period as reported~~  
167 ~~to the agency, and the newly licensed hospital must have a~~  
168 ~~formalized, written transfer agreement with a hospital that has~~  
169 ~~a Level II program, including written transport protocols to~~  
170 ~~ensure safe and efficient transfer of a patient within 60~~  
171 ~~minutes. A hospital meeting the requirements of this subsection~~  
172 ~~may apply for certification of Level I program status before~~  
173 ~~taking possession of the physical location of the former~~  
174 ~~hospital, and the effective date of Level I program status shall~~  
175 ~~be concurrent with the effective date of the newly issued~~  
176 ~~hospital license.~~

177 (4) ~~(5)~~ (a) The agency shall establish a technical advisory

21-01207-16

20161518\_\_

178 panel to develop procedures and standards for measuring outcomes  
179 of adult cardiovascular services. Members of the panel shall  
180 include representatives of the Florida Hospital Association, the  
181 Florida Society of Thoracic and Cardiovascular Surgeons, the  
182 Florida Chapter of the American College of Cardiology, and the  
183 Florida Chapter of the American Heart Association and others  
184 with experience in statistics and outcome measurement. Based on  
185 recommendations from the panel, the agency shall develop and  
186 adopt rules for the adult cardiovascular services that include  
187 at least the following:

188 1. A risk adjustment procedure that accounts for the  
189 variations in severity and case mix found in hospitals in this  
190 state.

191 2. Outcome standards specifying expected levels of  
192 performance in Level I and Level II adult cardiovascular  
193 services. Such standards may include, but shall not be limited  
194 to, in-hospital mortality, infection rates, nonfatal myocardial  
195 infarctions, length of stay, postoperative bleeds, and returns  
196 to surgery.

197 3. Specific steps to be taken by the agency and licensed  
198 hospitals that do not meet the outcome standards within  
199 specified time periods, including time periods for detailed case  
200 reviews and development and implementation of corrective action  
201 plans.

202 (b) Hospitals licensed for Level I or Level II adult  
203 cardiovascular services shall participate in clinical outcome  
204 reporting systems operated by the American College of Cardiology  
205 and the Society for Thoracic Surgeons.

206 Section 2. Paragraphs (m) and (n) of subsection (3) of

21-01207-16

20161518\_\_

207 section 408.036, Florida Statutes, are repealed.

208 Section 3. This act shall take effect July 1, 2016.