

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.

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 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.

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  
62 levels: 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,  
67 demonstration that, for the most recent 12-month period as  
68 reported to the agency, it has provided a minimum of 300 adult  
69 inpatient and outpatient diagnostic cardiac catheterizations or,  
70 for the most recent 12-month period, has discharged or  
71 transferred at least 300 inpatients with the principal diagnosis  
72 of ischemic heart disease and that it has a formalized, written  
73 transfer agreement with a hospital that has a Level II program,  
74 including written transport protocols to ensure safe and  
75 efficient transfer of a patient within 60 minutes. However, a  
76 hospital located more than 100 road miles from the closest Level  
77 II adult cardiovascular services program does not need to meet  
78 the 60-minute transfer time protocol if the hospital

79 demonstrates that it has a formalized, written transfer  
80 agreement with a hospital that has a Level II program. The  
81 agreement must include written transport protocols to ensure the  
82 safe and efficient transfer of a patient, taking into  
83 consideration the patient's clinical and physical  
84 characteristics, road and weather conditions, and viability of  
85 ground and air ambulance service to transfer the patient. At a  
86 minimum, the rules must require the following:

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

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

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

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

105 laboratory must have, throughout the training period:

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

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

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

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

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

119 5. Cardiac care nursing staff must be adept in hemodynamic  
120 monitoring, operation of temporary pacemakers, intra-aortic  
121 balloon pump management, management of indwelling arterial and  
122 venous sheaths, and identifying potential complications.

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

128 7. The applicant must certify that the hospital will use  
129 at all times the patient-selection criteria for the performance  
130 of primary angioplasty at hospitals without adult open-heart-

131 surgery programs issued by the American College of Cardiology  
132 and the American Heart Association.

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

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

146 (d) Compliance with the most recent guidelines of the  
147 American College of Cardiology and American Heart Association  
148 guidelines for staffing, physician training and experience,  
149 operating procedures, equipment, physical plant, and patient  
150 selection criteria to ensure patient quality and safety.

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

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

156 ~~(4) In order to ensure continuity of available services,~~

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

178 (4)~~(5)~~(a) The agency shall establish a technical advisory  
179 panel to develop procedures and standards for measuring outcomes  
180 of adult cardiovascular services. Members of the panel shall  
181 include representatives of the Florida Hospital Association, the  
182 Florida Society of Thoracic and Cardiovascular Surgeons, the

183 Florida Chapter of the American College of Cardiology, and the  
184 Florida Chapter of the American Heart Association and others  
185 with experience in statistics and outcome measurement. Based on  
186 recommendations from the panel, the agency shall develop and  
187 adopt rules for the adult cardiovascular services that include  
188 at least the following:

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

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

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

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

207 Section 2. Paragraphs (m) and (n) of subsection (3) of  
208 section 408.036, Florida Statutes, are repealed.



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2016

209

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