

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:

15
 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 The rules, at a minimum, must require the following:

67 1. Cardiologists must be experienced interventionists who
68 have performed a minimum of 50 interventions annually, averaged
69 over 2 years, that were performed in institutions performing
70 more than 200 total intervention procedures annually and more
71 than 36 primary intervention procedures annually.

72 2. The hospital must offer sufficient physician, nursing,
73 and laboratory staff to provide the services 24 hours a day, 7
74 days a week.

75 3. Nursing and technical staff must have demonstrated
76 experience in handling acutely ill patients requiring
77 intervention based on the staff members' previous experience in
78 dedicated interventional laboratories or surgical centers. In

79 order for experience acquired at a dedicated interventional
80 laboratory at a hospital without an approved adult open-heart-
81 surgery program to qualify, the cardiac interventional
82 laboratory must have, throughout the training period:

83 a. Had an annual volume of 500 or more percutaneous
84 coronary intervention procedures;

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

87 c. Experienced a complication rate of less than 5 percent
88 for percutaneous coronary intervention procedures; and

89 d. Performed diverse cardiac procedures, including, but
90 not limited to, balloon angioplasty and stenting, rotational
91 atherectomy, cutting balloon atheroma remodeling, and procedures
92 relating to left ventricular support capability.

93 4. Cardiac care nursing staff must be adept in hemodynamic
94 monitoring, operation of temporary pacemakers, intra-aortic
95 balloon pump management, management of indwelling arterial and
96 venous sheaths, and identifying potential complications.

97 5. Hospitals implementing the service must first undertake
98 a training program of 3 to 6 months' duration, which includes
99 establishing standards and testing logistics, creating quality
100 assessment and error management practices, and formalizing
101 patient-selection criteria.

102 6. The applicant must certify that the hospital will use
103 at all times the patient-selection criteria for the performance
104 of primary angioplasty at hospitals without adult open-heart-

105 surgery programs issued by the American College of Cardiology
106 and the American Heart Association.

107 (b) For a hospital seeking a Level I program,
108 demonstration that, for the most recent 12-month period as
109 reported to the agency, it has provided a minimum of 300 adult
110 inpatient and outpatient diagnostic cardiac catheterizations or,
111 for the most recent 12-month period, has discharged or
112 transferred at least 300 inpatients with the principal diagnosis
113 of ischemic heart disease and that it has a formalized, written
114 transfer agreement with a hospital that has a Level II program,
115 including written transport protocols to ensure safe and
116 efficient transfer of a patient within 60 minutes. However, a
117 hospital located more than 100 road miles from the closest Level
118 II adult cardiovascular services program does not need to meet
119 the 60-minute transfer time protocol if the hospital
120 demonstrates that it has a formalized, written transfer
121 agreement with a hospital that has a Level II program. The
122 agreement must include written transport protocols to ensure the
123 safe and efficient transfer of a patient, taking into
124 consideration the patient's clinical and physical
125 characteristics, road and weather conditions, and viability of
126 ground and air ambulance service to transfer the patient.

127 (c) For a hospital seeking a Level II program,
128 demonstration that, for the most recent 12-month period as
129 reported to the agency, it has performed a minimum of 1,100
130 adult inpatient and outpatient cardiac catheterizations, of

131 which at least 400 must be therapeutic catheterizations, or, for
132 the most recent 12-month period, has discharged at least 800
133 patients with the principal diagnosis of ischemic heart disease.

134 (d) Compliance with the most recent guidelines of the
135 American College of Cardiology and American Heart Association
136 guidelines for staffing, physician training and experience,
137 operating procedures, equipment, physical plant, and patient
138 selection criteria to ensure patient quality and safety.

139 (e) Establishment of appropriate hours of operation and
140 protocols to ensure availability and timely referral in the
141 event of emergencies.

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

144 ~~(4) In order to ensure continuity of available services,~~
145 ~~the holder of a certificate of need for a newly licensed~~
146 ~~hospital that meets the requirements of this subsection may~~
147 ~~apply for and shall be granted Level I program status regardless~~
148 ~~of whether rules relating to Level I programs have been adopted.~~
149 ~~To qualify for a Level I program under this subsection, a~~
150 ~~hospital seeking a Level I program must be a newly licensed~~
151 ~~hospital established pursuant to a certificate of need in a~~
152 ~~physical location previously licensed and operated as a~~
153 ~~hospital, the former hospital must have provided a minimum of~~
154 ~~300 adult inpatient and outpatient diagnostic cardiac~~
155 ~~catheterizations for the most recent 12-month period as reported~~
156 ~~to the agency, and the newly licensed hospital must have a~~

157 ~~formalized, written transfer agreement with a hospital that has~~
158 ~~a Level II program, including written transport protocols to~~
159 ~~ensure safe and efficient transfer of a patient within 60~~
160 ~~minutes. A hospital meeting the requirements of this subsection~~
161 ~~may apply for certification of Level I program status before~~
162 ~~taking possession of the physical location of the former~~
163 ~~hospital, and the effective date of Level I program status shall~~
164 ~~be concurrent with the effective date of the newly issued~~
165 ~~hospital license.~~

166 (4)~~(5)~~ (a) The agency shall establish a technical advisory
167 panel to develop procedures and standards for measuring outcomes
168 of adult cardiovascular services. Members of the panel shall
169 include representatives of the Florida Hospital Association, the
170 Florida Society of Thoracic and Cardiovascular Surgeons, the
171 Florida Chapter of the American College of Cardiology, and the
172 Florida Chapter of the American Heart Association and others
173 with experience in statistics and outcome measurement. Based on
174 recommendations from the panel, the agency shall develop and
175 adopt rules for the adult cardiovascular services that include
176 at least the following:

177 1. A risk adjustment procedure that accounts for the
178 variations in severity and case mix found in hospitals in this
179 state.

180 2. Outcome standards specifying expected levels of
181 performance in Level I and Level II adult cardiovascular
182 services. Such standards may include, but shall not be limited

183 to, in-hospital mortality, infection rates, nonfatal myocardial
184 infarctions, length of stay, postoperative bleeds, and returns
185 to surgery.

186 3. Specific steps to be taken by the agency and licensed
187 hospitals that do not meet the outcome standards within
188 specified time periods, including time periods for detailed case
189 reviews and development and implementation of corrective action
190 plans.

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

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

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