

1 A bill to be entitled
2 An act relating to cardiac programs; amending s.
3 395.1055, F.S.; requiring the Agency for Health Care
4 Administration to adopt rules establishing licensing
5 standards for pediatric cardiac catheterization and
6 pediatric open-heart surgery programs located in
7 licensed facilities; providing requirements for a
8 facility providing such programs, including requiring
9 the facility to be licensed by the Joint Commission;
10 establishing minimum standards for rules for such
11 pediatric cardiac programs; requiring hospitals with a
12 pediatric cardiac catheterization program to
13 participate in the clinical outcome reporting system
14 operated by the Society of Thoracic Surgeons;
15 requiring the agency to establish a pediatric cardiac
16 technical advisory panel and adopt rules based on the
17 panel's recommendations; providing duties of the
18 panel; specifying membership of the panel; amending s.
19 408.0361, F.S.; granting an exception from a transfer
20 time protocol requirement for certain hospitals
21 providing adult cardiovascular services; expanding
22 rulemaking criteria for the agency for licensure of
23 hospitals performing percutaneous cardiac intervention
24 procedures; amending s. 408.05, F.S.; requiring the
25 agency to contract with the Society of Thoracic

26 Surgeons for collection of certain data for
 27 publication on the agency's website for certain
 28 purposes; providing an effective date.

30 Be It Enacted by the Legislature of the State of Florida:

31
 32 Section 1. Subsection (9) of section 395.1055, Florida
 33 Statutes, is renumbered as subsection (11), and new subsections
 34 (9) and (10) are added to that section, to read:

35 395.1055 Rules and enforcement.—

36 (9) (a) The agency shall adopt rules establishing licensure
 37 standards for providers of pediatric cardiac catheterization
 38 services and pediatric open-heart surgery.

39 (b) In establishing licensure standards for a pediatric
 40 cardiac catheterization program, the rules, at a minimum, must
 41 require:

42 1. The program to be located in a facility in which
 43 pediatric open-heart surgery is being performed and which is
 44 completely equipped to provide necessary medical and surgical
 45 care to the patient. The facility must be accredited by the
 46 Joint Commission.

47 2. The cardiac catheterization team to include sufficient
 48 medical and support staff to provide necessary medical and
 49 surgical care to the patient.

50 3. The program to mobilize the pediatric cardiac
 51 catheterization team within a specified period of time for an
 52 emergency procedure.

53 4. The facility where the program is located to offer a
 54 range of noninvasive cardiac and diagnostic services, including,
 55 but not limited to:

56 a. Hematology studies or coagulation studies;

57 b. Electrocardiography;

58 c. Chest X-rays;

59 d. Blood gas studies;

60 e. Clinical pathology studies and blood chemistry

61 analysis;

62 f. A special procedure X-ray room;

63 g. A film storage and darkroom for proper processing of

64 films;

65 h. X-ray equipment with cineangiocardiology

66 capabilities;

67 i. An image intensifier;

68 j. An automatic injector;

69 k. A diagnostic X-ray examination table for special

70 procedures;

71 l. A blood gas analyzer;

72 m. A multichannel polygraph; and

73 n. Emergency equipment, including a temporary pacemaker
74 unit with catheters, ventilator assistance devices, and a DC-
75 defibrillator.

76 (c) In establishing licensure standards for a pediatric
77 open-heart surgery program, the rules, at a minimum, must
78 require:

79 1. The pediatric open-heart surgery team to include
80 sufficient surgical and support staff to provide necessary
81 medical and surgical care to the patient.

82 2. The program to:

83 a. Be available for nonemergent open-heart surgery 8 hours
84 per day, 5 days per week;

85 b. Be capable of mobilizing the surgical and medical
86 support teams within a specified period of time for emergency
87 cases; and

88 c. Provide 24-hour coverage by a physician or staff.

89 3. Postoperative care to be provided under the direction
90 of the cardiovascular surgeon who performed the surgery, in
91 communication with and with the support of the postoperative
92 cardiovascular team as prescribed by rule. Members of the team
93 must be on call or otherwise available for an emergency. A
94 patient must be cared for in an intensive care unit that
95 provides 24-hour-per-day nursing care with at least one
96 registered nurse for every two patients during the first hours
97 of postoperative care. Postoperative care must also include

98 | coverage for the operation of the cardiopulmonary bypass pump 24
99 | hours per day.

100 | 4. Each pediatric open-heart surgery program to have the
101 | capability to provide a full range of open-heart surgery
102 | operations, including:

103 | a. Repair or replacement of a heart valve;

104 | b. Repair of a congenital heart defect;

105 | c. Repair or reconstruction of an intrathoracic vessel;

106 | and

107 | d. Treatment of cardiac trauma.

108 | 5. A licensed facility with a pediatric open-heart surgery
109 | program to provide the following services:

110 | a. Consultation in cardiology, hematology, nephrology,
111 | pulmonary medicine, treatment of infectious diseases, and other
112 | appropriate pediatric subspecialties;

113 | b. Pathology, including anatomical, clinical, blood bank,
114 | and coagulation laboratory services;

115 | c. Anesthesiology, including respiratory therapy;

116 | d. Radiology, including diagnostic nuclear medicine;

117 | e. Neurology;

118 | f. Inpatient cardiac catheterization;

119 | g. Noninvasive cardiographics, including
120 | electrocardiography, exercise stress testing, and

121 | echocardiography;

122 | h. Intensive care; and

123 i. Emergency care available 24 hours per day for cardiac
124 emergencies.

125 (d) A hospital with a licensed pediatric cardiac
126 catheterization program shall participate in the clinical
127 outcome report system operated by the Society of Thoracic
128 Surgeons.

129 (10) The agency shall establish a technical advisory panel
130 to develop procedures and standards for measuring outcomes of
131 pediatric cardiac catheterization programs and pediatric open-
132 heart surgery programs.

133 (a) Voting members of the panel shall include:

134 1. A pediatric cardiac surgeon or pediatric cardiologist,
135 or a designee, from each of the following pediatric cardiac
136 centers:

137 a. Johns Hopkins All Children's Hospital in St.
138 Petersburg;

139 b. Arnold Palmer Hospital for Children in Orlando;

140 c. Joe DiMaggio Children's Hospital in Hollywood;

141 d. Nicklaus Children's Hospital in Miami;

142 e. St. Joseph's Children's Hospital in Tampa;

143 f. University of Florida Health Shands Children's Hospital
144 in Gainesville;

145 g. University of Miami/Jackson Memorial Medical Center
146 Holtz Children's Hospital in Miami;

147 h. Wolfson Children's Hospital in Jacksonville;

148 i. Florida Hospital for Children, Walt Disney Pavilion, in
149 Orlando; and

150 j. Nemours Children's Hospital in Orlando.

151 2. An at-large member, appointed by the Secretary of
152 Health Care Administration, who is either a pediatric
153 cardiologist or adult cardiologist with a special interest in
154 the care of adults with congenital heart disease.

155 (b) Nonvoting members of the panel shall include:

156 1. The Secretary of Health Care Administration, or a
157 designee;

158 2. The Surgeon General, or a designee; and

159 3. The Deputy Secretary of Children's Medical Services, or
160 a designee.

161 (c) The Secretary of Health Care Administration may
162 appoint up to four additional nonvoting members from the
163 following organizations:

164 1. The Florida Association of Children's Hospitals;

165 2. The Florida Chapter of the American Academy of
166 Pediatrics;

167 3. The Florida Society of Thoracic and Cardiovascular
168 Surgeons;

169 4. The Florida Chapter of the American College of
170 Cardiology; or

171 5. The Florida Chapter of the American Heart Association.

172 (d) Based on recommendations from the panel, the agency
173 shall develop and adopt rules for pediatric cardiac
174 catheterization programs and pediatric open-heart surgery
175 programs, consistent with the licensure requirements in
176 subsection (9), that include at least the following:

177 1. Outcome standards specifying expected levels of
178 performance in pediatric cardiac programs, using a risk
179 adjustment procedure that accounts for the variations in
180 severity and case mix. Such standards may include, but are not
181 limited to, in-hospital mortality, infection rates, and returns
182 to surgery.

183 2. Specific steps to be taken by the agency and a licensed
184 facility when such facility does not meet the outcome standards
185 within specified time periods, including time periods for
186 detailed case reviews and the development and implementation of
187 corrective action plans.

188 Section 2. Paragraph (b) of subsection (3) of section
189 408.0361, Florida Statutes, is amended to read:

190 408.0361 Cardiovascular services and burn unit licensure.—

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

193 (b)1. For a hospital seeking a Level I program,
194 demonstration that, for the most recent 12-month period as
195 reported to the agency, it has provided a minimum of 300 adult
196 inpatient and outpatient diagnostic cardiac catheterizations or,

197 for the most recent 12-month period, has discharged or
198 transferred at least 300 inpatients with the principal diagnosis
199 of ischemic heart disease and that it has a formalized, written
200 transfer agreement with a hospital that has a Level II program,
201 including written transport protocols to ensure safe and
202 efficient transfer of a patient within 60 minutes. ~~However,~~

203 2. A hospital located more than 100 road miles from the
204 closest Level II adult cardiovascular services program does not
205 need to meet the 60-minute transfer time protocol requirement in
206 subparagraph 1., if the hospital demonstrates that:

207 a. For the most recent 12-month period as reported to the
208 agency, it has provided a minimum of 100 adult inpatient and
209 outpatient diagnostic cardiac catheterizations, and that, for
210 the most recent 12-month period, it has discharged or
211 transferred at least 300 patients with the principal diagnosis
212 of ischemic heart disease; or

213 b. It has a formalized, written transfer agreement with a
214 hospital that has a Level II program. The agreement must include
215 written transport protocols to ensure the safe and efficient
216 transfer of a patient, taking into consideration the patient's
217 clinical and physical characteristics, road and weather
218 conditions, and viability of ground and air ambulance service to
219 transfer the patient.

220 3. At a minimum, the rules for adult cardiovascular
221 services must require nursing and technical staff to have

222 demonstrated experience in handling acutely ill patients
223 requiring intervention, based on the staff member's previous
224 experience in dedicated cardiac interventional laboratories or
225 surgical centers. If a staff member's previous experience is in
226 a dedicated cardiac interventional laboratory at a hospital that
227 does not have an approved adult open-heart-surgery program, the
228 staff member's previous experience qualifies only if, at the
229 time the staff member acquired his or her experience, the
230 dedicated cardiac interventional laboratory:

231 a. Had an annual volume of 500 or more percutaneous
232 cardiac intervention procedures;

233 b. Achieved a demonstrated success rate of 95 percent or
234 greater for percutaneous cardiac intervention procedures;

235 c. Experienced a complication rate of less than 5 percent
236 for percutaneous cardiac intervention procedures; and

237 d. Performed diverse cardiac procedures, including, but
238 not limited to, balloon angioplasty and stenting, rotational
239 atherectomy, cutting balloon atheroma remodeling, and procedures
240 relating to left ventricular support capability.

241 Section 3. Paragraph (k) is added to subsection (3) of
242 section 408.05, Florida Statutes, to read:

243 408.05 Florida Center for Health Information and
244 Transparency.—

245 (3) HEALTH INFORMATION TRANSPARENCY.—In order to
246 disseminate and facilitate the availability of comparable and

CS/HB 59

2017

247 | uniform health information, the agency shall perform the
248 | following functions:

249 | (k) Contract with the Society of Thoracic Surgeons to
250 | obtain data submitted pursuant to s. 395.1055(9)(d) for
251 | publication on the agency's website in a manner that will allow
252 | consumers to be informed of aggregate data and to compare
253 | pediatric cardiac catheterization programs.

254 | Section 4. This act shall take effect July 1, 2017.