



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 accredited by a nationally  
10          recognized accrediting organization; establishing  
11          minimum standards for rules for such pediatric cardiac  
12          programs; requiring hospitals with a pediatric cardiac  
13          catheterization program to participate in the clinical  
14          outcome reporting system operated by the Society of  
15          Thoracic Surgeons; requiring the agency to establish a  
16          pediatric cardiac technical advisory panel and adopt  
17          rules based on the panel's recommendations; providing  
18          duties of the panel; specifying membership of the  
19          panel; amending s. 408.0361, F.S.; granting an  
20          exception from volume requirements for diagnostic  
21          cardiac catheterization procedures and ischemic heart  
22          disease diagnoses for certain hospitals providing  
23          adult cardiovascular services; expanding rulemaking  
24          criteria for the agency for licensure of hospitals  
25          performing percutaneous cardiac intervention



CS/HB 59, Engrossed 1

2017

26 |       procedures; amending s. 408.05, F.S.; requiring the  
27 |       agency to contract with the Society of Thoracic  
28 |       Surgeons for collection of certain data for  
29 |       publication on the agency's website for certain  
30 |       purposes; providing an effective date.  
31 |

32 | Be It Enacted by the Legislature of the State of Florida:  
33 |

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

37 |       395.1055 Rules and enforcement.—

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

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

44 |       1. The program to be located in a facility in which  
45 | pediatric open-heart surgery is being performed and which is  
46 | completely equipped to provide necessary medical and surgical  
47 | care to the patient. The facility must be accredited by a  
48 | nationally recognized accrediting organization.



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

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

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

58            a. Hematology studies or coagulation studies;

59            b. Electrocardiography;

60            c. Chest X-rays;

61            d. Blood gas studies;

62            e. Clinical pathology studies and blood chemistry  
63 analysis;

64            f. A special procedure X-ray room;

65            g. A film storage and darkroom for proper processing of  
66 films;

67            h. X-ray equipment with cineangiocardiology  
68 capabilities;

69            i. An image intensifier;

70            j. An automatic injector;

71            k. A diagnostic X-ray examination table for special  
72 procedures;

73            l. A blood gas analyzer;



74 | m. A multichannel polygraph; and

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

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

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

84 | 2. The program to:

85 | a. Be available for nonemergent open-heart surgery 8 hours  
86 | per day, 5 days per week;

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

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

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



99 | of postoperative care. Postoperative care must also include  
100 | coverage for the operation of the cardiopulmonary bypass pump 24  
101 | hours per day.

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

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

106 | b. Repair of a congenital heart defect;

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

108 | and

109 | d. Treatment of cardiac trauma.

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

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

115 | b. Pathology, including anatomical, clinical, blood bank,  
116 | and coagulation laboratory services;

117 | c. Anesthesiology, including respiratory therapy;

118 | d. Radiology, including diagnostic nuclear medicine;

119 | e. Neurology;

120 | f. Inpatient cardiac catheterization;

121 | g. Noninvasive cardiographics, including  
122 | electrocardiography, exercise stress testing, and  
123 | echocardiography;



124 h. Intensive care; and  
125 i. Emergency care available 24 hours per day for cardiac  
126 emergencies.

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

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

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

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

139 a. Johns Hopkins All Children's Hospital in St.  
140 Petersburg;

141 b. Arnold Palmer Hospital for Children in Orlando;

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

143 d. Nicklaus Children's Hospital in Miami;

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

145 f. University of Florida Health Shands Children's Hospital  
146 in Gainesville;

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



- 149        h. Wolfson Children's Hospital in Jacksonville;  
150        i. Florida Hospital for Children, Walt Disney Pavilion, in  
151 Orlando; and  
152        j. Nemours Children's Hospital in Orlando.  
153        2. An at-large member, appointed by the Secretary of  
154 Health Care Administration, who is either a pediatric  
155 cardiologist or adult cardiologist with a special interest in  
156 the care of adults with congenital heart disease.  
157        (b) Nonvoting members of the panel shall include:  
158        1. The Secretary of Health Care Administration, or a  
159 designee;  
160        2. The Surgeon General, or a designee; and  
161        3. The Deputy Secretary of Children's Medical Services, or  
162 a designee.  
163        (c) The Secretary of Health Care Administration may  
164 appoint up to four additional nonvoting members from the  
165 following organizations:  
166        1. The Florida Association of Children's Hospitals;  
167        2. The Florida Chapter of the American Academy of  
168 Pediatrics;  
169        3. The Florida Society of Thoracic and Cardiovascular  
170 Surgeons;  
171        4. The Florida Chapter of the American College of  
172 Cardiology; or  
173        5. The Florida Chapter of the American Heart Association.



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

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

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

190 Section 2. Paragraph (b) of subsection (3) of section  
191 408.0361, Florida Statutes, is amended to read:

192 408.0361 Cardiovascular services and burn unit licensure.—

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

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





CS/HB 59, Engrossed 1

2017

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

206 2.a. A hospital located more than 100 road miles from the  
207 closest Level II adult cardiovascular services program does not  
208 need to meet the diagnostic cardiac catheterization volume and  
209 ischemic heart disease diagnosis volume requirements in  
210 subparagraph 1., if the hospital demonstrates that it has, for  
211 the most recent 12-month period as reported to the agency,  
212 provided a minimum of 100 adult inpatient and outpatient  
213 diagnostic cardiac catheterizations or that, for the most recent  
214 12-month period, it has discharged or transferred at least 300  
215 patients with the principal diagnosis of ischemic heart disease.

216 b. A hospital located more than 100 road miles from the  
217 closest Level II adult cardiovascular services program does not  
218 need to meet the 60-minute transfer time protocol requirement in  
219 subparagraph 1., if the hospital demonstrates that it has a  
220 formalized, written transfer agreement with a hospital that has  
221 a Level II program. The agreement must include written transport  
222 protocols to ensure the safe and efficient transfer of a  
223 patient, taking into consideration the patient's clinical and



224 physical characteristics, road and weather conditions, and  
225 viability of ground and air ambulance service to transfer the  
226 patient.

227 3. At a minimum, the rules for adult cardiovascular  
228 services must require nursing and technical staff to have  
229 demonstrated experience in handling acutely ill patients  
230 requiring intervention, based on the staff member's previous  
231 experience in dedicated cardiac interventional laboratories or  
232 surgical centers. If a staff member's previous experience is in  
233 a dedicated cardiac interventional laboratory at a hospital that  
234 does not have an approved adult open-heart-surgery program, the  
235 staff member's previous experience qualifies only if, at the  
236 time the staff member acquired his or her experience, the  
237 dedicated cardiac interventional laboratory:

238 a. Had an annual volume of 500 or more percutaneous  
239 cardiac intervention procedures;

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

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

244 d. Performed diverse cardiac procedures, including, but  
245 not limited to, balloon angioplasty and stenting, rotational  
246 atherectomy, cutting balloon atheroma remodeling, and procedures  
247 relating to left ventricular support capability.

248 Section 3. Paragraph (k) is added to subsection (3) of



CS/HB 59, Engrossed 1

2017

249 | section 408.05, Florida Statutes, to read:

250 |       408.05 Florida Center for Health Information and  
251 | Transparency.—

252 |       (3) HEALTH INFORMATION TRANSPARENCY.—In order to  
253 | disseminate and facilitate the availability of comparable and  
254 | uniform health information, the agency shall perform the  
255 | following functions:

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

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