

By the Committee on Health Policy; and Senator Grimsley

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1 A bill to be entitled
2 An act relating to cardiovascular services; creating
3 s. 391.224, F.S.; providing legislative findings and
4 intent; creating the Pediatric Cardiac Advisory
5 Council; determining the chair of the advisory
6 council; establishing the membership of the advisory
7 council; identifying the duties of the advisory
8 council; setting the minimum qualifications for the
9 designation of a facility as a Pediatric and
10 Congenital Cardiovascular Center of Excellence;
11 requiring a report to the Governor, the Legislature,
12 and the State Surgeon General; requiring the
13 Department of Health to develop rules relating to
14 pediatric cardiac services and facilities in the
15 Children's Medical Services Network; authorizing the
16 department to adopt rules relating to the council and
17 the designation of facilities as Pediatric and
18 Congenital Cardiovascular Centers of Excellence;
19 authorizing and preserving until amended specified
20 rules relating to pediatric cardiac services and
21 facilities; amending s. 408.0361, F.S.; expanding
22 rulemaking criteria for the Agency for Health Care
23 Administration for licensure of hospitals performing
24 percutaneous cardiac intervention procedures;
25 providing an effective date.

26
27 Be It Enacted by the Legislature of the State of Florida:

28
29 Section 1. Section 391.224, Florida Statutes, is created to
30 read:

31 391.224 Pediatric Cardiac Advisory Council.—

32 (1) LEGISLATIVE FINDINGS AND INTENT.—

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33 (a) The Legislature finds significant benefits in the
34 continued coordination of activities by several state agencies
35 regarding access to pediatric cardiac care in this state. It is
36 the intent of the Legislature that the Department of Health, the
37 department's cardiac consultants, and the Agency for Health Care
38 Administration maintain their long-standing interagency teams
39 and agreements for the development and adoption of guidelines,
40 standards, and rules for those portions of the state cardiac
41 care system within the statutory authority of each agency. This
42 coordinated approach will continue to ensure the necessary
43 continuum of care for the pediatric cardiac patient. The
44 department has the leadership responsibility for this activity.

45 (b) It is further the intent of the Legislature to
46 establish the Pediatric Cardiac Advisory Council, a statewide,
47 inclusive council within the department.

48 (2) PEDIATRIC CARDIAC ADVISORY COUNCIL.—

49 (a) The State Surgeon General shall appoint the Pediatric
50 Cardiac Advisory Council for the purpose of advising the
51 department on the delivery of cardiac services to children.

52 (b) The chair of the council shall be elected from among
53 the council members every 2 years and may not serve more than
54 two consecutive terms.

55 (c) The council shall meet upon the call of the chair or
56 two or more voting members or upon the call of the State Surgeon
57 General, but must meet at least quarterly. Council meetings must
58 be conducted by teleconference or through other electronic means
59 when feasible.

60 (d) The council shall be composed of no more than 13 voting
61 members with technical expertise in cardiac medicine. Members

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62 shall be appointed by the State Surgeon General for staggered
63 terms of 4 years. An employee of the department or a contracted
64 consultant paid by the department may not serve as an appointed
65 member or ex officio member of the council. Council members
66 shall include the following voting members:

67 1. Pediatric cardiologists or pediatric cardiovascular
68 surgeons who have been nominated by their respective chief
69 executive officers and approved by the State Surgeon General
70 from the following facilities for as long as such facilities
71 maintain their pediatric certificates of need:

72 a. All Children's Hospital in St. Petersburg;

73 b. Arnold Palmer Hospital for Children in Orlando;

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

75 d. Nicklaus Children's Hospital in Miami;

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

77 f. University of Florida Health Shands Hospital in

78 Gainesville;

79 g. University of Miami Holtz Children's Hospital in Miami;

80 and

81 h. Wolfson Children's Hospital in Jacksonville.

82
83 A hospital with a certificate of need for a pediatric cardiac
84 program that meets state and national standards as determined by
85 the council following an onsite visit by a panel from the
86 council shall have one of its pediatric cardiologists or
87 pediatric cardiovascular surgeons who has been nominated by its
88 chief executive officer and approved by the State Surgeon
89 General appointed to the council as a new voting member. The
90 voting privilege of a voting member of the council appointed

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91 pursuant to this subparagraph shall be suspended if the facility
92 he or she represents no longer meets state and national
93 standards as adopted by the council. Such individual may remain
94 a member of the council in an advisory capacity but shall
95 relinquish voting privileges until his or her facility meets
96 such standards.

97 2. Two physicians at large, not associated with a facility
98 that has a representative appointed as a voting member of the
99 council, who are pediatric cardiologists or subspecialists with
100 special expertise or experience in dealing with children or
101 adults with congenital heart disease. These physicians shall be
102 selected by the State Surgeon General in consultation with the
103 Deputy Secretary for Children's Medical Services and the
104 Director of Children's Medical Services.

105 3. One community physician who has ongoing involvement with
106 and special interest in children with heart disease and who is
107 not associated with a facility represented in subparagraph 1. or
108 one community-based medical internist having experience with
109 adults with congenital heart disease. The community physician
110 shall be selected by the State Surgeon General in consultation
111 with the Deputy Secretary of Children's Medical Services and the
112 Director of the Division of Children's Medical Services.

113 (e) The State Surgeon General may appoint nonvoting
114 advisory members to the council in consultation with the Deputy
115 Secretary for Children's Medical Services and the Director of
116 Children's Medical Services. Among such nonvoting advisory
117 members appointed to the council shall be one representative
118 from a pediatric health advocacy group. Such members may
119 participate in council discussions and subcommittees created by

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120 the council, but may not vote.

121 (f) The duties of the council include, but are not limited
122 to:

123 1. Recommending standards for personnel, diagnoses,
124 clinics, and facilities rendering cardiac services to the
125 department and the Division of Children's Medical Services.

126 2. Analyzing reports on the periodic review of cardiac
127 personnel, diagnoses, clinics, and facilities to determine if
128 established state and national standards for cardiac services
129 are met.

130 3. Making recommendations to the Director of Children's
131 Medical Services as to the approval or disapproval of reviewed
132 cardiac care personnel, diagnoses, clinics, and facilities.

133 4. Making recommendations as to the intervals for
134 reinspection of approved personnel, diagnoses, clinics, and
135 facilities for cardiac care.

136 5. Reviewing and inspecting hospitals upon the request of
137 the hospitals, the department, or the Agency for Health Care
138 Administration to determine if established state and national
139 standards for cardiac services are met.

140 6. Providing input on all aspects of the state's Children's
141 Medical Services cardiac programs, including rulemaking.

142 7. Addressing all components of the care of adults and
143 children with congenital heart disease and children with
144 acquired heart disease, as indicated and appropriate.

145 8. Abiding by the recognized state and national
146 professional standards of care for children with heart disease.

147 9. Making recommendations to the State Surgeon General for
148 legislation and appropriations for children's cardiac services.

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149 10. Providing advisory opinions to the Agency for Health
150 Care Administration before the agency approves a certificate of
151 need for children's cardiac services.

152 (g) A council member shall serve without compensation, but
153 is entitled to reimbursement for per diem and travel expenses in
154 accordance with s. 112.061.

155 (h) At the recommendation of the Pediatric Cardiac Advisory
156 Council and with the approval of the Director of Children's
157 Medical Services, the State Surgeon General shall designate
158 facilities meeting the council's approved state and national
159 professional standards of care for children with heart disease
160 as "Pediatric and Congenital Cardiovascular Centers of
161 Excellence." The designation is withdrawn automatically if a
162 particular center no longer meets such standards.

163 1. The council shall develop and recommend to the State
164 Surgeon General measurable performance standards and goals for
165 determining whether a facility meets the requirements for
166 designation as a "Pediatric and Congenital Cardiovascular Center
167 of Excellence."

168 2. The council shall develop and recommend to the State
169 Surgeon General evaluation tools for measuring the goals and
170 performance standards of the facilities seeking and receiving
171 the "Pediatric and Congenital Cardiovascular Center of
172 Excellence" designation.

173 (3) ANNUAL REPORT.—The council shall submit an annual
174 report to the Governor, the President of the Senate, the Speaker
175 of the House of Representatives, and the State Surgeon General
176 by January 1 of each year, beginning in 2017. The report must
177 summarize the council's activities for the preceding fiscal year

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178 and include data and performance measures for all pediatric
179 cardiac facilities that participate in the Children's Medical
180 Services Network relating to surgical morbidity and mortality.
181 The report must also recommend any policy or procedural changes
182 that would increase the council's effectiveness in monitoring
183 the pediatric cardiovascular programs in the state.

184 (4) RULEMAKING.—The department, in coordination with the
185 Agency for Health Care Administration, shall develop rules
186 related to pediatric cardiac facilities that participate in the
187 Children's Medical Services Network. The rules may establish
188 standards relating to the training and credentialing of medical
189 and surgical personnel, facility and physician minimum case
190 volumes, and data reporting requirements for monitoring and
191 enhancing quality assurance. The department may adopt rules
192 relating to the establishment, operations, and authority of the
193 Pediatric Cardiac Advisory Council and the establishment, goals,
194 performance standards, and evaluation tools for designating
195 facilities as Pediatric and Congenital Cardiovascular Centers of
196 Excellence. The rules relating to pediatric cardiac services and
197 facilities in effect on October 1, 2015, are authorized pursuant
198 to this subsection and shall remain in effect until amended
199 pursuant to this subsection.

200 Section 2. Paragraph (b) of subsection (3) of section
201 408.0361, Florida Statutes, is amended to read:

202 408.0361 Cardiovascular services and burn unit licensure.—

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

205 (b) For a hospital seeking a Level I program, demonstration
206 that, for the most recent 12-month period as reported to the

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207 agency, it has provided a minimum of 300 adult inpatient and
208 outpatient diagnostic cardiac catheterizations or, for the most
209 recent 12-month period, has discharged or transferred at least
210 300 inpatients with the principal diagnosis of ischemic heart
211 disease and that it has a formalized, written transfer agreement
212 with a hospital that has a Level II program, including written
213 transport protocols to ensure safe and efficient transfer of a
214 patient within 60 minutes. However, a hospital located more than
215 100 road miles from the closest Level II adult cardiovascular
216 services program does not need to meet the 60-minute transfer
217 time protocol if the hospital demonstrates that it has a
218 formalized, written transfer agreement with a hospital that has
219 a Level II program. The agreement must include written transport
220 protocols to ensure the safe and efficient transfer of a
221 patient, taking into consideration the patient's clinical and
222 physical characteristics, road and weather conditions, and
223 viability of ground and air ambulance service to transfer the
224 patient. At a minimum, the rules for adult cardiovascular
225 services must require nursing and technical staff to have
226 demonstrated experience in handling acutely ill patients
227 requiring intervention based on the staff members' previous
228 experience in dedicated cardiac interventional laboratories or
229 surgical centers. If a staff member's previous experience is in
230 a dedicated cardiac interventional laboratory at a hospital that
231 does not have an approved adult open-heart-surgery program, the
232 staff member's previous experience qualifies only if, at the
233 time the staff member acquired his or her experience, the
234 dedicated cardiac interventional laboratory:

- 235 1. Had an annual volume of 500 or more percutaneous cardiac

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236 intervention procedures;

237 2. Achieved a demonstrated success rate of 95 percent or
238 greater for percutaneous cardiac intervention procedures;

239 3. Experienced a complication rate of less than 5 percent
240 for percutaneous cardiac intervention procedures; and

241 4. Performed diverse cardiac procedures, including, but not
242 limited to, balloon angioplasty and stenting, rotational
243 atherectomy, cutting balloon atheroma remodeling, and procedures
244 relating to left ventricular support capability.

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