

By Senator Harrell

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1 A bill to be entitled
2 An act relating to the Pediatric Cardiac Technical
3 Advisory Panel; amending s. 395.1055, F.S.;
4 authorizing the reimbursement of per diem and travel
5 expenses to members of the pediatric cardiac technical
6 advisory panel, established within the Agency for
7 Health Care Administration; revising panel membership
8 to include certain alternate at-large members;
9 providing term limits for voting members; providing
10 immunity from civil and criminal liabilities to
11 members of the panel; requiring the Secretary of
12 Health Care Administration to consult the panel for
13 advisory recommendations on certain certificate of
14 need applications; authorizing the secretary to
15 request announced or unannounced site visits to any
16 existing pediatric cardiac surgical centers or
17 facilities seeking licensure as a pediatric cardiac
18 surgical center through the certificate of need
19 process; providing a process for the appointment of
20 physician experts to a site visit team; requiring each
21 member of a site visit team to submit a report to the
22 panel; requiring the panel to discuss such reports and
23 present an advisory opinion to the secretary;
24 providing requirements for an on-site inspection;
25 requiring the Surgeon General of the Department of
26 Health to provide specified reports to the secretary;
27 providing an effective date.

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

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Section 1. Present subsections (9) through (12) of section 395.1055, Florida Statutes, are amended, and new subsections (10), (13), and (14) are added to that section, to read:

395.1055 Rules and enforcement.—

(9) The agency shall establish a pediatric cardiac technical advisory panel, pursuant to s. 20.052, to develop procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric cardiovascular surgery programs.

(a) Members of the panel must have technical expertise in pediatric cardiac medicine, shall serve without compensation, and may ~~not~~ be reimbursed for per diem and travel expenses.

(b) Voting members of the panel shall include: 3 at-large members, and 3 alternate at-large members with different program affiliations, including 1 cardiologist who is board certified in caring for adults with congenital heart disease and 2 board-certified pediatric cardiologists, neither of whom may be employed by any of the hospitals specified in subparagraphs 1.-10. or their affiliates, each of whom is appointed by the Secretary of Health Care Administration, and 10 members, and an alternate for each member, each of whom is a pediatric cardiologist or a pediatric cardiovascular surgeon, each appointed by the chief executive officer of the following hospitals:

1. Johns Hopkins All Children's Hospital in St. Petersburg.
2. Arnold Palmer Hospital for Children in Orlando.
3. Joe DiMaggio Children's Hospital in Hollywood.
4. Nicklaus Children's Hospital in Miami.

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- 59 5. St. Joseph's Children's Hospital in Tampa.
60 6. University of Florida Health Shands Hospital in
61 Gainesville.
62 7. University of Miami Holtz Children's Hospital in Miami.
63 8. Wolfson Children's Hospital in Jacksonville.
64 9. Florida Hospital for Children in Orlando.
65 10. Nemours Children's Hospital in Orlando.
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67 Appointments made under subparagraphs 1.-10. are contingent upon
68 the hospital's maintenance of pediatric certificates of need and
69 the hospital's compliance with this section and rules adopted
70 thereunder, as determined by the Secretary of Health Care
71 Administration. A member appointed under subparagraphs 1.-10.
72 whose hospital fails to maintain such certificates or comply
73 with standards may serve only as a nonvoting member until the
74 hospital restores such certificates or complies with such
75 standards. A voting member may serve a maximum of two 2-year
76 terms and may be reappointed to the panel after being retired
77 from the panel for a full 2-year term.

78 (c) The Secretary of Health Care Administration may appoint
79 nonvoting members to the panel. Nonvoting members may include:

- 80 1. The Secretary of Health Care Administration.
81 2. The Surgeon General.
82 3. The Deputy Secretary of Children's Medical Services.
83 4. Any current or past Division Director of Children's
84 Medical Services.
85 5. A parent of a child with congenital heart disease.
86 6. An adult with congenital heart disease.
87 7. A representative from each of the following

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88 organizations: the Florida Chapter of the American Academy of
89 Pediatrics, the Florida Chapter of the American College of
90 Cardiology, the Greater Southeast Affiliate of the American
91 Heart Association, the Adult Congenital Heart Association, the
92 March of Dimes, the Florida Association of Children's Hospitals,
93 and the Florida Society of Thoracic and Cardiovascular Surgeons.

94 (d) The panel shall meet biannually, or more frequently
95 upon the call of the Secretary of Health Care Administration.
96 Such meetings may be conducted telephonically, or by other
97 electronic means.

98 (e) The duties of the panel include recommending to the
99 agency standards for quality of care, personnel, physical plant,
100 equipment, emergency transportation, and data reporting for
101 hospitals that provide pediatric cardiac services.

102 (f) Beginning on January 1, 2020, and annually thereafter,
103 the panel shall submit a report to the Governor, the President
104 of the Senate, the Speaker of the House of Representatives, the
105 Secretary of Health Care Administration, and the State Surgeon
106 General. The report must summarize the panel's activities during
107 the preceding fiscal year and include data and performance
108 measures on surgical morbidity and mortality for all pediatric
109 cardiac programs.

110 (g) Members of the panel are immune from any civil or
111 criminal liability for events resulting from the good faith
112 performance of duties assigned to them by the Secretary of
113 Health Care Administration.

114 (10) The Secretary of Health Care Administration shall
115 consult the pediatric cardiac technical advisory panel for an
116 advisory recommendation on all certificate of need applications

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117 to establish pediatric cardiac surgical centers.

118 (11)~~(10)~~ Based on the recommendations of the pediatric
119 cardiac technical advisory panel ~~in subsection (9)~~, the agency
120 shall adopt rules for pediatric cardiac programs which, at a
121 minimum, include:

122 (a) Standards for pediatric cardiac catheterization
123 services and pediatric cardiovascular surgery including quality
124 of care, personnel, physical plant, equipment, emergency
125 transportation, data reporting, and appropriate operating hours
126 and timeframes for mobilization for emergency procedures.

127 (b) Outcome standards consistent with nationally
128 established levels of performance in pediatric cardiac programs.

129 (c) Specific steps to be taken by the agency and licensed
130 facilities when the facilities do not meet the outcome standards
131 within a specified time, including time required for detailed
132 case reviews and the development and implementation of
133 corrective action plans.

134 (12)~~(11)~~ A pediatric cardiac program shall:

135 (a) Have a pediatric cardiology clinic affiliated with a
136 hospital licensed under this chapter.

137 (b) Have a pediatric cardiac catheterization laboratory and
138 a pediatric cardiovascular surgical program located in the
139 hospital.

140 (c) Have a risk adjustment surgical procedure protocol
141 following the guidelines established by the Society of Thoracic
142 Surgeons.

143 (d) Have quality assurance and quality improvement
144 processes in place to enhance clinical operation and patient
145 satisfaction with services.

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146 (e) Participate in the clinical outcome reporting systems
147 operated by the Society of Thoracic Surgeons and the American
148 College of Cardiology.

149 (13) (a) The Secretary of Health Care Administration may
150 request announced or unannounced site visits to any existing
151 pediatric cardiac surgical centers or facilities seeking
152 licensure as a pediatric cardiac surgical center through the
153 certificate of need process, to ensure compliance with this
154 section and rules adopted hereunder.

155 (b) At the request of the Secretary of Health Care
156 Administration, the pediatric cardiac technical advisory panel
157 shall recommend in-state physician experts to conduct an on-site
158 visit. The Secretary may also appoint up to two out-of-state
159 physician experts.

160 (c) A site visit team shall conduct an on-site inspection
161 of the designated hospital's pediatric medical and surgical
162 programs, and each member shall submit a written report of its
163 findings to the panel. The panel shall discuss the written
164 reports and present an advisory opinion to the Secretary of
165 Health Care Administration which includes recommendations and
166 any suggested actions for correction.

167 (d) Each on-site inspection must include all of the
168 following:

169 1. An inspection of the program's physical facilities,
170 clinics, and laboratories.

171 2. Interviews with support staff and hospital
172 administration.

173 3. A review of:

174 a. Randomly selected medical records and reports,

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175 including, but not limited to, advanced cardiac imaging,
176 computed tomography, magnetic resonance imaging, cardiac
177 ultrasound, cardiac catheterization, and surgical operative
178 notes.

179 b. The program's clinical outcome data submitted to the
180 Society of Thoracic Surgeons and the American College of
181 Cardiology pursuant to s. 408.05(3)(k).

182 c. Mortality reports from cardiac-related deaths that
183 occurred in the previous year.

184 d. Program volume data from the preceding year for
185 interventional and electrophysiology catheterizations and
186 surgical procedures.

187 (14) The Surgeon General shall provide quarterly reports to
188 the Secretary of Health Care Administration consisting of data
189 from the Children's Medical Services' critical congenital heart
190 disease screening program for review by the advisory panel.

191 (15)~~(12)~~ The agency may adopt rules to administer the
192 requirements of part II of chapter 408.

193 Section 2. This act shall take effect July 1, 2019.