1 A bill to be entitled 2 An act relating to the Pediatric Cardiac Technical 3 Advisory Panel; amending s. 395.1055, F.S.; authorizing the reimbursement of per diem and travel 4 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 advisory recommendation on certain certificate of need 13 14 applications; authorizing the Secretary to request 15 announced or unannounced site visits to any existing 16 or pediatric cardiac surgical centers or facilities 17 seeking licensure as a pediatric cardiac surgical center through the certificate of need process; 18 19 providing a process for the appointment of physician experts to a site visit team; requiring each member of 20 21 a site visit team to submit a report to the panel; 22 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

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26 Health to provide specified reports to the Secretary; 27 providing an effective date. 28 29 Be It Enacted by the Legislature of the State of Florida: 30 31 Section 1. Present subsections (9) through (12) of section 32 395.1055, Florida Statutes, are amended, and new subsections 33 (10), (13), and (14) are added to that section, to read: 34 395.1055 Rules and enforcement.-35 (9) The agency shall establish a pediatric cardiac 36 technical advisory panel, pursuant to s. 20.052, to develop 37 procedures and standards for measuring outcomes of pediatric 38 cardiac catheterization programs and pediatric cardiovascular 39 surgery programs. Members of the panel must have technical expertise in 40 (a) 41 pediatric cardiac medicine, shall serve without compensation, 42 and may not be reimbursed for per diem and travel expenses. 43 (b) Voting members of the panel shall include: 3 at-large 44 members, and 3 alternate at-large members with different program 45 affiliations, including 1 cardiologist who is board certified in 46 caring for adults with congenital heart disease and 2 boardcertified pediatric cardiologists, neither of whom may be 47 employed by any of the hospitals specified in subparagraphs 1.-48 10. or their affiliates, each of whom is appointed by the 49 50 Secretary of Health Care Administration, and 10 members, and an

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51	alternate for each member, each of whom is a pediatric
52	cardiologist or a pediatric cardiovascular surgeon, each
53	appointed by the chief executive officer of the following
54	hospitals:
55	1. Johns Hopkins All Children's Hospital in St.
56	Petersburg.
57	2. Arnold Palmer Hospital for Children in Orlando.
58	3. Joe DiMaggio Children's Hospital in Hollywood.
59	4. Nicklaus Children's Hospital in Miami.
60	5. St. Joseph's Children's Hospital in Tampa.
61	6. University of Florida Health Shands Hospital in
62	Gainesville.
63	7. University of Miami Holtz Children's Hospital in Miami.
64	8. Wolfson Children's Hospital in Jacksonville.
65	9. Florida Hospital for Children in Orlando.
66	10. Nemours Children's Hospital in Orlando.
67	
68	Appointments made under subparagraphs 110. are contingent upon
69	the hospital's maintenance of pediatric certificates of need and
70	the hospital's compliance with this section and rules adopted
71	thereunder, as determined by the Secretary of Health Care
72	Administration. A member appointed under subparagraphs 110.
73	whose hospital fails to maintain such certificates or comply
74	with standards may serve only as a nonvoting member until the
75	hospital restores such certificates or complies with such
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76 standards. A voting member may serve a maximum of two 2-year 77 terms and may be reappointed to the panel after being retired 78 from the panel for a full 2-year term. 79 The Secretary of Health Care Administration may (C) 80 appoint nonvoting members to the panel. Nonvoting members may 81 include: 82 1. The Secretary of Health Care Administration. 83 2. The Surgeon General. 3. The Deputy Secretary of Children's Medical Services. 84 85 4. Any current or past Division Director of Children's 86 Medical Services. 87 5. A parent of a child with congenital heart disease. 88 6. An adult with congenital heart disease. 89 7. A representative from each of the following 90 organizations: the Florida Chapter of the American Academy of Pediatrics, the Florida Chapter of the American College of 91 92 Cardiology, the Greater Southeast Affiliate of the American 93 Heart Association, the Adult Congenital Heart Association, the 94 March of Dimes, the Florida Association of Children's Hospitals, 95 and the Florida Society of Thoracic and Cardiovascular Surgeons. 96 The panel shall meet biannually, or more frequently (d) 97 upon the call of the Secretary of Health Care Administration. 98 Such meetings may be conducted telephonically, or by other electronic means. 99 100 The duties of the panel include recommending to the (e)

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101 agency standards for quality of care, personnel, physical plant, 102 equipment, emergency transportation, and data reporting for 103 hospitals that provide pediatric cardiac services.

104 Beginning on January 1, 2020, and annually thereafter, (f) 105 the panel shall submit a report to the Governor, the President 106 of the Senate, the Speaker of the House of Representatives, the 107 Secretary of Health Care Administration, and the State Surgeon 108 General. The report must summarize the panel's activities during 109 the preceding fiscal year and include data and performance 110 measures on surgical morbidity and mortality for all pediatric 111 cardiac programs.

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

116 (10) The Secretary of Health Care Administration shall 117 consult the pediatric cardiac technical advisory panel for an 118 advisory recommendation on all certificate of need applications 119 to establish pediatric cardiac surgical centers.

120 <u>(11) (10)</u> Based on the recommendations of the <u>pediatric</u> 121 <u>cardiac technical</u> advisory panel in subsection (9), the agency 122 shall adopt rules for pediatric cardiac programs which, at a 123 minimum, include:

(a) Standards for pediatric cardiac catheterization
services and pediatric cardiovascular surgery including quality

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of care, personnel, physical plant, equipment, emergency 126 127 transportation, data reporting, and appropriate operating hours 128 and timeframes for mobilization for emergency procedures. 129 (b) Outcome standards consistent with nationally 130 established levels of performance in pediatric cardiac programs. 131 Specific steps to be taken by the agency and licensed (C) facilities when the facilities do not meet the outcome standards 132 within a specified time, including time required for detailed 133 134 case reviews and the development and implementation of 135 corrective action plans. (12) (11) A pediatric cardiac program shall: 136 137 (a) Have a pediatric cardiology clinic affiliated with a hospital licensed under this chapter. 138 139 (b) Have a pediatric cardiac catheterization laboratory 140 and a pediatric cardiovascular surgical program located in the hospital. 141 142 (C) Have a risk adjustment surgical procedure protocol 143 following the guidelines established by the Society of Thoracic 144 Surgeons. 145 Have quality assurance and quality improvement (d) 146 processes in place to enhance clinical operation and patient 147 satisfaction with services. Participate in the clinical outcome reporting systems 148 (e) operated by the Society of Thoracic Surgeons and the American 149 College of Cardiology. 150 Page 6 of 8

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151	(13)(a) The Secretary of Health Care Administration may
152	request announced or unannounced site visits to any existing or
153	pediatric cardiac surgical centers or facilities seeking
154	licensure as a pediatric cardiac surgical center through the
155	certificate of need process, to ensure compliance with this
156	section and rules adopted hereunder.
157	(b) At the request of the Secretary of Health Care
158	Administration, the pediatric cardiac technical advisory panel
159	shall recommend in-state physician experts to conduct an on-site
160	visit. The Secretary may also appoint up to two out-of-state
161	physician experts.
162	(c) A site visit team shall conduct an on-site inspection
163	of the designated hospital's pediatric medical and surgical
164	programs and each member shall submit a written report of its
165	findings to the panel. The panel shall discuss the written
166	reports and present an advisory opinion to the Secretary of
167	Health Care Administration which includes recommendations and
168	any suggested actions for correction.
169	(d) Each on-site inspection must include all of the
170	following:
171	1. An inspection of the program's physical facilities,
172	clinics, and laboratories.
173	2. Interviews with support staff and hospital
174	administration.
175	3. A review of:
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176	a. Randomly selected medical records and reports,
177	including, but not limited to, advanced cardiac imaging,
178	computed tomography, magnetic resonance imaging, cardiac
179	ultrasound, cardiac catheterization, and surgical operative
180	notes.
181	b. The program's clinical outcome data submitted to the
182	Society of Thoracic Surgeons and the American College of
183	Cardiology pursuant to s. 408.05(3)(k).
184	c. Mortality reports from cardiac related deaths that
185	occurred in the previous year.
186	d. Program volume data from the preceding year for
187	interventional and electrophysiology catheterizations and
188	surgical procedures.
189	(14) The Surgeon General shall provide quarterly reports
190	to the Secretary of Health Care Administration consisting of
191	data from the Children's Medical Services' critical congenital
192	heart disease screening program for review by the advisory
193	panel.
194	(15) (12) The agency may adopt rules to administer the
195	requirements of part II of chapter 408.
196	Section 2. This act shall take effect July 1, 2019.
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