

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: The Professional Staff of the Committee on Health Policy

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**BILL:** CS/SB 362

**INTRODUCER:** Health Policy Committee and Senator Harrell

**SUBJECT:** Pediatric Cardiac Care

**DATE:** February 18, 2021      **REVISED:** \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Smith	Brown	HP	<b>Fav/CS</b>
2.			JU	
3.			RC	

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**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

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**I. Summary:**

CS/SB 362 amends s. 395.1055, F.S., to:

- Modify the composition of the Pediatric Cardiac Technical Advisory Panel (panel), as established within the Agency for Health Care Administration (AHCA).
- Clarify that time spent as an alternate member of the panel does not count toward member term limits.
- Require the panel to meet at least quarterly rather than biannually.
- Require the chair and vice chair of the panel, in consultation with the AHCA, to develop the agendas for panel meetings.
- Require the annual report submitted by the panel to the Governor and the Legislature to be composed by the panel and signed by the chair and vice chair of the panel.
- Establish that all members of a site review team are agents of the state for purposes of s. 768.28, F.S., relating to sovereign immunity in tort actions.
- Require pediatric cardiac programs to include certain cases in their required surgical volume.
- Authorize site visit teams to conduct virtual site inspections during a declared state of emergency.
- Authorize the panel to alter certain requirements for virtual site inspections.
- Establish that pediatric cardiac surgical centers that are deemed by the panel to be noncompliant with the AHCA's standards for such programs must come into compliance with those standards within 24 months.

- Authorize the panel to recommend that a center have its license to perform congenital cardiac surgery revoked if the center does not come into compliance within 24 months.
- Authorize the Secretary of Health Care Administration to accept or modify the panel's recommendations for corrective actions or revocation of licensure and to require the Secretary to enforce compliance with the AHCA's standards accordingly.
- Require that data in quarterly reports submitted by the Surgeon General to the Secretary of Health Care Administration follow the guidelines and suggestions established by the Cardiac Subcommittee on the Children's Medical Services' Genetics and Newborn Screening Advisory Council in consultation with the panel.

The bill provides an effective date of July 1, 2021.

## **II. Present Situation:**

### **Technical Advisory Panel for Pediatric Cardiac Programs**

During the 2017 and 2018 legislative sessions, the Technical Advisory Panel for Pediatric Cardiac Programs (panel) was established to develop procedures and standards for measuring outcomes of pediatric catheterization programs and pediatric cardiac cardiovascular programs, and to make recommendations about regulatory guidelines for pediatric open heart surgery programs.<sup>1</sup> The panel is housed administratively at the Agency for Health Care Administration (AHCA), and appointments to the panel are made by the Secretary of Health Care Administration and the chief executive officers of specified hospitals in accordance with statutory guidelines. Members of the panel must have technical expertise in pediatric cardiac medicine. Members serve without compensation and are not reimbursed for any travel costs or per diem.<sup>2</sup>

The Secretary of Health Care Administration appoints three at-large members, and three alternate at-large members, one of whom is a cardiologist who is board-certified in caring for adults with congenital heart disease and two board-certified pediatric cardiologists. Neither of the latter at-large members may be employed by any of the hospitals who have specific representation on the panel. The panel has 10 other members who are appointed by the chief executive officers of their 10 respective hospitals, which are named in statute, plus an alternate member for each hospital. A hospital-appointed member, either the voting member or the alternate, must be a pediatric cardiologist or pediatric cardiovascular surgeon.

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<sup>1</sup> Chapter 2017-151, s. 1, and ch. 2018-24, s. 32, Laws of Fla.

<sup>2</sup> Section 395.1055(10)(a), F.S.

<b>Cardiac Program Technical Advisory Panel Membership<sup>3</sup></b>			
<b>Member/Type of Member</b>	<b>Voting</b>	<b>Alternate</b>	<b>Non-Voting</b>
<b>3 At-Large Members with different program affiliations appointed by Secretary of Health Care Administration:</b>			
<i>1 Cardiologist- Board Certified in caring for adults with congenital health disease</i>	■	■	
<i>1 Pediatric Cardiologist – Board Certified</i>	■	■	
<i>1-Pediatric Cardiologist – Board Certified</i>	■	■	
<b>Members appointed by the CEO of the following hospitals:</b>			
Johns Hopkins All Children’s Hospital in St. Petersburg	■	■	
Arnold Palmer Hospital for Children in Orlando	■	■	
Nicklaus Children’s Hospital in Miami	■	■	
St. Joseph’s Children’s Hospital in Tampa	■	■	
University of Florida Health Shands Hospital in Gainesville	■	■	
University of Miami Holtz Children’s Hospital in Miami	■	■	
Wolfson Children’s Hospital in Jacksonville	■	■	
Florida Hospital for Children in Orlando	■	■	
Nemours Children’s Hospital in Orlando	■	■	
<b>Secretary of Health Care Administration may appoint following nonvoting members:</b>			
Secretary of Health Care Administration			■
Surgeon General			■
Deputy Secretary of Children’s Medical Services			■
Any current or past Director of Children’s Medical Services			■
A parent of a child with congenital heart disease			■
An adult with congenital heart disease			■
A representative from the Florida Chapter of the American Academy of Pediatrics			■
A representative from the Florida Chapter of the American College of Cardiology			■
A representative from the Greater Southeast Affiliate of the American Heart Association			■
A representative from the Adult Congenital Heart Association			■
A representative from the March of Dimes			■
A representative from the Florida Association of Children’s Hospitals			■
A representative from the Florida Society of Thoracic and Cardiovascular Surgeons			■

The panel is required to meet at least biannually, or more frequently, upon the call of the Secretary of Health Care Administration. Meetings may be held telephonically or by other electronic means.<sup>4</sup> Records of the panel’s meetings and those of its subcommittees, including draft standards, meeting minutes, and handouts, are posted on the AHCA’s website.<sup>5</sup>

At the request of the Secretary of Health Care Administration, the pediatric cardiac technical advisory panel shall recommend in-state physician experts to conduct an announced or unannounced onsite visit to any existing pediatric cardiac surgical center or facility seeking licensure as a pediatric cardiac surgical center to ensure compliance with s. 395.1055, F.S., and

<sup>3</sup> Section 395.1055(10)(b) and (c), F.S.

<sup>4</sup> Section 395.1055(10)(d), F.S.

<sup>5</sup> See Agency for Health Care Administration, *Pediatric Cardiac Technical Advisory Panel*, available at <http://ahca.myflorida.com/SCHS/PCTAP/index.shtml> (last visited Feb. 12, 2021).

rules adopted thereunder.<sup>6</sup> Each member of a site visit team must submit a written report of his or her findings to the panel, and the panel submits an advisory opinion, based on the reports, to the Secretary of Health Care Administration which includes recommendations and suggested actions for corrections.<sup>7</sup>

The panel must provide the AHCA with recommendations for rules for pediatric cardiac programs which must include:

- Standards for pediatric cardiac catheterization services and pediatric cardiovascular surgery services, including quality of care, personnel, physical plant, equipment, emergency transportation, data reporting, and appropriate operating hours and timeframes for mobilization for emergency procedures;
- Outcome standards consistent with nationally established levels of performance in pediatric cardiac programs; and
- Specific steps to be taken by the AHCA and licensed facilities when the facilities do not meet the outcome standards within a specified time, including time required for detailed case reviews and the development and implementation of corrective action plans.<sup>8</sup>

The AHCA is required to adopt rules for pediatric cardiac programs based on the recommendations of the panel.<sup>9</sup>

### ***Activities and Progress of the Panel***

To develop recommendations for pediatric cardiac care, the panel organized itself into three subcommittees: Surgical Rule Subcommittee, Cardiology Rule Subcommittee, and Public Reporting and Transparency Subcommittee.<sup>10</sup> Fourteen public subcommittee meetings were held in 2018.<sup>11</sup> The subcommittees' recommendations were compiled into draft standards and submitted to the AHCA in February 2019.<sup>12</sup> The AHCA presented preliminary draft language in mid-September 2019 and was vetted by the full panel during public meetings on September 20 and October 15.<sup>13</sup> The panel approved the draft language during its October 2019 meeting.<sup>14</sup>

The licensure standards developed by the panel were presented for public comment at a workshop held February 27, 2020, for AHCA's Proposed Rule 59A-3.248<sup>15</sup> relating to Pediatric Cardiac Programs.<sup>16</sup> Comments received were incorporated into the draft rule and approved by

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<sup>6</sup> Section 395.1055(14), F.S.

<sup>7</sup> *Id.*

<sup>8</sup> Section 395.1055(12), F.S.

<sup>9</sup> *Id.*

<sup>10</sup> Agency for Health Care Administration, *Pediatric Cardiac Technical Advisory Panel Annual Report 2019* (Jan. 2020) available at <https://ahca.myflorida.com/SCHS/PCTAP/docs/PCTAPAnnualReport2019.pdf> (last visited Feb. 12, 2021).

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> Proposed Rule 59A-3.248, Fla. Admin. Register, available at <https://www.flrules.org/gateway/ruleno.asp?id=59A-3.248> (last visited Feb 12, 2021).

<sup>16</sup> Agency for Health Care Administration, *Pediatric Cardiac Technical Advisory Panel Annual Report 2020* (Dec. 2020) available at <https://ahca.myflorida.com/SCHS/PCTAP/docs/PCTAPAnnualReport2020.pdf> (last visited Feb. 12, 2021).

the panel.<sup>17</sup> The AHCA is currently preparing to submit the proposed language to the Joint Administrative Procedures Committee and to publish the rule for final public review.<sup>18</sup>

The full panel met 24 times in 2018, seven times in 2019, and four times in 2020.<sup>19</sup> The draft minutes from the July 30, 2020 meeting reflect that the panel discussed the proposed rule, the possibility of virtual site visits, compliance with the Sunshine Law, and the delay in posting surgical outcome data due to the Society of Thoracic Surgeons (STS) transitioning warehouse vendors.<sup>20</sup> The panel also asked AHCA for guidance as to whether serving as an alternate member counts toward a member's term limit.<sup>21</sup>

The panel has submitted two annual reports to the Governor, President of the Senate, the Speaker of the House of Representatives, the Secretary of Health Care Administration, and the Surgeon General.<sup>22</sup> The reports summarize the panel's activities during the preceding fiscal year and include data and performance measures on surgical morbidity and mortality for all pediatric cardiac programs.<sup>23</sup>

### III. Effect of Proposed Changes:

**Section 1** amends s. 395.1055, F.S., to:

- Modify the composition of the panel, by:
  - Providing that the none of the at-large members or alternate at-large members who are appointed by the Secretary of Health Care Administration and are required to be board-certified in caring for adults with congenital heart disease or board-certified in pediatric cardiology, may be employed by any of the 10 hospitals whose CEOs make appointments, or affiliates of those hospitals; and
  - Requiring that for each member and corresponding alternate member appointed by the CEOs of the 10 hospitals, one must be a pediatric cardiologist and the other must be a pediatric cardiovascular surgeon.
- Clarify that time spent as an alternate member of the panel does not count toward member term limits.
- Require the panel to meet at least quarterly rather than biannually.
- Require the chair and vice chair of the panel, in consultation with the AHCA, to develop the agendas for panel meetings.
- Require the annual report submitted by the panel to the Governor and the Legislature to be composed by the panel and signed by the chair and vice chair of the panel.
- Establish that all members of a site review team are agents of the state for purposes of s. 768.28, F.S., relating to sovereign immunity in tort actions. Currently, only members of the panel are considered agents of the state.

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<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> Agency for Health Care Administration, *Senate Bill 362 Analysis* (Feb. 17, 2021) (on file with the Senate Committee on Health Policy).

<sup>20</sup> Draft Minutes, Agency for Health Care Administration, Pediatric Cardiac Technical Advisory Panel (July 30, 2020) available at <https://ahca.myflorida.com/SCHS/PCTAP/docs/102920/DraftMinutes073020.pdf> (last visited Feb. 12, 2021)

<sup>21</sup> *Id.*

<sup>22</sup> *Supra* notes 10 and 16.

<sup>23</sup> Section 395.1055(10)(f), F.S.

- Require a pediatric cardiac program to include in its surgical volume cases involving children younger than 18 years of age with any type of acquired or congenital heart disease and adults with congenital heart disease. The bill provides that cases involving open surgical placement of a pacing wire count toward the surgical volume.
- Authorize a site visit team to conduct a virtual site inspection in lieu of an onsite inspection during a declared state of emergency.
- Authorize the panel to alter the requirements for the patient-specific data to be reviewed virtually in such virtual site inspections, as appropriate to comply with the federal Health Insurance Portability and Accountability Act and other laws governing the electronic sharing of protected medical information.
- Establish that a pediatric surgical center has 24 consecutive months following a site inspection to come into compliance if the panel determines, based on information in the site visit reports, that the center is noncompliant with the AHCA's standards for pediatric cardiac programs.
- Authorize the panel to recommend to the Secretary of Health Care Administration that a center have its license to perform congenital cardiac surgery revoked if the panel deems the center is still noncompliant with the standards after the 24-month period.
- Authorize the Secretary of Health Care Administration to accept or modify the panel's recommendation regarding the revocation of a center's license or recommendations of suggested actions for correction and to require the Secretary to enforce compliance with the AHCA's standards accordingly.
- Require that critical congenital heart disease screening data in quarterly reports submitted by the Surgeon General to the Secretary of Health Care Administration follow the guidelines and suggestions established by the Cardiac Subcommittee on the Children's Medical Services' Genetics and Newborn Screening Advisory Council in consultation with the panel.

**Section 2** provides the bill takes effect on July 1, 2021.

#### **IV. Constitutional Issues:**

**A. Municipality/County Mandates Restrictions:**

None.

**B. Public Records/Open Meetings Issues:**

None.

**C. Trust Funds Restrictions:**

None.

**D. State Tax or Fee Increases:**

None.

E. Other Constitutional Issues:

None.

**V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None. The AHCA does not expect this bill to have a fiscal impact.<sup>24</sup>

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends section 395.1055 of the Florida Statutes.

**IX. Additional Information:**

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

**CS by Health Policy on February 17, 2021:**

The CS:

- Clarifies the qualifications required of members to serve on the panel.
- Requires the chair and vice chair of the panel, in consultation with the agency, to develop agendas for panel meetings.
- Requires the annual report submitted by the panel to the Governor and the Legislature to be composed by the panel and signed by the chair and vice chair of the panel.
- Authorizes the Secretary of Health Care Administration to accept or modify a panel's recommendation regarding the revocation of a center's license or recommendations of suggested actions for correction and requires the Secretary to enforce compliance with the AHCA's standards accordingly.

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<sup>24</sup> *Supra* note 19.

B. Amendments:

None.

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This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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