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.)

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

BILL: SB 1126

INTRODUCER: Senator Harrell

SUBJECT: Pediatric Cardiac Technical Advisory Panel

DATE: March 8, 2019 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Brown	HP	**Pre-Meeting**
2.			AHS	
3.			AP	

I. Summary:

SB 1126 amends s. 395.1055, F.S., and modifies the authority and duties of the Pediatric Cardiac Technical Advisory Panel (panel) by:

- Authorizing travel reimbursement for panel members.
- Adding three alternate, non-voting panel members affiliated with three different programs.
- Establishing a maximum term limit of two 2-year terms, but allowing a panel member to return after a full 2-year retirement period.
- Providing civil and criminal immunity for panel members relating to events resulting from good faith performance of duties that are assigned to them.
- Requiring the Secretary of the Agency for Health Care Administration (AHCA) to consult with and receive a recommendation from the panel for all certificate of need applications to establish pediatric surgical centers.
- Permitting the AHCA Secretary to request panel members to conduct announced or unannounced site visits to any existing pediatric cardiac facility or a facility seeking such a license, to ensure compliance.
- Allowing panel members, at the request of the AHCA Secretary, to recommend in-state physician experts and up to two out-of-state physician experts for such visits.
- Providing parameters for site visit inspections and contents of site visit reports.
- Requiring Department of Health, State Surgeon General to provide quarterly data on critical congenital heart disease to AHCA Secretary for panel review.

The fiscal impact of the bill is indeterminate and will depend on the number of site visits and inspections requested by the AHCA Secretary and travel requests of the panel Members.

The effective date of the bill is July 1, 2019.

II. Present Situation:

Children's Medical Services

Children's Medical Services (CMS) is a group of programs administered by the Department of Health (DOH) that serve children with special health care needs. Within CMS, individual services and health care programs are designed to address specific conditions or family needs, such as the newborn screening program under ss. 383.14 and 383.145, F.S., early intervention screenings under the Early Steps program as established in s. 391.301, F.S., or the more comprehensive CMS Managed Care Plan described in ss. 391.055 and 409.974(4), F.S. To be eligible for these programs, children must meet designated eligibility criteria that usually include both a clinical determination and a financial eligibility requirement.

CMS is created under ch. 391, F.S., and divided into three parts: Part I (General Provisions), Part II (Children's Medical Services Councils and Panels), and Part III (Developmental Evaluation and Intervention Programs).

The State Surgeon General has general authority under s. 391.223, F.S., to establish technical advisory panels to assist with the development of specific policies and procedures for the Children's Medical Services program.

Children's Medical Services Managed Care Plan Advisory Panel

In September 2015, the State Surgeon General created a Children's Medical Services Managed Care Plan Advisory Panel to advise the DOH as it transited from a direct service provider network to a managed care plan.[1] The panel includes pediatricians, pediatric specialists, parents of children with special health care needs, representatives from managed health care plans, and academic health care centers. Members of the panel are appointed to serve one-year terms. The creating document for the panel entitles members to per diem and reimbursement of travel expenses pursuant s. 113.061, F.S., and meetings were to be held upon the call of the Surgeon General, CMS Plan President, or CMS Plan Chief Executive Officer.[2] No meetings of the panel are currently scheduled.[3]

Repeal of the Cardiac Advisory Council

Prior to the 2001 Regular Session, a Cardiac Advisory Council in the Division of Children's Medical Services existed.[4] The council was appointed by the DOH Secretary and included eight members with technical expertise in cardiac medicine who were charged with:

- Recommending standards for personnel and facilities rendering cardiac services.

[1] Fla. Dep't of Health, *Department of Health announces creation of Children's Medical Services Managed Care Plan Advisory Panel* (Sept. 21, 2015), *available at* http://www.floridahealth.gov/newsroom/2015/09/092115-cms-tap.html (last visited Mar. 5, 2019).

[2] Fla. Dep't of Health, *Creation of the Children's Medical Services Managed Care Plan Technical Advisory Panel* (Sept. 21, 2015), *available at* http://www.floridahealth.gov/_documents/cms-plan-tap.pdf (last visited Mar. 5, 2019).

[3] Fla. Dep't of Health, *CMS Plan Technical Advisory Panel, http://www.floridahealth.gov/programs-and-services/childrens-health/cms-plan/tap/index.html* (last visited Mar. 5, 2019).

[4] *See* s. 391.222, F.S. (2000).

- Receiving reports of the periodic review of cardiac personnel and facilities to determine if established standards of care for cardiac care are met.
- Making recommendations to the director as to the approval or disapproval of reviewed personnel and facilities.
- Providing input on all aspects of the Children's Medical Services Network cardiac program, including the rulemaking process.[5]

The statute was repealed effective June 30, 2001, as part of an exhaustive review of more than three dozen boards, committees, committees, and councils to determine whether to continue or abolish each entity.[6] The DOH recommended the repeal of the council and indicated it would absorb the council's functions in 2001.[7]

Department of Health Repeal of Rule 64C-4.003, F.A.C.

Rule 64C-4.003, F.A.C., established and incorporated by reference quality assurance standards and criteria for the approval and operation of CMS pediatric cardiac facilities. On October 12, 2015, the DOH proposed the repeal of that rule after determining that it did not have the statutory authority to establish the standards, inspect the facilities, or prepare inspection reports for the technical advisory panel to review as provided for under the rule.[8] A group of CMS participants who require cardiac care services believed the repeal of the rule would affect their interests and were concerned that without the standards created in the rule, the quality of care available to them under the CMS program would be reduced. Several affected parties filed an administrative challenge through the Division of Administrative Hearings (DOAH).[9]

A final administrative hearing was held on November 20 and 23, 2015, and a Final Order was issued on December 16, 2015. On January 9, 2017, the DOH published *A Notice of Disposition* in the *Florida Administrative Register* adopting the ruling in the DOAH Final Order. The notice stated that in the case of *W.D., C.V., K.E., and K.M. vs. Department of Health, Case No. 15-6009RP; Rule 64C-4.003.*

> Petitioners lacked standing to challenge the proposed repeal of a rule that would deregulate certain cardiac facilities, because no real or immediate injury was shown, and because common good such as quality health care is not within the zone of interest.[10]

The Petitioners appealed DOAH's final order in both the First and Third District Courts of Appeal. The case was voluntarily dismissed at the First District Court of Appeal on February 15, 2016, and, in the Third District Court of Appeal, the court affirmed the findings of the DOAH administrative law judge and dismissed the petition for lack of jurisdiction.[11] The rule was

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[5] *Id.*
[6] Chapter 2001-89, s. 27, Laws of Fla.
[7] Senate Committee on Governmental Oversight and Productivity, *CS/SB 1410 Staff Analysis and Fiscal Impact Statement,* (March 28, 2001), pg. 9, http://archive.flsenate.gov/data/session/2001/Senate/bills/analysis/pdf/2001s1410.go.pdf (last visited Mar. 6, 2019).
[8] Vol. 43, Fla. Admin. Register 145 (Aug. 28, 2017).
[9] *See W.D., C.V., and K.M. v. Dep't of Health,* Case No. 15-6009RP (Fla. DOAH 2015).
[10] Vol. 43, Admin. Register 145 (Jan. 9, 2017).
[11] *K.M. v. Dep't of Health*, 237 So. 3d 1084 (Fla. 3d DCA 2017).

effectively repealed March 20, 2018, 90 days after the disposition date from the Third District Court of Appeal.

Current Standards for Pediatric Cardiac Services

Hospital facilities are regulated by the AHCA under ch. 395, F.S., and the general licensure provisions of ch. 408, F.S. Hospitals are also subject to the certificate of need (CON) provisions in Part I of ch. 408, F.S.

A CON is a written statement issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service. Certain specialty programs offered within a hospital may also be subject to a CON process as prescribed by statute. Under s. 408.036, F.S., all health-care-related projects described in that section are subject to review and must file a CON application with the AHCA unless specifically exempted from the process. Examples of covered health-care-related projects include hospice services, skilled nursing facilities, intermediate care facilities for the developmentally disabled, organ transplantation, and neonatal intensive care unit level II and level III. Programs for both pediatric cardiac catheterization and pediatric open heart surgery fall under paragraph (1)(f) of the section: *the establishment of tertiary health services, including inpatient comprehensive rehabilitation services.*[12]

The AHCA has four batching cycle per calendar year for CON, and the cycles are segmented into cycles for just hospital beds and cycles for Other Beds and Programs.[13] If requested, a public hearing may be held on a CON application if either the applicant or other interested parties request such a hearing.

For some CON projects, the AHCA will publish a Fixed Need Pool for the service which projects the expected need over a specified period of time in a designated area.[14] The minimum base filing fee for an application is $10,000. In addition to the base filing fee, the fee shall also include $0.015 of each dollar of any proposed expenditure, except that no fee shall exceed $50,000.[15] Applications are reviewed on a comparative basis.

Pediatric Open Heart Surgery Programs

Pediatric open heart surgery programs are regulated through the CON process and an existing rule governs the program under Rule 59C-1.033, F.AC. The administrative rule establishes five service areas, defines the pediatric patient as those patients under 15 years of age, and what services are included in a pediatric open heart surgery program. To be considered for an open heart surgery program, the rule requires that a facility must be able to, at a minimum:

- Repair or replace heart valves.
- Repair congenital heart defects.
- Perform cardiac revascularization.

[12] *See* s. 408.036(1)(f), F.S. (2018) and Rule 59C-1.004, F.A.C.
[13] Agency for Health Care Administration, *Certificate of Need Program Overview,* https://ahca.myflorida.com/MCHQ/CON_FA/index.shtml (last visited Mar. 7, 2019).
[14] Rule 59C-1.008(2), F.A.C.
[15] Rule 59C-1.008(3), F.A.C.

- Repair or reconstruct intrathoracic vessels.
- Treat cardiac trauma.

A health care facility that performs pediatric open heart surgery must also provide these additional services:
- Cardiology, hematology, nephrology, pulmonary medicine, and treatment of infectious diseases.
- Pathology, including anatomical, clinical blood bank and coagulation laboratory services.
- Anesthesiology, including respiratory therapy.
- Radiology, including diagnostic nuclear medicine and magnetic resonance imaging studies.
- Neurology.
- Inpatient cardiac catheterization.
- Non-invasive cardiographics, including electrocardiography, exercise stress testing, transthoracic and transesophageal echocardiography.
- Intensive care.
- Emergency care available 24 hours per day for cardiac emergencies.
- Extracorporeal life support (ECLS).

The pediatric open heart surgery team must be available for elective open heart surgery eight hours per day, five days per week and be available for rapid mobilization for emergency cases 24 hours a day, seven days per week. Rapid mobilization means a waiting period for surgery of a maximum of two hours.[16]

For pediatric open heart surgery, any CON applicant must document an adequate number of the following properly trained personnel that can perform during surgery:
- A cardiovascular surgeon, board certified by the American Board of Thoracic Surgery, or board eligible.
- A physician to assist the operating surgeon.
- A board certified or board eligible anesthesiologist trained in open heart surgery.
- A registered nurse or certified operating room technician trained to serve in open heart surgery operations and perform circulating duties.
- A perfusionist to perform extracorporeal perfusion, or a physician or specially trained nurse, technician, or physician assistant under the supervision of the operating surgeon to operate the heart-lung machine.[17]

Follow-up care after open heart surgery must be provided in an intensive care unit that provides 24 hour nursing coverage with a nurse-to-patient ratio of no less than one nurse for every two patients for the first hours of post-operative care. The facility must have at least one board-certified or board-eligible pediatric cardiac surgeon on the staff of the hospital seeking the CON for a pediatric open heart surgery.[18] Back-up personnel must be available for consultation to the surgical team, including a clinical cardiologist, cardiologist, anesthesiologist, pathologist, thoracic surgeon, and radiologist.

[16] Rule 59C-1.033(4)(b), F.A.C.
[17] Rule 59C-1.033(5)(a), F.A.C.
[18] Rule 59C-1.033(5)(b), F.A.C.

Pediatric Cardiac Catheterization and Angioplasty Institutional Health Services

As with the requirements for the pediatric open heart surgery program, the pediatric cardiac catheterization program requires a hospital to have a CON before it may operate its program. A cardiac catheterization is a medical procedure requiring the passage of a catheter into one or more cardiac chambers with or without coronary arteriograms, for the purpose of diagnosing congenital or acquired cardiovascular diseases, or for determining measurement of blood pressure flow. Cardiac catheterization also includes the selective catheterization of the coronary ostia with injection of contrast medium into the coronary arteries.[19]

A facility must demonstrate as part of the CON approval process that it is capable of providing immediate endocardiac catheter pacemaking in cases of cardiac arrest, and pressure recording to evaluate valvular disease or heart failure.[20] The facility must also make this range of services available within the health facility:

- Hematology studies or coagulation studies
- Electrocardiography
- Chest X-ray
- Blood gas studies
- Clinical pathology studies and blood chemistry analysis[21]

The program must also include:

- A special procedure X-ray room
- A film storage and darkroom for proper processing of films
- X-ray equipment with the capability in cineangiocardiography[22], or equipment with similar capabilities
- An image intensifier
- An automatic injector
- A diagnostic X-ray examination table for special procedures
- An electrocardiograph
- A blood gas analyzer
- A multi-channel polygraph
- Emergency equipment, including but not limited to, a temporary pacemaker unit with catheters, ventilatory assistance devices, and a DC defibrillator
- Biplane angiography, with framing rates of 30-60 fps and injection rates of up to 40mL/s
- One or more crash carts containing the necessary medication and equipment for ventilatory support, which must be located in each pediatric cardiac catheterization procedure room.[23]

[19] Rule 59C-1.032(2), F.A.C.
[20] Rule 59C-1.032(3)(a), F.A.C.
[21] Rule 59C-1.032(3)(b), F.A.C.
[22] According to the Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition, cineangiocardiography is the photographic recording of fluoroscopic images of the heart and great vessels by motion picture techniques.
[23] Rule 59C-1.032(3)(b), F.A.C.

The cardiac catheterization team must be capable of rapidly mobilizing within 30 minutes, 24 hours a day, seven days a week for emergency procedures.[24] The team must be capable of providing immediate endocardiac catheter pacemaking in cases of cardiac arrest, and pressure recording for monitoring and to evaluate valvular disease, or heart failure.[25] The team must be able to document these standards.

In addition to documentation of the required staff[26] that is available to perform the pediatric cardiac catheterization and angiographic processes, the CON applicant facility is also required to have a department, service, or other similar unit organized, directed, staffed, and integrated with the other units and departments of the hospital to assure the provision of quality of care.[27] A pediatric catheterization program must also be co-located at a facility where pediatric open heart surgeries are being performed.[28]

Pediatric cardiac facilities granted CONs under either program are also required to provide the AHCA with quarterly utilization reports within 45 days of the end of each quarter showing the number of pediatric procedures under both programs.

Facility Standards

State Facility Standards and Inspections

Hospitals must maintain a current state license to operate as a hospital under the provisions of ch. 395, part I, F.S. and ch. 408, part II, F.S. Hospitals may elect to be Medicare certified and may choose to be accredited by one of several accrediting organizations. If a hospital is accredited, the AHCA will accept the reports of the accrediting agency in lieu of a state licensure inspection.[29] A facility may still be subject to a licensure inspection if the hospital has been denied accreditation and has not submitted an acceptable corrective plan of action; received full accreditation but has not authorized release of the report to the AHCA; or has not ensured that the AHCA received the accrediting organization's report prior to the AHCA's scheduling of a licensure inspection.[30]

The AHCA is authorized to conduct investigations based upon investigatory findings, complaints, or non-conformance with accreditation standards. Sanctions can also be imposed on facilities by the AHCA in accordance with s. 395.1065, F.S.,[31] where a corrective plan of action

[24] Rule 59C-1.032(4)(a), F.A.C.
[25] Rule 59C-1.032(3)(a), F.A.C.
[26] The staff required for these programs are listed in Rule 59C-1.032(b), F.A.C.
[27] Rule 59C-1.032(5)(a), F.A.C.
[28] Rule 59C-1.032(6), F.A.C.
[29] Rule 59A 3.253(3), F.A.C.
[30] Rule 59A 3.253(3)(a), F.A.C.
[31] Section 395.1065, F.S., authorizes the AHCA to impose administrative fines for operating a facility without a license of up to $500 per day for a first offense and no more than $1,000 for each subsequent offense. Administrative fines, not to exceed $1,000 per violation, per day, may also be imposed by the AHCA for violations of part I or part II of chapter 408 based on the severity of the violation, probability that death or serious harm to the health or safety of any one person will result or has resulted, the severity of any actual or potential harm, the actions taken by the licensee to correct the violations or to remedy the complaints, and any previous violations of the licensee. The AHCA may also impose a moratorium on elective admissions to any licensed facility when the AHCA determines that any condition in the facility presents a threat to public

is not submitted or actions are not implemented to correct deficiencies identified by either an accrediting organization or the AHCA.[32] Inspections may also be conducted by the AHCA, as it deems necessary, for:

- Inspections directed by the federal Centers for Medicare & Medicaid Services.
- Validation inspections.
- Lifesafety inspections.
- Licensure complaint investigations, including full licensure investigations with a review of all licensure standards as outlined in the administrative rules. Complaints received by the AHCA from individuals, organizations, or other sources are subject to review and investigation by the AHCA.
- Emergency access investigations.[33]

Accreditation by the Joint Commission[34] requires the organization to demonstrate that it will continually assess and improve the quality of its care, treatment, and services. The hospital must provide services that can be evaluated by Joint Commission standards and can provide review records equal to ten percent of the average daily census for the initial survey. Tests, treatments or interventions provided at the hospital must be prescribed or ordered by a licensed independent practitioner in accordance with state and federal requirements.[35]

One of the newest accreditation organizations is the Center for Improvement in Healthcare Quality Accreditation program (CIHQ).[36] The program received initial approval in July 2013.[37] Currently, 62 hospitals nationally have achieved accreditation under this standard, including one Florida hospital.[38] Standards for accreditation under CIHQ track to the required components of the federal Code of Federal Regulations.

Florida also recognizes accreditation for hospitals by DNV GL which was introduced in 2008.[39] The DNV GL program provides accreditation for acute care, critical access, ancillary, and psychiatric hospitals. The program also offers clinical specialty certifications in several areas:

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health or safety. The AHCA may also rely on the findings and investigations of the Department of Health in lieu of conducting its own investigation.

[32] Rule 59A 3.253(9), F.A.C.

[33] Section 395.0161, F.S.

[34] *See* The Joint Commission, https://www.jointcommission.org/accreditation/hospital_audience.aspx (last visited Mar. 6, 2019).

[35] The Joint Commission, *Eligibility for Hospital Accreditation* (January 15, 2015), https://www.jointcommission.org/eligibility_hospital_accreditation/ (last visited Mar. 6, 2019).

[36] Center for Improvement in Healthcare Quality, https://cihq.org/hospital_accreditation_division.asp (last visited Mar. 6, 2019).

[37] Centers for Medicare and Medicaid Services, *Annual Report to Congress: Review of Medicare's Program for Oversight of Accrediting Organizations and the Clinical Laboratory Improvement Validation Program* (Fiscal Year 2015), pg. 64, *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-07.pdf (last visited Mar. 6, 2019).

[38] The one Florida hospital with this accreditation is Landmark Hospital of Southwest Florida, LLC located in East Naples, Florida. Full accreditation was achieved on September 30, 2018. *See* https://cihq.org/hospital_list.asp (last visited Mar. 6, 2019).

[39] DNV GNL, *Accreditation, Certification & Training,* https://www.dnvgl.us/assurance/healthcare/ac.html (last visited Mar. 6, 2019).

hip & knee, heart failure, and ventricular assist devices.[40] Rather than multi-year surveys, the DNV GL standards are based on an annual survey of the facility's processes.

Medicare Accreditation

With all of these accreditation programs discussed above, if a hospital achieves accreditation under one of these programs, the hospital could also be deemed in compliance with all of the applicable Medicare conditions. The federal Centers for Medicare & Medicaid Services is authorized under Section 1865(a) of the Social Security Act to recognize and approve national accrediting organizations that demonstrate that their health and safety standards and survey and oversight processes meet or exceed those used to determine a health care provider's compliance with Medicare's Conditions for Certification or requirements.[41] To be eligible to receive Medicare reimbursement, certain types of health care facilities must demonstrate compliance with Medicare's conditions of participation (CoPs), conditions for coverage (CfCs), or conditions for certification.[42]

General Participation Requirements

Under 42 CFR §482.11, to participate in Medicare, a hospital must be in compliance with all applicable federal laws related to the health and safety of patients. Additionally, the hospital must be licensed and approved as meeting the standards established by the licensing state or other regulatory bodies. The federal regulations set out the standards of care for patients, and for the hospital administration, chief executive officer, the institutional plan and budget, contracted services, and emergency services.[43] The hospital is also required to protect and promote each patient's rights which includes establishing a process for the prompt resolution of grievances, allowing patients to participate in the development and implementation of his or her plan of care, permitting patients to make informed decisions about their care, acknowledging each patient's right to privacy and right to confidentiality of their records, and providing patients the right to be free from restraint or seclusion.[44] Other areas that indicate compliance with the general participation requirements for hospitals are found in the following table:

[40] *Id.*
[41] Centers for Medicare and Medicaid Services, State Operations Manual, *Chapter 2-The Certification Process, Section 2003C – Deemed Status Providers/Suppliers, Excluding CLIA,* pg. 25, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf (last visited Mar. 6, 2019).
[42] Centers for Medicare and Medicaid Services, *Annual Report to Congress: Review of Medicare's Program for Oversight of Accrediting Organizations and the Clinical Laboratory Improvement Validation Program* (Fiscal Year 2015), pg. 7, *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-07.pdf (last visited Mar. 6, 2019).
[43] 42 CFR §482.12 – Condition of participation: Governing body.
[44] 42 CFR §482.13.

General Participation Requirements for Hospitals Code of Federal Regulations – Sampling of Citations							
Citation	**Title**	**Citation**	**Title**	**Citation**	**Title**	**Citation**	**Title**
482.11	Compliance with Federal, State, and Local Laws	**482.23**	Nursing Services	**482.30**	Utilization Review	**482.53**	Nuclear medicine
482.12	Governing Body	**482.24**	Medical Record Services	**482.41**	Physical environment	**482.54**	Outpatient services
482.13	Patient's Right	**482.25**	Pharmaceutical Services	**482.42**	Infection control	**482.55**	Emergency services
482.15	Emergency Preparedness	**482.26**	Radiological Services	**482.43**	Discharge planning	**482.56**	Rehabilitation services
482.21	Quality Assessment and Performance Improvement Program	**482.27**	Laboratory Services	**482.51**	Surgical services	**482.57**	Respiratory care services
482.22	Medical Staff	**482.28**	Food and dietetic services	**482.52**	Anesthesia services		

Additionally, for a hospital to be eligible for reimbursement under the Florida Medicaid program, for either inpatient or outpatient services, federal and state regulations require, among other requirements, that the hospital meet the Medicare conditions of participation and be licensed or formally approved by the state licensing entity.[45,46]

If a facility is not meeting the conditions for participation and such failures are significant, the federal government may determine that the findings constitute "an immediate or serious threat to patient health and safety." The federal regulations define "immediate jeopardy" as:

> *As situation in which the provider's noncompliance with one or more requirements of participation has, or is likely to cause, serious injury, harm, impairment, or death, to a resident.*[47]

Under the requirements, only one individual needs to be at risk, and the serious harm, injury, impairment, or death does not have to occur before considering immediate jeopardy. There needs only to be a high potential in the near future for these outcomes to occur. Additionally, the serious harm can result from both abuse and neglect, and psychological harm is considered just as serious as physical harm.[48] Common triggers include:

- Failure to protect from abuse.
- Failure to prevent neglect.
- Failure to protect from psychological harm.

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[45] 42 CFR 440.10 and 42 CFR 440.20.
[46] Rule 59G-4.150, F.A.C.
[47] 42 CFR 489.3
[48] Centers for Medicare and Medicaid Services, State Operations Manual, *Appendix Q – Guidelines for Determining Immediate Jeopardy* (Rev. 102, Issued 02-14-14), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_q_immedjeopardy.pdf (last visited Mar. 7, 2019).

- Failure to protect from undue adverse medication consequences and/or failure to provide medications as prescribed.
- Failure to provide adequate nutrition and hydration to support and maintain health.
- Failure to protect from widespread nosocomial infection; e.g.; failure to practice standard precautions, failure to maintain sterile techniques during invasive procedures and/or failure to identify and treat nosocomial infections.
- Failure to correctly identify individuals.
- Failure to safely administer blood products and safely monitor organ transplantation.
- Failure to provide safety from fire, smoke and environment hazards and/or failure to educate staff in handling emergency situations.
- Failure to provide initial medical screening, stabilization of emergency medical conditions and safe transfer for individuals and women in active labor seeking emergency treatment (Emergency Medical Treatment and Active Labor Act).[49]

In November 2018, the *Tampa Bay Times* began a series of articles on the rising infection and mortality rates in the pediatric heart surgical program at Johns Hopkins All Children's Hospital (All Children's) in St. Petersburg, Florida.[50] In June 2015, a similar series of stories by CNN on a pediatric heart program at St. Mary's Medical Center in West Palm Beach led to the closure of that hospital's program.[51] By January 2019, federal and state inspectors visited All Children's for inspections, and, shortly thereafter, the federal Centers for Medicare & Medicaid Services issued an "immediate jeopardy" warning and gave All Children's until February 10, 2019, to file a corrective action plan.[52] The report indicated widespread issues from communication, infection control, and physician competency issues. The hospital had a Joint Commission survey visit on February 22, 2019, which had no findings, and still maintains its accreditation.[53] The "immediate jeopardy" label has also been removed from the hospital and the corrective action plan was accepted, according to newspaper reports.[54]

Technical Advisory Panel for Pediatric Cardiac Programs

During the 2018 Legislative Session, a Technical Advisory Panel (panel) for Pediatric Cardiac Programs 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. The panel is housed administratively at the AHCA, and appointments to the panel are made by the AHCA Secretary in accordance with the statutory guidelines.

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[49] *Id.*

[50] Kathleen McCrory and Neil Bedi, *Heartbroken: Johns Hopkins Promised to Elevate All Children's Heart Institute. Then Patients Start to Die at an Alarming Rate.* TAMPA BAY TIMES, Nov. 28, 2018, Special Report, http://www.tampabay.com/projects/2018/investigations/heartbroken/all-childrens-heart-institute/ (last visited Mar. 7, 2019).

[51] Margie Menzel, *Pediatric Cardiac Surgery Standards Eyed,* HEALTH NEWS FLORIDA, Oct. 13, 2015, https://health.wusf.usf.edu/post/pediatric-cardiac-surgery-standards-eyed (last visited Mar. 7, 2019).

[52] Agency for Health Care Administration, Statement of Deficiencies – Reports(January 11, 2019), http://apps.ahca.myflorida.com/dm_web/DMWeb_Docs/9379109.pdf (last visited Mar. 7, 2019).

[53] Johns Hopkins All Children's Hospital, Inc. *Quality Report, https://www.qualitycheck.org/quality-report/?bsnId=6908* (last visited Mar. 7, 2019).

[54] Kathleen McCrory and Neil Bedi, *New Federal Report Details Widespread Problems at All Children's,* TAMPA BAY TIMES, Feb. 22, 2019, Investigations, http://www.tampabay.com/investigations/2019/02/22/federal-investigators-found-systemic-failures-at-all-childrens/ (last visited Mar. 7, 2019).

To be eligible as a voting member on the Panel, a hospital must maintain its pediatric CON and the individual member must have technical expertise in pediatric cardiac medicine. Members serve without compensation and are not reimbursed for any travel costs or per diem.[55]

The AHCA Secretary appoints three 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. None of the three at-large members may be employed by any of the named facilities who have specific representation on the panel. The panel has 10 other members who are appointed by the chief executive officer of their respective hospitals, plus an alternate member. The named member, either the voting member or the alternate, must be a pediatric cardiologist or pediatric cardiovascular surgeon.

The Panel Membership is comprised of the following:

Cardiac Program Technical Advisory Panel Membership[56]			
Members\Type of Members:	**Voting**	**Alternate**	**Non-Voting**
Johns Hopkins All Children's in St. Petersburg	■	■	
Arnold Palmer Hospital in Hollywood	■	■	
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	■	■	
AHCA Secretary may appoint following nonvoting members:			
Agency for Health Care Administration Secretary			■
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			■
3- At Large Members			
1 Cardiologist- Board Certified in caring for adults with congenital health disease	■		
1 Pediatric Cardiologist – Board Certified	■		
1-Pediatric Cardiologist Board Certified	■		
A representative from each of the following organizations:			
Florida Chapter of the American Academy of Pediatrics			■
Florida Chapter of the American College of Cardiology			■
Greater Southeast Affiliate of the American Heart Association			■
Adult Congenital Heart Association			■
March of Dimes			■
Florida Association of Children's Hospitals			■
Florida Society of Thoracic and Cardiovascular Surgeons			■

[55] Section 395.1055(9)(a) and (b), F.S.
[56] Section 395.1055(9)(b) and (c), F.S.

The panel is required to meet at least biannually, or more frequently, upon the call of the AHCA Secretary. Meetings may be held telephonically or by other electronic means. The panel has held at least 26 meetings since its inception in 2017 and has been working towards proposed rules and policies on cardiology, surgery, public reporting and transparency, and facility standards.

At a minimum, the statute requires the panel to make recommendations for rules and standards 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.
- 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.

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.[57] The most recent draft of pediatric and congenital cardiovascular center standards are dated September 2018 and were last edited at a telephonic meeting held on January 29, 2019. The most recently posted draft meeting minutes on the panel's website are from the panel's December 13, 2018 meeting. Those draft minutes and draft standards include recommendations for the panel being consulted for CON applications for new programs, a requirement that programs maintain a two-star rating as determined by the Society of Thoracic Surgeons (STS), and that if a program drops below a two-star rating, the program can be subject to a corrective action plan as determined by the panel.[58]

The draft proposal also includes recommendations that pediatric centers must:

- Be located in a healthcare facility that maintains accreditation by the Joint Commission on the Accreditation of Healthcare Organizations, also known as the Joint Commission (JCAHO), or the National Committee for Quality Assurance (NCQA).[59]
- Be compliant with the Health Insurance Portability and Accountability Act (HIPAA).[60]

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[57] *See* Agency for Health Care Administration, *Pediatric Cardiac Technical Advisory Panel,* http://ahca.myflorida.com/SCHS/PCTAP/index.shtml (last visited Mar. 5, 2019).

[58] Agency for Health Care Administration, Pediatric Cardiology Technical Advisory Panel, *Pediatric and Congenital Cardiovascular Center Standards* (September 2018), pg. 1, *available at* http://ahca.myflorida.com/SCHS/PCTAP/docs/121318/DraftPCTAPWorkingDocument120418Revised.pdf (last viewed Mar. 6, 2018).

[59] The National Committee for Quality Assurance (NCQA) was formed in 1990 as a nonprofit organization that focused on measuring and then accrediting health plans. The NCQA now also measures the quality of care delivered at the provider and practice level. *See* https://www.ncqa.org/about-ncqa/ (last visited Mar. 7, 2019).

[60] The Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Public Law 104-191) included administrative simplifications provisions which required the federal Department of Health and Human Services to adopt national standards on health care standards for electronic health care transactions and security. There are several parts to the Act: the Privacy Rule which set national standards to protect individually identifiable health information across different entities and the Security Rule which set national standards to protect the confidentiality, integrity, and availability of electronic protected

- Provide limited English proficiency services the meet federal guidelines.
- Set guidelines for medical records reviews and onsite reviews.
- Establish draft volume standards.
- Have quality assurance and quality improvement processes.
- Actively participate in the required STS databases.
- Collect and submit quality assurance data annually
- Implement electronic medical records.
- Have providers meet specified standards based on their roles within the center.
- Provide equipment and facility space based on designated specifications.[61]

By January 1, 2020, an annual report must be provided to the Governor, President of the Senate, the Speaker of the House of Representatives, the AHCA Secretary, and the Surgeon General which summarizes the panel's activities during the preceding fiscal year. The report must include data and performance measures on surgical morbidity and mortality for all pediatric cardiac programs.[62]

The current statute already provides some minimal standards for cardiac programs. For example, a pediatric cardiac program must:

- Be affiliated with a hospital licensed under chapter 395.
- Have a pediatric cardiac catheterization laboratory and pediatric cardiovascular surgical program located in the hospital.
- Have a risk adjusted surgical procedure protocol which follows the guidelines established by the STS.[63]

The AHCA is authorized to adopt rules to implement this section. Once the panel has developed its recommendations for pediatric cardiac care, the panel expects to forward those recommendations to the AHCA for adoption through the formal administrative rulemaking process.[64]

Liability for Good Faith Actions

Currently, the volunteer physicians and other members of the panel are not covered by any liability or immunity clauses in the panel's implementing statute. During panel meetings, the members have had discussions relating to sovereign immunity for panel members when they are

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health information. A third rule, the Enforcement Rule, provides the Standards for the enforcement of all the administrative simplification rules.

[61] *Supra* note 15, at 3 - 17.

[62] Section 395.1055(9)(f), F.S.

[63] The Society for Thoracic Surgeons National Database was established in 1989 as a quality improvement initiative. It has four components: Adult Cardiac, General Thoracic, Congenital Heart Surgery, and the Interagency Registry for Mechanically Assisted Circulatory Support (Intermacs) Databases. The Database has participants in all 50 states and 13 countries with approximately 6.7 million surgical records and more than 90 percent of the groups that perform cardiac surgery in the United States. In 2011, the STS Research Center was launched to provide scientific evidence and research to held cardiothoracic surgeons and other interested parties improve surgical outcome and patient quality of care. *See* The Society of Thoracic Surgeons, https://www.sts.org/about-sts (last visited Mar. 5, 2019).

[64] *See* s. 395.1055(10)(a-c) and (12), F.S.

engaged in activities related to the panel.[65] Members on other panels, board of directors or volunteers in programs by the Legislature have been granted similar provisions of immunity for their official actions, such as individuals in the Division of Rehabilitation and Liquidation of the Department of Financial Services, 66 guardians ad litem,[67] and employees and board of directors of the Health Maintenance Organization Consumer Assistance Plan.[68]

III. Effect of Proposed Changes:

The bill modifies the composition of the Pediatric Cardiac Technical Advisory Panel (panel) as established in the Agency for Health Care Administration (AHCA) by:

- Authorizing the appointment of three alternate, at-large members from affiliations different than those of the voting at-large members.
- Adding a two-year term limit to voting panel members; however, members may be re-appointed to the panel after a two-year retirement period.
- Allowing members of the panel to be reimbursed for travel and per diem.
- Providing Panel members immunity from criminal and civil liability for any good faith performance of duties assigned to them by the AHCA Secretary.
- Requiring the AHCA Secretary to consult with the panel for an advisory recommendation on all CON applications to establish pediatric cardiac surgical centers.
- Authorizing the AHCA Secretary to request announced or unannounced site visits to any existing pediatric cardiac surgical center or a facility seeking licensure as a pediatric cardiac surgical center through the CON process to ensure compliance with the process.
- Permitting the panel, at the request of the AHCA Secretary, to make recommendations for in-state physician experts to conduct site visits and up to two out-of-state physician experts.
- Establishing the procedures for the on-site inspection of a hospital's pediatric medical and surgical programs and providing the required contents of the written inspection reports, advisory opinion, and suggested actions for correction, which include:
  - An inspection of the program's physical facilities, clinics and laboratories.
  - Interviews with support staff and hospital administration.
  - A review of medical records and reports, clinical outcome data from STS, mortality reports, and program volumes.
- Requiring the Surgeon General to provide quarterly reports to the AHCA Secretary data from CMS' critical congenital heart disease screening program for review by the panel.

The effective date of the bill is July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

[65] Agency for Health Care Administration, Pediatric Cardiology Technical Advisory Panel Meeting Minutes (Oct. 2, 2018), pg. 3, http://ahca.myflorida.com/SCHS/PCTAP/docs/102518/PCTAPDraftMinutes100218.pdf (last visited Mar. 7, 2019).
[66] *See* s. 631.391, F.S.
[67] *See* s. 61.405, F.S.
[68] *See* s. 631.825, F.S.

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:

The panel is composed of private and public medical providers reviewing medical data about other private and public medical providers. Changes in the bill will permit panel members, at the request of the AHCA Secretary only, to conduct site visits on private health care facilities. Such site visits may be beneficial to the public once completed; however, they may also be time consuming to the health care facility. The outcome of the inspection and review may also result in licensing action by the AHCA.

C. Government Sector Impact:

SB 1126 directs the AHCA Secretary to consult with the panel for advisory recommendations if there is a CON application process to establish pediatric cardiac surgical centers. The AHCA Secretary is not required to follow the panel's advisory recommendation but is required to consult with the panel as part of the CON process for pediatric surgical centers.

The bill also provides the AHCA Secretary with the authority to request that the panel conduct announced or unannounced site visits upon pediatric cardiac centers or facilities and provides the parameters for the site visit teams and the contents of the inspection reports. While the AHCA Secretary currently has the authority to direct her/his own staff to inspect any facility, this provision provides another set of technical experts for such tasks. Such site visits and inspections; however, will likely have a fiscal impact, and no estimate of the bill's fiscal impact has been provided by the AHCA. The costs of such visits and inspections would likely depend on the location of the facility, the number of technical experts sent to the location, where the experts were located, and if any out-of-state experts were also included.

To the extent that any publicly owned hospitals also have a pediatric cardiac care facility that may be subject to an announced or unannounced inspection, such facilities would be impacted by hosting those inspections and by any findings from the reports.

The DOH and the State Surgeon General will be required to produce a quarterly report for the AHCA Secretary that shows the data from the Children's Medical Services critical congenital heart disease screening program. This data will be reviewed by the panel. It is unknown at this time whether there is a fiscal impact to the DOH to produce to this data.

The bill also allows for panel members to receive travel reimbursement.

The total fiscal impact of the bill is indeterminate and will dependent on the number of site visits and inspections requested by the AHCA Secretary and travel requests of the panel members. At the time the total fiscal impact is not known.

VI. Technical Deficiencies:

SB 1126 modifies the travel reimbursement provision to allow panel members to be reimbursed for travel and per diem; however, the provision does not include the statutory cross reference to s. 112.061, F.S., that limits travel reimbursement for those who travel on public business. Without the cross reference to the state guidelines, a different travel reimbursement schedule might be implemented for the panel members.

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 Changes:

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

None.

B. Amendments:

None.

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