HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 59 Adult Cardiovascular Services
SPONSOR(S): Health & Human Services Committee; Pigman
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	15 Y, 0 N	Langston	Poche
2) Health Care Appropriations Subcommittee	15 Y, 0 N	Clark	Pridgeon
3) Health & Human Services Committee	17 Y, 0 N, As CS	Langston	Calamas

SUMMARY ANALYSIS

The Agency for Health Care Administration (AHCA) regulates hospitals under chapter 395, F.S., and the general licensure provisions of part II of chapter 408, F.S. Adult cardiovascular services (ACS) were previously regulated through AHCA's Certificate-of-Need (CON) program. Florida eliminated CON review for adult cardiac catheterization and adult open-heart surgery services in 2007. Hospitals are now approved to provide these services by AHCA through the licensure process.

CS/HB 59 requires AHCA's licensure rules for hospitals providing Level I ACS to include, at a minimum, a requirement that all nursing and technical staff have demonstrated experience in handling acutely ill patients requiring percutaneous cardiac intervention in dedicated cardiac interventional laboratories or surgical centers. Level II facilities must also meet Level I requirements, so these changes will apply to ACS programs.

Previously, all nursing and technical staff had to obtain their perquisite experience in a dedicated cardiac interventional laboratory at a hospital with a Level II ACS. The bill will enable Level I ACS programs to train their nursing and technical catheterization laboratory staff at their own facilities instead of requiring that their staff be trained in a Level II ACS program, if the Level I ACS program meets certain requirements. The bill also allows an adult diagnostic cardiac catheterization program to become a Level I ACS, even if the program that is more than 100 road miles from the closest Level II ACS program if certain volumes are met for number of diagnostic cardiac catheterizations performed and diagnoses of ischemic heart disease.

Currently, pediatric cardiac catheterization and pediatric open-heart surgery are subject to CON review and approval prior to implementation. The CON approval process includes standards that are not in licensure laws and rules, so there is no requirement to maintain compliance with these standards as a condition of licensure.

The bill requires AHCA to develop and adopt rules requirements for licensure for pediatric cardiac catheterization programs and pediatric open-heart surgery programs and establishes minimum standards for those rules. It also creates the Pediatric Cardiac Technical Advisory Panel to recommend licensure standards for pediatric cardiac programs and requires AHCA to base the rules on those recommendations. The rules must, at a minimum, establish outcome standards and specific steps to be taken by AHCA and licensed facilities when the outcome standards are not met within specified times.

The Society of Thoracic Surgeons (STS) National Database collects data on pediatric heart procedures from hospitals, which receive quarterly performance reports. The bill requires pediatric cardiac catheterization programs to participate in the clinical outcome report system operated by STS. AHCA must contract with STS to obtain certain data for publication on its website.

The bill does not have a fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Hospital Licensure

The Agency for Health Care Administration (AHCA) regulates hospitals under chapter 395, F.S., and the general licensure provisions of part II, of chapter 408, F.S. Hospitals offer a range of health care services with beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care.[1] Hospitals must make regularly available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, and other definitive medical treatment.[2]

Hospitals must meet initial licensing requirements by submitting a completed application and required documentation, and the satisfactory completion of a facility survey. Section 395.1055, F.S., authorizes AHCA to adopt rules for hospitals; these rules must include minimum standards to ensure:

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards.[3]

The minimum standards for hospital licensure are contained in Chapter 59A-3, F.A.C.

Percutaneous Cardiac Intervention

Percutaneous cardiac intervention (PCI), commonly known as coronary angioplasty or angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease.[4] PCI uses a catheter to insert a stent in the heart to reopen blood vessels that have been narrowed by plaque build-up, a condition known as atherosclerosis.[5] The catheter is threaded through blood vessels into the heart where the coronary artery is narrowed.[6] Once in place, a balloon tip covered with a stent is inflated to compress the plaque and expand the stent.[7] When the plaque is compressed and the stent is in place, the balloon is deflated and withdrawn, leaving the stent to hold the artery open.[8]

PCI Best Practices

In 2014, the Society for Cardiovascular Angiography and Interventions, the American College of Cardiology (ACC) and the American Heart Association (AHA) issued an Expert Consensus document

[1] S. 395.002(12), F.S.
[2] Id.
[3] S. 395.1055(1), F.S.
[4] George A Stouffer, III, and Pradeep K Yadav, *Percutaneous Coronary Intervention (PCI)*, MEDSCAPE, Oct. 12, 2016, available at http://emedicine.medscape.com/article/161446-overview (last visited March 19, 2017).
[5] Percutaneous coronary intervention (PCI or angioplasty with stent), Heart and Stroke, available at https://www.heartandstroke.ca/heart/treatments/surgery-and-other-procedures/percutaneous-coronary-intervention (last visited March 19, 2017).
[6] Id.
[7] Id.
[8] Id.

on PCI without on-site surgical backup, which acknowledged advances and best practices in PCI performed in hospitals without on-site surgery (Level I adult cardiovascular services facilities).[9] The Expert Consensus document noted that while PCI peaked in 2006, PCIs at hospitals without on-site surgery have increased since 2007.[10] The Expert Consensus document recommends the PCI programs without on-site surgery have experienced nursing and technical laboratory staff with training in interventional laboratories.[11] The Expert Consensus document continues to recommend PCI procedures should not be performed in facilities performing fewer than 200 procedures, with few exceptions.[12] The Expert Consensus document also recommends that a 95% success rate and a less than 5% complication rate are more important factors than overall volume of procedures performed.[13]

Regulation of Adult Cardiovascular Services

Adult cardiovascular services (ACS), including PCI, were previously regulated through the Certificate-of-Need (CON)[14] program. In 2007, Florida eliminated CON review for adult cardiac catheterization and adult open-heart surgery services[15] and regulation was accomplished through the licensure process. Hospitals that provided ACS at the time the CON review process was eliminated were grandfathered into the current licensure program.[16] However, those hospitals were required to meet licensure standards applicable to existing programs for every subsequent licensure period.[17]

Section 408.0361, F.S., establishes two levels of hospital program licensure for ACS. A level I program is authorized to perform adult PCI without onsite cardiac surgery and a level II program is authorized to perform PCI with onsite cardiac surgery.[18]

Adult Diagnostic Cardiac Catheterization Program

Diagnostic cardiac catheterization is a procedure requiring the passage of a catheter into one or more chambers of the heart, with or without coronary arteriograms,[19] for diagnosing congenital or acquired cardiovascular diseases, or for measuring blood pressure flow.[20] It also includes the selective catheterization of the coronary ostia[21] with injection of contrast medium into the coronary arteries.[22]

AHCA regulates the operation of adult inpatient diagnostic cardiac catheterization programs through licensure. This license permits the program to perform only diagnostic procedures;[23] the license does

[9] Gregory J. Dehmer, et al., *SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup*, Society for Cardiovascular Angiography and Interventions, the American College of Cardiology Foundation, and the American Heart Association, Inc., Mar. 17, 2014.
[10] Id.
[11] Id.
[12] Id. The Expert Consensus document cites data from a 2010-2011 National Cardiovascular Data Registry showing that half (49%) of reporting facilities performed fewer than 400 PCIs annually and of these, 65% of the facilities without on-site surgery backup had an annual case volume of less than 200 PCIs.
[13] Supra, note 9.
[14] The CON regulatory process under chapter 408, F.S., requires specified health care services and facilities to be approved by AHCA before they are made available to the public. To obtain a CON a facility must demonstrate a need for a new, converted, expanded, or otherwise significantly modified health care facility or health service. Section 408.036, F.S., specifies which health care projects are subject to review and provides three levels of review: full, expedited and exempt. Unless a hospital project is exempt from the CON program under s. 408.036(3), F.S., it must undergo a full comparative review or an expedited review.
[15] Ch. 2007-214, Laws of Fla. CON review remains in effect for pediatric cardiac catheterization and pediatric open-heart surgery. Rule 59C-1.002(41), F.A.C.
[16] Existing providers and any provider with a notice of intent to grant a CON or a final order of the agency granting a CON for ACS or burn units were considered grandfathered and received a license for their programs effective July 1, 2004. The grandfathered license was effective for three years or until July 1, 2008, whichever was longer. S. 408.0361(2), F.S.; s. 2, ch. 2004-382, Laws of Fla.
[17] S. 408.0361(2), F.S.
[18] S. 408.0361(3)(a), F.S.
[19] An arteriogram is an imaging test that uses x-rays and a contrast dye to see inside the arteries of the heart.
[20] Rule 59A-3.2085(13)(b)1., F.A.C.
[21] A coronary ostia is either of the two openings in the aortic sinuses – the pouches behind each of the three leaflets of the aortic valve – that mark the origins of the left and right coronary arteries.
[22] Rule 59A-3.2085(13)(b)1., F.A.C.
[23] Diagnostic procedures include left heart catheterization with coronary angiography and left ventriculography; right heart

not allow for the performance of therapeutic procedures.[24] [25] Providers of diagnostic cardiac catheterization services comply with the most recent guidelines of the ACC and AHA for cardiac catheterization and cardiac catheterization laboratories.[26]

As of December 1, 2016, there are 22 general acute care hospitals with an adult diagnostic cardiac catheterization program in Florida.[27]

Level I ACS Programs

Licensed Level I ACS programs provide diagnostic and therapeutic cardiac catheterization services, including PCI, on a routine and emergency basis, but do not have on-site open-heart surgery capability.[28] For a hospital seeking a Level I ACS program license, it must demonstrate that, for the most recent 12-month period as reported to AHCA, it has:

- Provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations; or
- Discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease;[29] and that it has formalized, written transfer agreement with a hospital that has a Level II program to ensure the safe and efficient transfer of a patient within 60 minutes.[30]

However, a hospital located more than 100 road miles from the closest Level II adult cardiovascular services program that has a formalized, written transfer agreement with a hospital that has a Level II program is exempt from the second requirement.[31]

Licensed Level I ACS programs must comply with the guidelines that apply to diagnostic cardiac catheterization services[32] and PCI, including guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality

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catheterization; hemodynamic monitoring line insertion; aortogram; emergency temporary pacemaker insertion; myocardial biopsy; diagnostic trans-septal procedures; intra-coronary ultrasound (CVIS); fluoroscopy; and hemodynamic stress testing. Rule 59A-3.2085(13)(b)4., F.A.C.

[24] Examples of therapeutic procedures are PCI or stent insertion, intended to treat an identified condition or the administration of intra-coronary drugs, such as thrombolytic agents. Rule 59A-3.2085(13)(b)3., F.A.C.

[25] S. 408.0361(1)(b), F.S.

[26] S. 408.0361(1)(a), F.S.; Rule 59A-3.2085(13)(g), F.A.C., requires compliance with the guidelines found in the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCAI Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214, available at http://www.scai.org/asset.axd?id=d4338c24-9beb-4f5a-8f14-a4edaeff7461&t=633921658057830000 (last visited March 19, 2017). These guidelines address, among other things, clinical proficiency, patient outcomes, equipment maintenance and management, quality improvement program development, and minimum caseload volumes for cardiac catheterization laboratories as well as patient preparations, procedural issues, performance issues, and post procedural issues for the performance of cardiac catheterization.

[27] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports*, available at http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Adult_Inpatient_Diagnostic_Cath_Labs.pdf (last visited March 19, 2017).

[28] Rule 59A-3.2085(16)(a), F.A.C. Level I programs are prohibited from performing any therapeutic procedure requiring trans-septal puncture, any lead extraction for a pacemaker, biventricular pacer or implanted cardioverter defibrillator.

[29] Heart condition caused by narrowed heart arteries. This is also called “coronary artery disease” and “coronary heart disease.”

[30] S. 408.0361(3)(b), F.S.

[31] Id.

[32] Rule 59A-3.2085(16)(a)5., F.A.C.

and safety.[33] Additionally, they must comply with the reporting requirements of the American College of Cardiology-National Cardiovascular Data Registry.[34]

Level I ACS programs must meet the following staffing requirements.

- Each cardiologist shall be an experienced physician who has performed a minimum of 75 interventional cardiology procedures, exclusive of fellowship training, within the previous 12 months from the date of the Level I ACS application or renewal application.
- Physicians with less than 12 months experience shall fulfill applicable training requirements prior to being allowed to perform emergency PCI in a hospital that is not licensed for a Level II ACS program.
- Nursing and technical catheterization laboratory staff must:
  - Be experienced in handling acutely ill patients requiring intervention or balloon pump;
  - Have at least 500 hours of previous experience in dedicated cardiac interventional laboratories at a hospital with a Level II adult cardiovascular services program;
  - Be skilled in all aspects of interventional cardiology equipment; and
  - Participate in a 24-hour-per-day, 365 day-per-year call schedule.
- A member of the cardiac care nursing staff who is adept in hemodynamic monitoring and Intra-aortic Balloon Pump management shall be in the hospital at all times.[35]

As of December 1, 2016, there are 54 general acute care hospitals with a Level I ACS program in Florida.[36]

Level II ACS Programs

Licensed Level II ACS programs provide diagnostic and therapeutic cardiac catheterization services on a routine and emergency basis, and also have on-site open-heart surgery capability.[37] For a hospital seeking a Level II program license, it must demonstrate that, for the most recent 12-month period as reported to AHCA, it has:

- Performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations; or
- Discharged at least 800 patients with the principal diagnosis of ischemic heart disease.[38]

In addition to the licensure requirements for a Level I ACS program, Level II ACS programs must also comply with guidelines from the ACC and AHA, which include standards regarding staffing, physician

[33] Rule 59A-3.2085(16)(a)2., F.A.C., requires compliance with the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCA&I Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214. The rule also requires compliance the *ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention)* available at http://circ.ahajournals.org/content/113/1/156.full.pdf+html (last visited March 19, 2017), which revises the guidelines for procedural complications, quality assurance, volume of elective procedures, the role of on-site cardiac surgical back-up, treatment of patients with certain diagnoses or medical history, the use of specified procedures and devices, and the use of certain drugs.

[34] Rule 59A-3.2085(16)(a)8., F.A.C. The reporting requirements include patient demographics; provider and facility characteristics; history/risk factors, cardiac status, treated lesions; intracoronary device utilization and adverse event rates; appropriate use criteria for coronary revascularization; and compliance with ACC/AHA clinical guideline recommendations.

[35] Rule 59A-3.2085(16)(b), F.A.C.

[36] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports,* available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Level_I_ACS_Listing.pdf (last visited March 19, 2017).

[37] Rule 59A-3.2085(17)(a), F.A.C.

[38] S. 408.0361(3)(c), F.S.

training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[39]

Level II ACS programs must also document an ongoing quality improvement plan to ensure that their cardiac catheterization, PCI, and cardiac surgical programs meet or exceed national quality and outcome benchmarks reported by the American College of Cardiology-National Cardiovascular Data Registry and the Society of Thoracic Surgeons.[40] In addition to the reporting requirements for Level I ACS Programs, Level II ACS programs must meet the reporting requirements for the Society of Thoracic Surgeons National Database.[41]

As of December 1, 2016, there are 77 general acute care hospitals[42] with a Level II ACS program in Florida.[43]

Regulation of Pediatric Cardiac Services

Currently, pediatric cardiac catheterization and pediatric open-heart surgery are subject to CON review and approval prior to implementation of services pursuant to ss. 408.036(1) and 408.032(17), F.S. As conditions of CON approval, AHCA requires that:

- The program director for a pediatric cardiac catheterization program be board-eligible or board-certified in pediatric cardiology;[44]
- Pediatric cardiac catheterization programs be located in a hospital in which pediatric open-heart surgery is being performed;[45] and
- Pediatric open-heart surgery programs have at least one physician who is board-eligible or board-certified as a pediatric cardiac surgeon on the staff of a hospital.[46]

Licensure standards do not include pediatric cardiac service standards that exist within the CON process. There is no authority to maintain compliance with pediatric cardiology standards as a condition of licensure.[47]

Pediatric Cardiac Catheterization

Pediatric cardiac catheterization is a nonsurgical procedure used in infants, children, and teens to determine if there is a problem with the heart or repair a problem.[48] Cardiac catheterization in children is performed by inserting a catheter into an artery and vein, usually in the groin, and threading it through the bloodstream into the heart and its large blood vessels to measure pressures and blood

[39] Rule 59A-3.2085(16)(a)5., F.A.C. A Level II ASC must comply with the ACC/AHA 2004 Guideline Update for Coronary Artery Bypass Graft Surgery: A Report of the ACC/AHA Task Force on Practice Guidelines (Committee to Update the 1999 Guidelines for Coronary Artery Bypass Graft Surgery) Developed in Collaboration With the American Association for Thoracic Surgery and the Society of Thoracic Surgeons.
[40] Id. Eligible professionals must satisfactorily report 50 percent performance on at least nine quality measures for the annual reporting period. The measures address topics such as preoperative screenings, length of postoperative intubation, and length of postoperative stay.
[41] Rule 59A-3.2085(16)(a)5., F.A.C. The data collection form is available at https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/tvt-registry_2_0_tavr_data-collection-form.pdf (last visited March 19, 2017).
[42] 64 Level II ACS programs were licensed pursuant to the grandfathering provisions of Chapters 2004-382 and 2004-383, Laws of Fla.; Agency for Health Care Administration, *Agency Analysis of SB 58 2017 Legislative Session*, Nov. 28, 2016 (on file with Health Innovation Subcommittee staff).
[43] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports,* available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Level_II_ACS_Listing.pdf (last visited March 10, 2017).
[44] Rule 59C-1.032(5)(b)1., F.A.C.
[45] Rule 59C-1.032(6)(c)., F.A.C.
[46] 59C-1.003(5)(b), F.A.C.
[47] Agency for Health Care Administration, Agency Analysis of 2017 SB 62, p. 2, (Nov. 30, 2016) (on file with Health and Human Services Committee staff).
[48] Nemours, *Cardiac Catheterization in Children,* https://www.nemours.org/service/medical/delaware-valley-pediatric-cardiac-center/treatment-and-testing/cardiac-catheterization-in-children.html?location=naidhc, (last visited on March 19, 2017).

oxygen levels and take X-rays of the heart and blood vessels.[49] Pediatric diagnostic cardiac catheterization is a test that's done to determine the exact details of a child's heart and how it functions.[50] An interventional catheterization is performed like diagnostic and allows the pediatric cardiologist to perform procedures such as:

- Closure of abnormal connections inside and outside the heart;
- Closure of holes between upper or lower chambers of the heart;
- Closing off an abnormal blood vessel between the aorta and lung artery with a small coil or a special plug;
- Balloon angioplasty;[51]
- Balloon valvuloplasty;[52] and
- Stent implantation.

Pediatric Heart Surgery

Pediatric heart surgery may treat either congenital heart defects, which are heart diseases present at birth, or heart problems developed later in childhood, called acquired heart disease.[53] Surgery may be either open-heart or closed-heart.[54] In a closed-heart surgery, sometimes called a thoracotomy, an incision is made on the side of the chest, between the ribs.[55] In an open-heart surgery:

- An incision is made through sternum while the child is under general anesthesia;
- Tubes are used to re-route the blood through a special pump called a heart-lung bypass machine;[56]
- The heart is then stopped while the surgeon repairs the heart muscle itself, the heart valves, or the blood vessels outside the heart:;
- After the repair is done, the heart is started again, and the machine is removed;
- The breastbone and the skin incision are then closed.[57]

<u>High Mortality Rate at St. Mary's Medical Center Pediatric Surgery Unit</u>

In 2009 St. Mary's Medical Center in West Palm Beach was awarded a CON to operate a pediatric cardiovascular center.[58] Dr. Gerold Schiebler, a former director of Children's Medical Services (CMS), raised concerns about St. Mary's to the division's then director in 2013. Generally, he was concerned that St. Mary's was not working under the training and expertise of the University of Miami, which ran its own pediatric heart surgery program, which was initially a condition of CON but was but later removed by AHCA. He also raised concerns about the low volume of pediatric open-heart surgeries St. Mary's performed.

[49] Id.
[50] Id.
[51] Id. In a balloon angioplasty a small balloon is inflated inside the blood vessel to stretch narrowed arteries and veins.
[52] Id. In a balloon valvulplasty a small balloon is used to stretch the opening of heart valves.
[53] Nemours, *Pediatric Cardiac Surgery,* https://www.nemours.org/service/medical/delaware-valley-pediatric-cardiac-center/treatment-and-testing/pediatric-cardiac-surgery.html (last visited March 19, 2017).
[54] U.S. National Library of Medicine, Pediatric Heart Surgery, https://medlineplus.gov/ency/article/007363.htm (last visited March 19, 2017).
[55] Id.
[56] This machine adds oxygen to the blood and keeps the blood warm and moving through the rest of the body while the surgeon is repairing the heart.
[57] *Supra*, note 54
[58] Letter from Dr. Gerold L. Schiebler to Mary Beth Vickers, Director, Division of CMS, Florida Department of Health, RE; Certificate of Need (CON) # 10055 awarded to Tenent St. Mary's Inc. for a Pediatric Open Heart Surgery Program (Jul. 12, 2103), available at https://assets.documentcloud.org/documents/2094703/gerold-schiebler-letter-to-cms.pdf (last visited March 19, 2017).

In April 2014, the CMS Cardiac Technical Advisory Panel (CTAP)[59] visited St. Mary's to conduct a voluntary peer-review the program and found many of the program's vital tests and services for children's hearts lacking.[60] The CTAP expressed concerns about the volume of cases, noting that "[t]he number of cardiac surgical procedures performed [at St. Mary's] seems to be too low for the institution and its staff to acquire and maintain proficiency in these types of challenging procedures," and reported that it was "common knowledge that multiple pediatric cardiac surgeons ... have expressed serious concern about babies having complex pediatric cardiac surgery [at] St. Mary's Medical Center." The CTAP recommended that St. Mary's not perform any heart surgeries on babies under 6 months of age and not perform any complex procedure on older children. DOH sent St. Mary's a copy of the CTAP review in June 2014.[61] Following the review by the CTAP, DOH told the CTAP that it had overstepped its authority in its site visits to hospital cardiac programs and in enforcing existing standards.

In June 2015, an investigation by CNN found that the mortality rate at St. Mary's pediatric open-heart surgery program was three times the national average in 2011-2013 with at least eight babies dying after having surgery in the hospital's program.[62] The program's mortality rate was 12.5 percent, as compared to the national average of 3.3 percent.[63] St. Mary's closed its pediatric cardiothoracic surgery program in August 2015.[64]

Children's Medical Services

Children's Medical Services (CMS) is a group of programs that serve children with special health care needs under the supervision of the Department of Health (DOH). Within CMS, individual services or programs are designed to address specific conditions or family needs such as the newborn screening program, early intervention screenings, or its Medicaid managed care plan known as the CMS Plan. CMS is created under ch. 391, F.S.

Statewide CMS Network Advisory Council

The State Surgeon General has the discretion under s. 391.221, F.S., to appoint a 12-member Statewide CMS Network Advisory Council to serve as an advisory body to DOH. The council's duties include, but are not limited to:

- Recommending standards and credentialing requirements for health care providers in the CMS network of providers;
- Making recommendations to the director of CMS concerning the selection of CMS providers;
- Providing input to the CMS program on the policies governing the CMS network;
- Reviewing the financial reports and financial status of the CMS network and making recommendations concerning the methods of payment and costs controls for the CMS Network;
- Reviewing and recommending the scope of benefits for the CMS network; and

[59] The CTAP provided programmatic and technical advice about pediatric cardiac programs to DOH and the CMS program from 2013 through 2015. *See* pp. 9-10, *infra.*
[60] Letter from Dr. Celeste Philip, Deputy Secretary of Health, Florida Department of Health, to Davide Carbone, CEO, Palm Beach Children's Hospital, St. Mary's Medical Center, and Dr. Michael Black, Director of Pediatric Cardiovascular Surgery, Palm Beach Children's Hospital, St. Mary's Medical Center, RE: CMS Program Evaluation and Development Peer Review Palm Beach Children's Hospital (St, Mary's Hospital) (Jun. 26, 2014), available at https://assets.documentcloud.org/documents/2083890/program-evaluation-reviews.pdf (last visited March 19, 2017).
[61] Id.
[62] CNN, *Secret deaths: CNN finds high surgical death rate for children at a Florida hospital*, Jun. 15, 2015, http://www.cnn.com/2015/06/01/health/st-marys-medical-center/ (last visited March 19, 2017).
[63] Id.
[64] Palm Beach Post, *St. Mary's closes disparaged pediatric heart surgery program*, Aug. 17, 2015, http://www.mypalmbeachpost.com/news/local/mary-closes-disparaged-pediatric-heart-surgery-program/wfQsK6WOV48nnmigdwEioM/ (last visited March 19, 2017).

- Reviewing CMS network performance measures and outcomes and making recommendations for improvements to the CMS network and its maintenance and collection of data and information.[65]

DOH does not currently have an appointed Statewide CMS Network Advisory Council.

Cardiac Advisory Council

Prior to 2001, s. 391.222, F.S., established a Cardiac Advisory Council at CMS.[66] The council was appointed by the secretary of DOH and included eight members with technical expertise in cardiac medicine who were charged with:

- Recommending standards for personnel and facilities rendering cardiac services;
- Receiving reports of the periodic review of cardiac personnel and facilities to determine if established standards for cardiac care are met;
- Making recommendations to the director as to the approval or disapproval of reviewed personnel and facilities; and
- Providing input on all aspects of the CMS cardiac program, including the rulemaking process.[67]

The statute that created the council was repealed June 30, 2001,[68] as part of an exhaustive review of more than three dozen boards, committees, commissions, and councils to determine whether to continue or abolish each entity.[69] DOH recommended the repeal of the council and indicated it would absorb its functions.[70]

Cardiac Technical Advisory Panel

The State Surgeon General also has authority under s. 391.223, F.S., to establish technical advisory panels to assist with the development of specific policies and procedures for the CMS program. On October 21, 2013, then State Surgeon General John Armstrong created the CMS Cardiac Technical Advisory Panel (CTAP) to provide both programmatic and technical advice to DOH and the CMS program.[71] The enabling document charged the CTAP with:

- Developing recommended standards for personnel and facilities rendering pediatric congenital cardiac services as well as heart disease;
- Developing recommendations for legislative initiatives, including appropriation items, related to the cardiac program and developing rules;
- Developing recommendations for statewide cardiac initiatives, including identifying panel members who will collaborate with other DOH councils or committees or state agencies;
- Assisting the AHCA, or as requested by individual hospitals, or as outlined in their individual contract with CMS, with the ongoing evaluation and development of congenital cardiovascular programs;
- Giving priority status to weight control programs and their implementation in all pediatric cardiovascular centers and clinics; and
- Developing recommendations to the DOH and the AHCA for congenital heart disease quality improvement to improve patient care and health and decrease the cost of care.[72]

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[65] S. 391.221, F.S.
[66] *See* s. 391.222, F.S. (2000).
[67] Id.
[68] Chapter 2001-89, s. 27, Laws of Fla.
[69] Florida Senate, *Senate Staff Analysis and Economic Impact Statement of CS/SB 1410,* (Mar. 28, 2001), p. 9, available at http://archive.flsenate.gov/data/session/2001/Senate/bills/analysis/pdf/2001s1410.go.pdf (last visited March 19, 2017).
[70] Id.
[71] Florida Department of Health, *Creation of the Children's Medical Services Cardiac Technical Advisory Panel,* (Oct. 2013), available at http://www.cmsctap.com/_files/documents/CTAP-Creation.pdf (last visited March 19, 2017).
[72] Id.

The CTAP is non-operational; its last meeting was October 30, 2015.[73]

CMS Pediatric Cardiac Facility Standards

In 2005, DOH adopted Rule 64C-4.003, F.A.C., which established and incorporated by reference quality assurance standards and criteria for the approval and operation of pediatric cardiac facilities in the CMS network that performed pediatric non-invasive cardiology laboratory procedures, pediatric cardiac catheterization procedures, and pediatric cardiac open-heart and closed-heart surgical procedures. All CMS-approved cardiac facilities were required to:

- Be located within a healthcare facility that maintains accreditation by the Joint Commission on Accreditation of Healthcare Organizations and/or the National Committee for Quality Assurance;
- Be HIPAA compliant;
- Provide limited English proficiency services, in accordance with federal guidelines;
- Have quality assurance and quality improvement processes in place that continuously enhanced the clinical operation and patient satisfaction with services;
- Actively participate in the Society of Thoracic Surgeons Congenital Heart Surgery Database and submit data every 6 months;
- Collect and submit specified quality assurance data annually, to CMS;
- Implement electronic medical record technology to the extent that the resources are available within the institution;
- Have neonatal screening program using pulse oximetry to detect critical congenital heart disease if the facility had a birthing center; and
- Have a multidisciplinary cardiac team that included pediatric cardiology, cardiovascular surgery, cardiovascular anesthesia, nursing, ancillary and support staff associated with pre-operative patient selection and preparation, the surgical or catheterization procedure, and post-operative care and follow-up.[74]

In addition to the general facility requirements, CMS also had specific standards for pediatric cardiology clinics, pediatric cardiac catheterization laboratories, and pediatric surgery programs related to staffing, equipment, facilities, patient care, and volume and outcome requirements for procedures.[75] Following the initial approval, CMS reviewed programs on a triennial basis to verify compliance.[76]

On October 12, 2015, DOH held a rule hearing regarding the proposed repeal of the standards for pediatric cardiac facilities, Rule 64C-4.003, F.A.C.[77] Following that hearing, DOH determined it had no statutory authority to establish the standards, inspect facilities, or prepare inspection reports for the technical advisory panel to review. A group of CMS beneficiaries who require cardiac care services were concerned that repeal of Rule 64C-4.003, F.A.C., would reduce the quality of care that would be available to them within the CMS program and challenged the department's actions through the Division of Administrative Hearings (DOAH).[78]

[73] Department of Health, Agency Analysis of 2017 SB 62, p. 2 (Jan. 17, 2017) (on file with Health and Human Services Committee staff).
[74] Children's Medical Services, *Pediatric Cardiac Facilities Standards*, available at https://www.flrules.org/gateway/readRefFile.asp?refId=2278&filename=CMS%20Cardiac%20Facilities%20Standards%20October%202012.docm (last visited March 19, 2017).
[75] Id.
[76] Id.
[77] Notice of Public Hearing on the repeal of Rule 64C-4.003, F.A.C., https://www.flrules.org/Gateway/View_notice.asp?id=16493218 (last visited March 19, 2017).
[78] Petition for Determination of Invalidity of proposed rule, *W.D., C.V., K.E., and K.M., v. Dept.of Health*, Case No. 15-6009RP (Fla. DOAH 2015), available at https://www.doah.state.fl.us/DocDoc/2015/006009/15006009_408_10222015_13420367_e.pdf (last visited March 19, 2017).

A final hearing was held on November 20 and 23, 2015, before an administrative law judge and a Final Order was issued on December 16, 2015.[79] The Final Order, in finding that the petitioners lacked standing to challenge DOH's repeal of the rule, concluded that the repeal of the rule was not for the purpose of lowering the quality of care for CMS recipients or other patients, nor would the repeal cause facilities to stop providing quality cardiac services.[80]

On January 9, 2017, DOH published *A Notice of Disposition* in the *Florida Administrative Register* adopting the ruling in the DOAH Final Order. The notice stated that the "[p]etitioners 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."[81]

The Petitioners appealed DOAH's Final Order in both the First and Third District Courts of Appeal. The case was voluntarily dismissed in the First District Court of Appeal on February 15, 2016,[82] but is pending before the Third District Court of Appeal.[83]

Advisory Councils

Chapter 20, F.S., authorizes the creation of a number of different types of entities to assist state government in the efficient performance of its duties and functions. Under s. 20.03(7), F.S., a "council" or "advisory council" is defined as an advisory body created by statute to study problems arising in a specified functional or program area of state government and to provide recommendations and policy alternatives.

Advisory bodies, commissions, and boards may only be created by statute in furtherance of a public purpose and must meet a statutorily defined purpose.[84] The Legislature must terminate these advisory bodies, commissions, and boards once they notify the Legislature that they are no longer necessary or beneficial to the furtherance of a public purpose.[85] The advisory bodies, commissions, and boards are required to keep Legislature and the public informed of their numbers, purposes, memberships, activities, and expenses.[86]

Society of Thoracic Surgeons National Database

The Society of Thoracic Surgeons (STS) National Database was established in 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons.[87] It collects data on 25 different pediatric heart operations from more than 100 hospitals nationwide; there are currently 11 hospitals in Florida reporting to its Congenital Heart Surgery Database.[88] The data is analyzed and reported back to the participating hospitals. Hospitals receive quarterly performance outcome reports in a risk-adjusted format that allows for comparison of local outcomes to regional benchmarks and national standards.[89] STS also allows participating hospitals to voluntarily report their performance to the public using a

[79] *W.D., C.V., K.E., and K.M., v. Dept. of Health*, Case No. 15-6009RP (Fla. DOAH 2015), available at https://www.doah.state.fl.us/ROS/2015/15006009.pdf (last visited March 19, 2017).
[80] Id.
[81] Vol. 43 Fla. Admin. Register 145 (Department of Health Jan. 9, 2017), available at https://www.flrules.org/Gateway/View_notice.asp?id=18464355 (last visited March 19, 2017).
[82] Order Granting Voluntary Dismissal, *W.D., C.V., and K.E., v. Dept. of Health*, No. 1D-15-5948 (Fla. 1 DCA Feb. 15, 2016), available at https://www.doah.state.fl.us/DocDoc/2015/006009/15006009OOC-021516-09062506.PDF (last visited March 19, 2017).
[83] *K.M. v. Dep't of Health*, No, 3D16-23 (Fla. 3 DCA). Oral argument has taken place but an opinion has not been issued. http://jweb.flcourts.org/pls/ds/ds_docket?p_caseyear=2016&p_casenumber=23&pscourt=3 (last visited March 19, 2017).
[84] S. 20.052, F.S.
[85] S. 20.052(2), F.S.
[86] S. 20.052(3), F.S.
[87] Society of Thoracic Surgeons, *STS National Database*, https://www.sts.org/national-database (last visited March 20, 2017).
[88] Society of Thoracic Surgeons, *Society for Thoracic Surgeons (STS) National Database: Congenital Heart Surgery Database Participants*, available at https://www.sts.org/sites/default/files/documents/congenitalMap1.13.17.pdf (last visited March 20, 2017)
[89] Society of Thoracic Surgeons, *Commit to improve the quality of patient care through the STS National Database*, available a https://www.sts.org/sites/default/files/documents/pdf/ndb/2016NationalDatabaseBrochureFINAL.pdf (last visited March 20, 2017).

three-star rating system.[90] There are currently five hospitals in Florida using the STS Congenital Heart Surgery voluntary public reporting.[91]

Effect of the Bill

Regulation of Adult Cardiovascular Services

Nursing and Technical Staff Demonstrated Experience

HB 59 requires AHCA's licensure rules for hospitals providing Level I ACS to include, at a minimum, a requirement that all nursing and technical staff have demonstrated experience in handling acutely ill patients requiring PCI in dedicated cardiac interventional laboratories or surgical centers. Level II facilities must meet requirements applicable to Level I facilities, so these changes will apply to all hospitals providing ACS.

Nursing and Technical Staff Prerequisite Experience

Previously all nursing and technical staff had to obtain their perquisite experience in a dedicated cardiac interventional laboratory at a hospital with a Level II ACS. The bill offers an alternate location where to obtain the prerequisite experience, if certain qualifications are met. They may now obtain their 500 hours of prerequisite experience in a dedicated cardiac interventional laboratory at a hospital with a Level I ACS program, if, throughout the training period, the Level I ACS program:

- Has an annual volume of 500 or more PCI;
- Achieves a demonstrated success rate of 95 percent or greater for PCIs;
- Experiences a complication rate of less than 5 percent for PCIs; and
- Performs diverse cardiac procedures, including, but not limited to, balloon angioplasty and stenting, rotational atherectomy, cutting balloon atheroma remodeling, and procedures relating to left ventricular support capability.

The bill will enable Level I ACS programs to train their nursing and technical catheterization laboratory staff at their facilities instead of requiring that their staff be trained in a Level II ACS program.

Level I ACS Minimum Requirements

The bill allows an adult diagnostic cardiac catheterization program to become a Level I ACS, even if the program that is more than 100 road miles from the closest Level II ACS program if certain volumes are met for number of diagnostic cardiac catheterizations performed and diagnoses of ischemic heart disease. The program must, for the most recent 12-month period as reported to AHCA:

- Have provided a minimum of 100 adult inpatient and outpatient diagnostic cardiac catheterizations; and
- Discharged or transferred at least 300 patients with the principal diagnosis of ischemic heart disease

The Lower Keys Medical Center in Key West is the only diagnostic cardiac catheterization that would qualify for this exemption to become a Level I ACS.[92]

[90] *Supra*, note 87.
[91] Society of Thoracic Surgeons, *STS Congenital Heart Surgery Public Reporting*, https://www.sts.org/congenital-public-reporting-module-search?field_cong_hosp_name_value=&field_state_value=FL (last visited March 20, 2017).
[92] Email from Orlando Pryor, Legislative Affairs Director, Agency for Health Care Administration, RE: HB 59 Amendments (Mar. 19, 2017) (on file with Health and Human Services Committee staff).

Regulation of Pediatric Cardiovascular Services

Minimum Licensure Requirements

The bill requires AHCA to adopt rules imposing standards for pediatric cardiac catheterization programs and pediatric open-heart surgery programs. The bill also establishes minimum standards for these rules. The rules for pediatric cardiac catheterization programs must require, at a minimum, that the program:

- Be located in a facility in which pediatric open-heart surgery is being performed and which is completely equipped to provide necessary medical and surgical care to the patient and is accredited by the Joint Commission;
- Have a cardiac catheterization team comprised of sufficient medical and support staff to provide necessary medical and surgical care to the patient;
- Mobilize the pediatric cardiac catheterization team within a specified time for an emergency procedure; and
- Be located in a facility that offers a range of non-invasive cardiac and diagnostic services, including, but not limited to:
    - Hematology studies or coagulation studies;
    - Electrocardiography;
    - Chest x-ray;
    - Blood gas studies;
    - Clinical pathology studies and blood chemistry analysis;
    - A special procedure x-ray room;
    - A film storage and darkroom for proper processing of films;
    - X-ray equipment with cineangiocardiography capabilities;
    - An image intensifier;
    - An automatic injector;
    - A diagnostic x-ray examination table for special
    - procedures;
    - A blood gas analyzer;
    - A multichannel polygraph; and
    - Emergency equipment including a temporary pacemaker unit with catheters, ventilator assistance devices, and a DC defibrillator.

The rules for pediatric open-heart surgery programs must require, at a minimum, that:

- The pediatric open-heart surgery team includes sufficient surgical and support staff to provide necessary medical and surgical care to the patient.
- The program is available for non-emergent open-heart surgery 8 hours per day, 5 days per week; is capable of mobilizing the surgical and medical support teams within a specified time for emergency cases; and provides 24 hour coverage by a physician or staff.
- Post-operative care[93] is provided under the direction of the cardiovascular surgeon who performed the surgery, in communication with and support of the post-operative cardiovascular team[94] as prescribed by rule.
- Each pediatric open-heart surgery program has the capability to provide a full range of open-heart surgery operations, including:
    - Repair or replacement of a heart valve;
    - Repair of a congenital heart defect;
    - Repair or reconstruction of an intrathoracic vessel; and

[93] A patient must be cared for in an intensive care unit that provides 24 hour per day nursing care with at least one registered nurse for every two patients during the first hours of post-operative care. Post-operative care must also include coverage for operation of the cardiopulmonary bypass pump 24 hours per day.
[94] Members of the team must be on call or otherwise available for an emergency.

    - Treatment of cardiac trauma.
- A licensed facility with a pediatric open-heart surgery program provides the following services:
    - Availability of consultation in cardiology, hematology, nephrology, pulmonary medicine, treatment of infectious diseases, and other appropriate pediatric subspecialties;
    - Pathology, including anatomical, clinical, blood bank, and coagulation laboratory services;
    - Anesthesiology, including respiratory therapy;
    - Radiology, including diagnostic nuclear medicine;
    - Neurology;
    - Inpatient cardiac catheterization;
    - Non-invasive cardiographics, including electrocardiography, exercise stress testing, and echocardiography;
    - Intensive care; and
    - Emergency care available 24 hours per day for cardiac emergencies.

Data Reporting

The bill requires licensed pediatric cardiac catheterization programs to participate in the clinical outcome report system operated by STS. AHCA must then contract with STS to obtain certain data for publication on AHCA's website.

Technical Advisory Panel

The bill also creates the Pediatric Cardiac Technical Advisory Panel to recommend licensure standards for pediatric cardiac programs. AHCA must develop and adopt rules for pediatric cardiac catheterization programs and pediatric open-heart surgery programs based on recommendations from the panel. These rules must be consistent with the minimum standards for licensure established by the bill and, at a minimum, must establish:

- Outcome standards specifying expected levels of performance in pediatric cardiac programs, using a risk adjustment procedure that accounts for the variations in severity and case mix. Such standards may include, but are not limited to, in-hospital mortality, infection rates, and returns to surgery; and
- Specific steps to be taken by the agency and licensed facilities that do not meet the outcome standards within specified time periods, including time periods for detailed case reviews and development and implementation of corrective action plans.

The bill specifies the voting and nonvoting membership of the panel. Voting members of the panel must include:

- A pediatric cardiac surgeon or pediatric cardiologist, or a designated alternate, from each of the following pediatric cardiac centers:
    - Johns Hopkins All Children's Hospital in St. Petersburg;
    - Arnold Palmer Hospital for Children in Orlando;
    - Joe DiMaggio Children's Hospital in Hollywood;
    - Nicklaus Children's Hospital in Miami;
    - St. Joseph's Children's Hospital in Tampa;
    - University of Florida, Shands Children's Hospital in Gainesville;
    - University of Miami, Holtz Children's Hospital in Miami;
    - Wolfson Children's Hospital in Jacksonville;
    - Florida Hospital, Disney Children's Hospital in Orlando; and
    - Nemours Children's Hospital in Orlando; and
- An at-large member appointed by the Secretary of the Agency for Health Care Administration, who is either a pediatric cardiologist or adult cardiologist with a special interest in the care of adults with congenital heart disease.

The nonvoting members of the panel include the Secretary of AHCA or his or her designee, the Surgeon general or his or her designee, and the Deputy Secretary of CMS or his or her designee. Additionally, the Secretary of AHCA may appoint up to four additional nonvoting members from the following organizations:

- The Florida Association of Children's Hospitals;
- The Florida Chapter of the American Academy of Pediatrics;
- The Florida Society of Thoracic and Cardiovascular Surgeons;
- The Florida Chapter of the American College of Cardiology; or
- The Florida Chapter of the American Heart Association.

B. SECTION DIRECTORY:

Section 1: Amends s. 395.1055, F.S., relating to rules and enforcement.
Section 2: Amends s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure.
Section 3: Amends s. 408.05, F.S., relating to the Florida Center for Health Information and Transparency.
Section 4: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 17, 2017, the Health and Human Services Committee adopted two amendments that:

- Created the Pediatric Cardiac Technical Advisory Panel to recommend licensure standards for pediatric cardiac programs;
- Required AHCA to adopt rules establishing standards for pediatric cardiac programs, based on recommendations from the Pediatric Cardiac Technical Advisory Panel;
- Established minimum standards for rules for pediatric cardiac catheterization programs and pediatric open-heart surgery programs;
- Required pediatric cardiac catheterization programs and pediatric open-heart surgery programs to report data to the Society of Thoracic Surgeons;
- Required AHCA to contract with the Society of Thoracic Surgeons to obtain certain data for publication on the AHCA's website; and
- Created an exemption from the 60-minute transfer time protocol for a Level I adult cardiovascular services program that is more than 100 road miles from the closest Level II adult cardiovascular services program if certain volumes are met for number of diagnostic cardiac catheterizations performed and diagnoses of ischemic heart disease.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.