Health & Human Services Committee

Thursday, January 18, 2018
8:00 AM – 10:00 AM
Morris Hall (17 HOB)

Richard Corcoran
Speaker

W. Travis Cummings
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health & Human Services Committee

Start Date and Time:	Thursday, January 18, 2018 08:00 am
End Date and Time:	Thursday, January 18, 2018 10:00 am
Location:	Morris Hall (17 HOB)
Duration:	2.00 hrs

Consideration of the following bill(s):

HB 119 Adult Cardiovascular Services by Pigman
HR 157 Public Health Crisis Created by Pornography by Spano
HB 281 Incarcerated Parents by Williams, Daniels
HB 283 Cardiac Programs by Raschein
CS/HB 313 Access to Health Care Practitioner Services by Health Quality Subcommittee, Grant, M.
CS/HB 429 Donation and Transfer of Human Tissue by Health Quality Subcommittee, Pigman
HB 513 Distributing Pharmaceutical Drugs and Devices by Rommel
HB 721 Mental Health and Substance Abuse Services by Silvers
HM 817 Renewal of Title IV-E Waivers for Child Welfare Services by Harrell
HB 855 Genetic Information Used for Insurance by Brodeur
HB 973 Performance of Physician Assistants and Advanced Registered Nurse Practitioners by Daniels, Plasencia
HB 6049 Medical Marijuana Growers by Jones, Newton

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Wednesday, January 17, 2018.

By request of the Chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Wednesday, January 17, 2018.

NOTICE FINALIZED on 01/16/2018 3:55PM by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 119 Adult Cardiovascular Services
SPONSOR(S): Pigman
TIED BILLS: **IDEN./SIM. BILLS:** SB 144

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	12 Y, 0 N	Langston	Crosier
2) Health Care Appropriations Subcommittee	12 Y, 0 N	Clark	Pridgeon
3) Health & Human Services Committee		Langston	Calamas

SUMMARY ANALYSIS

Percutaneous coronary intervention (PCI), commonly known as coronary angioplasty or angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease. PCI uses a catheter to insert a stent to reopen blood vessels in the heart that have been narrowed by plaque build-up.

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.

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. Level I ACS programs must comply with national guidelines that apply to diagnostic cardiac catheterization services and PCI. Additionally, they must comply with national reporting requirements and meet specified staffing requirements. For example, nursing and technical catheterization laboratory staff in a Level I ACS program must have 500 hours of experience in a dedicated cardiac interventional laboratory at a hospital with a Level II ACS program.

Licensed Level II ACS programs provide the same services as a Level I ACS program, but have on-site open-heart surgery capability. In addition to Level I requirements, Level II programs must comply with additional requirements for staffing, physician training and experience, operating procedures, equipment, physical plant, patient selection criteria, and reporting requirements.

HB 119 expands where nursing and technical staff may obtain their prerequisite experience. It authorizes them to 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 program:

- Has an annual volume of 500 or more PCIs;
- Achieves a demonstrated success rate of 95 percent or greater for PCIs;
- Experiences a complication rate of less than five percent for PCIs; and
- Performs diverse cardiac procedures.

Additionally, the bill replaces the term "cardiac" with coronary in reference to PCIs to reflect current terminology.

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

The bill provides an effective date of July 1, 2018.

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 Coronary Intervention

Percutaneous coronary 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]

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[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 January 12, 2018).
[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 January 12, 2018).
[6] Id.
[7] Id.
[8] Id.

Regulation of Adult Cardiovascular Services

Adult cardiovascular services (ACS), including PCI, were previously regulated through the Certificate-of-Need (CON)[9] program. In 2007, Florida eliminated CON review for adult cardiac catheterization and adult open-heart surgery services[10] 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.[11] However, those hospitals were required to meet licensure standards applicable to existing programs for every subsequent licensure period.[12]

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.[13]

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,[14] for diagnosing congenital or acquired cardiovascular diseases, or for measuring blood pressure flow.[15] It also includes the selective catheterization of the coronary ostia[16] with injection of contrast medium into the coronary arteries.[17]

AHCA regulates the operation of adult inpatient diagnostic cardiac catheterization programs through licensure. This license permits the program to perform only diagnostic procedures;[18] the license does not allow for the performance of therapeutic procedures.[19] [20] Providers of diagnostic cardiac catheterization services comply with the most recent guidelines of the American College of Cardiology and American Heart Association for cardiac catheterization and cardiac catheterization laboratories.[21]

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[9] 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.

[10] 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.

[11] 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.

[12] S. 408.0361(2), F.S.

[13] S. 408.0361(3)(a), F.S.

[14] An arteriogram is an imaging test that uses x-rays and a contrast dye to see inside the arteries of the heart.

[15] Rule 59A-3.2085(13)(b)1., F.A.C.

[16] 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.

[17] Rule 59A-3.2085(13)(b)1., F.A.C.

[18] Diagnostic procedures include left heart catheterization with coronary angiography and left ventriculography; right heart 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.

[19] 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.

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

[21] 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 January 12, 2018). 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.

As of November 1, 2017, there are 21 general acute care hospitals with an adult diagnostic cardiac catheterization program in Florida.[22]

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.[23] 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;[24] and that it has formalized, written transfer agreement with a hospital that has a Level II program.[25]

The criteria cannot be met by combining the two volume options; either the sessions volume is met or the inpatient principle diagnosis volume is met.[26] Once a hospital obtains the designation it does not need to verify volume thresholds to maintain the designation.

Licensed Level I ACS programs must comply with the guidelines that apply to diagnostic cardiac catheterization services[27] and PCI, including guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[28] Additionally, they must comply with the reporting requirements of the American College of Cardiology-National Cardiovascular Data Registry.[29]

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;

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[22] 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 January1 2, 2018).

[23] 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.

[24] Heart condition caused by narrowed heart arteries. This is also called "coronary artery disease" and "coronary heart disease."

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

[26] Agency for Health Care Administration, Analysis of 2018 House Bill 283, Oct. 5, 2017 (on file with Health Innovation Subcommittee Staff).

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

[28] 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 January 12, 2018), 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.

[29] 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.

- 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.[30]

As of November 1, 2017, there are 56 general acute care hospitals with a Level I ACS program in Florida.[31]

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.[32] 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.[33]

In addition to the licensure requirements for a Level I ACS program, Level II ACS programs must also comply with guidelines from the American College of Cardiology and the American Heart Association, which include standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[34] 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.[35] 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.[36]

As of November 1, 2017, there are 79 general acute care hospitals with a Level II ACS program in Florida.[37]

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[30] Rule 59A-3.2085(16)(b), F.A.C.
[31] 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 January 12, 2018).
[32] Rule 59A-3.2085(17)(a), F.A.C.
[33] S. 408.0361(3)(c), F.S.
[34] 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.
[35] 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.
[36] 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 January 12, 2018).
[37] 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 January 12, 2018). 64 of these 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 HB 119 2018 Legislative Session*, Sept. 5, 2017 (on file with Health Innovation Subcommittee staff).

PCI Best Practices

In 2014, the Society for Cardiovascular Angiography and Interventions, the ACC and AHA issued an Expert Consensus document on PCI without on-site surgical backup, which acknowledged advances and best practices in PCI performed in hospitals without on-site surgery (Level I facilities).[38] The Expert Consensus document noted that while PCI peaked in 2006, PCIs at hospitals without on-site surgery have increased since 2007.[39] The Expert Consensus document recommends the PCI programs without on-site surgery have experienced nursing and technical laboratory staff with training in interventional laboratories.[40] The Expert Consensus document continues to recommend PCI procedures should not be performed in facilities performing fewer than 200 procedures, with few exceptions.[41] 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.[42]

Effect of the Bill

Regulation of Adult Cardiovascular Services

Nursing and Technical Staff Experience

HB 119 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 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 they may 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.

Additionally, the bill replaces the term "cardiac" with coronary in reference to PCIs to reflect current terminology.

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[38] 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.
[39] Id.
[40] Id.
[41] 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.
[42] Supra, note 38.

B. SECTION DIRECTORY:

Section 1: Amends s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure.
Section 2: Provides an effective date of July 1, 2018.

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

A bill to be entitled

An act relating to adult cardiovascular services; amending s. 408.0361, F.S.; establishing criteria that must be included by the Agency for Health Care Administration in rules relating to the licensure of certain hospitals performing percutaneous coronary intervention procedures; providing an effective date.

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

Section 1. Paragraphs (a) and (b) of subsection (3) of section 408.0361, Florida Statutes, are amended to read:

408.0361 Cardiovascular services and burn unit licensure.—

(3) In establishing rules for adult cardiovascular services, the agency shall include provisions that allow for:

(a) Establishment of two hospital program licensure levels: a Level I program authorizing the performance of adult percutaneous coronary ~~cardiac~~ intervention without onsite cardiac surgery and a Level II program authorizing the performance of percutaneous coronary ~~cardiac~~ intervention with onsite cardiac surgery.

(b) For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or,

for the most recent 12-month period, has discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes. However, a hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the 60-minute transfer time protocol if the hospital demonstrates that it has a formalized, written transfer agreement with a hospital that has a Level II program. The agreement must include written transport protocols to ensure the safe and efficient transfer of a patient, taking into consideration the patient's clinical and physical characteristics, road and weather conditions, and viability of ground and air ambulance service to transfer the patient. At a minimum, the rules for adult cardiovascular services must require nursing and technical staff to have demonstrated experience in handling acutely ill patients requiring intervention based on the staff members' previous experience in dedicated cardiovascular interventional laboratories or surgical centers. If a staff member's previous experience is in a dedicated cardiovascular interventional laboratory at a hospital that does not have an approved adult open-heart surgery program, the staff member's previous experience qualifies only if, at the

time the staff member acquired his or her experience, the dedicated cardiovascular interventional laboratory:

1. Had an annual volume of 500 or more percutaneous coronary intervention procedures;

2. Achieved a demonstrated success rate of 95 percent or greater for percutaneous coronary intervention procedures;

3. Experienced a complication rate of less than 5 percent for percutaneous coronary intervention procedures; and

4. Performed 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.

Section 2. This act shall take effect July 1, 2018.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HR 157 Public Health Crisis Created by Pornography
SPONSOR(S): Spano
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Committee		Gilani OG	Calamas
2) Rules & Policy Committee			

SUMMARY ANALYSIS

In the past two decades, internet usage and mobile technology have become ubiquitous, especially among teens and young adults. The internet has also has made creation and dissemination of pornography seamless. The majority of Americans, including minors, are exposed to pornography online regularly. Twenty-seven percent of young adults first view pornography before the onset of puberty, 70 percent of teens accidentally view pornography online, and teens have experienced an increase in unwanted exposure to pornographic content online.

While legal and ethical constraints limit research that can determine causal links between pornography and negative outcomes, several studies make correlational findings. Adolescents who view pornography:

- Are more likely to have sexually permissive views, have more sexual partners in their lifetime, and are more likely to have engaged in oral and anal sex;
- Tend to display more aggression, have more traditional gender role attitudes, and view women as sex objects; and
- Report feeling insecure about their ability to perform sexually and the way they look, and reduce their pornography use as their self-confidence increases and their relationships with family and friends improve.

Pornography addiction is not recognized by the American Psychiatric Association as an addiction; however, a growing body of research suggests that one can develop a compulsive disorder related to problematic pornography use.

HR 157 recognizes pornography as a public health crisis and acknowledges the need for education, prevention, research, and policy change to protect the citizens of Florida.

In support of the resolution, HR 157 makes various findings related to the negative impacts of pornography on children and teens; the role of pornography in the demand for human trafficking, prostitution, and child pornography; the potential for addiction to pornography; mental and physical illnesses caused by pornography; and the negative impact on intimate relationships and families.

Legislative resolutions do not have the force of law and are not subject to the Governor's approval and veto powers.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation:

Effects of Pornography

Rapidly advancing technology has made the creation and dissemination of pornography seamless.[1] Specifically, internet usage and mobile technology in the past two decades have become ubiquitous, especially among teens and young adults.[2] The majority of Americans come across pornography online and roughly half will seek it out.[3] Twenty-seven percent of young adults first view pornography before the onset of puberty,[4] 70 percent of teens accidentally stumble upon pornography online,[5] and teens have experienced an increase in unwanted exposure to pornographic content online.[6]

With pornography increasingly accessible to children and teens, there is growing concern about the adverse effects of such early exposure.[7]

Scientific Research

Scientific research on the effects of pornography exists, but is not robust. In order to determine causal links between pornography use and long-term negative outcomes, researchers would need to expose minors to pornography. Legal and ethical constraints prevent researchers from exposing minors to pornography and subjecting them to potentially lasting adverse effects.[8] Instead, researchers must rely on participants who are willing to self-disclose their pornography use and who may also have preexisting co-variables. Therefore, prevailing research is not representative of the general population and does not determine causation, but does establish correlational links between pornography use and negative consequences.

Since the 1990s, there has been a significant and steady decline in teen sex, pre-teen sex, teen births, and sexually transmitted diseases in teens.[9] Violent and sex crime rates have also declined

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[1] Eric W. Owens et al., *The Impact of Internet Pornography on Adolescents: A Review of the Research*, 19(1-2) SEXUAL ADDICTION & COMPULSIVITY 99, 99-100 (2012).

[2] Id. *See also* PEW RESEARCH CENTER, *Teens, Social Media & Technology Overview 2015: Smartphones Facilitate Shifts in Communication Landscape for Teens*, http://www.pewinternet.org/2015/04/09/teens-social-media-technology-2015/ (last visited Jan. 14, 2018).

[3] Josh McDowell Ministry, THE PORN PHENOMENON: THE IMPACT OF PORNOGRAPHY IN THE DIGITAL AGE (2016), research summary available at https://www.barna.com/research/porn-in-the-digital-age-new-research-reveals-10-trends/ (last visited Jan. 14, 2018).

[4] Id.

[5] KAISER FAMILY FOUNDATION, *Generation Rx.com: How Young People Use the Internet for Health Information*, December 2001, at 12, available at https://kaiserfamilyfoundation.files.wordpress.com/2001/11/3202-genrx-report.pdf (last visited Jan. 14, 2018).

[6] Kimberly J. Mitchell et al., *Trends in Youth Reports of Sexual Solicitations, Harassment and Unwanted Exposure to Pornography on the Internet*, 40 JOURNAL OF ADOLESCENT HEALTH 116, 124 (2007), available at: http://unh.edu/ccrc/pdf/CV135.pdf (last visited Jan. 14, 2018).

[7] *Supra* note 1, at 101. *See also*, Kimberly J. Mitchell et al., *Trends in Youth Reports of Sexual Solicitations, Harassment and Unwanted Exposure to Pornography on the Internet*, 40 JOURNAL OF ADOLESCENT HEALTH 116, 116 (2007), available at: http://unh.edu/ccrc/pdf/CV135.pdf (last visited Jan. 14, 2018).

[8] *Supra* note 1, at 102. *E.g.*, s. 847.0133, F.S., making it a third-degree felony to knowingly show any obscene material to a minor. *See generally*, SOCIETY FOR RESEARCH IN CHILD DEVELOPMENT, *Ethical Standards in Research*, https://www.srcd.org/about-us/ethical-standards-research (last visited Jan. 14, 2018).

[9] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, *Morbidity and Mortality Weekly Report: Youth Risk Behavior Surveillance – United States, 2015*, June 10, 2016, at 26-30,119-121 available at: https://www.cdc.gov/healthyyouth/data/yrbs/pdf/2015/ss6506_updated.pdf (last visited Jan. 14, 2018). *See also* U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, *Morbidity and Mortality Weekly Report: Reduced Disparities in Birth Rates among Teens Aged 15-19 Years – United States, 2006-2007 and 2013-2014*, available at: https://www.cdc.gov/mmwr/volumes/65/wr/mm6516a1.htm (last visited Jan. 14, 2018); U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, *Birth Rates (Live Births) per 1,000 Females Aged 15-19 Years, by Race and*

significantly.[10] Nevertheless, research suggests that adolescents who view pornography tend to have more sexually permissive attitudes, have more sexual partners in their lifetime, and are more likely to have engaged in oral and anal sex.[11] Similarly, adolescents who viewed pornography tended to display more aggression, have more traditional gender role attitudes, and view women as sex objects.[12] Due to the correlational nature of these findings, researchers were unable to determine if these characteristics were precursors to pornography use or a consequence of it;[13] however, they were able to identify pornography use as a strong exacerbating factor in individuals who have preexisting markers for sexual aggression.[14]

There is limited research on the effect of internet pornography on adolescents' emotional health, but sexualized media is known to negatively affect girls' and women's self-esteems and lead to eating disorders and depression.[15] Adolescents who view pornography report feeling insecure about their ability to perform sexually or how they look, and tend to decrease their pornography use as their self-confidence increases or they develop positive relationships with friends and family.[16]

During adolescence, the brain is still developing. Unlike adults, when adolescents view pornography, they are less able to control or suppress sexual cravings, thoughts, and behaviors.[17] This vulnerability makes children and teens susceptible to developing problematic pornography use if exposed to pornography during this period of cognitive growth.[18]

One study found that individuals with problematic pornography use have less gray matter and reactivity in the reward system of the brain.[19] This is consistent with the brain composition of those suffering from addictions, suggesting that overstimulation of the reward system changes the composition of the brain.[20] However, the researchers cautioned that this could be a precondition that conversely requires the individual to engage in stronger stimuli in order to stimulate the reward system of the brain.[21]

Ethnicity, 2007-2015, https://www.cdc.gov/teenpregnancy/about/alt-text/birth-rates-chart-2007-2015-text.htm (last visited Jan. 14, 2018).

[10] U.S. DEPARTMENT OF JUSTICE, OFFICE OF JUSTICE PROGRAMS, BUREAU OF JUSTICE STATISTICS, *Criminal Victimization, 2015*, Oct. 2016, https://www.bjs.gov/content/pub/pdf/cv15.pdf *(last visited Jan. 14, 2018). See also* CRIMES AGAINST CHILDREN RESEARCHER CENTER, *Have Sexual Abuse and Physical Abuse Declined Since the 1990s?,* Nov. 2012, *http://www.unh.edu/ccrc/pdf/CV267_Have%20SA%20%20PA%20Decline_FACT%20SHEET_11-7-12.pdf* (last visited Jan. 14, 2018).

[11] Debra K. Braun-Corville & Mary Rojas, *Exposure to Sexually Explicit Web Sites and Adolescent Sexual Attitudes and Behaviors,* 45(2) J ADOLESCENT HEALTH 153, 156-162 (2009). *See also* Jane D. Brown & Kelly L. L'Engles, *X-Rated: Sexual Attitudes and Behaviors Associated with U.S. Early Adolescents' Exposure to Sexually Explicit Media* 36 COMM. RSCH. 129-151 (2009). *Contra*, Marie-Therese Luder et al., *Associations between Online Pornography and Sexual Behavior among Adolescents: Myth or Reality?* 40(5) ARCHIVES OF SEXUAL BEHAVIOR 1027-1035 (2011) (finding that pornography use had no association with early sexual imitation or risky sexual behaviors).

[12] Eileen M. Alexy et al., *Pornography as a Risk Marker for an Aggressive Pattern of Behavior among Sexually Reactive Children and Adolescents*, 14(6) J AM. PSYCHIATRIC NURSES ASS'N 442, 450 (2009). *See also* Elisabet Haggstrom-Nordin et al., *Experiences of and Attitudes towards Pornography among a Group of Swedish High School Students*, 14 EURO. J CONTRACEPTION AND REPRODUCTIVE HEALTH CARE 277, 277-284 (2009).

[13] *Supra* note 1, at 107.

[14] Michelle L. Ybarra & Kimberly J. Mitchell, *X-Rated Material and Perpetration of Sexually Aggressive Behavior Among Children and Adolescents: Is There a Link?* 8 CyberPsychology and Behavior 473, 473-486 (2011). *See generally*, Paul J. Wright, *A Meta-Analysis of Pornography Consumption and Actual Acts of Sexual Aggression in General Population Studies,* 66(1) J COMM 183-205 (2016).

[15] AMERICAN PSYCHOLOGICAL ASSOCIATION, *Sexualization of Girls is Linked to Common Mental Health Problems in Girls and Women—Eating Disorders, Low Self-Esteem, and Depression; An APA Task Force Reports*, Feb. 19, 2007, http://www.apa.org/news/press/releases/2007/02/sexualization.aspx (last visited Jan. 14, 2018).

[16] Lotta Lofgren-Martenson & Sven-Axel Mason, *Lust, Love, and Life: A Qualitative Study of Swedish Adolescents' Perceptions and Experiences with Pornography* 47 J SEX RSCH. 568, 575 (2010).

[17] *Supra* note 1, at 113-115.

[18] Id.

[19] Simone Kuhn & Jurgen Gallinat, *Brain Structure and Functional Connectivity Associated with Pornography Consumption*, 71(7) JAMA PSYCHIATRY 827, 827-834, *available at* https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874574?utm_source=Silverchair%20Information%20Systems&utm_medium=email&utm_campaign=JAMAPsychiatry:OnlineFirst05/28/2014#Discussion (last visited Jan. 14, 2018).

[20] Id.

[21] Id.

The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V),[22] does not recognize sex or pornography addictions, but there is growing research supporting the concept of a compulsive disorder[23] related to problematic pornography use. A major distinction between addiction and compulsion is that addiction includes an experience of pleasure, whereas a compulsion does not. Studies have shown that individuals who struggle with pornography use have similar neurological responses to sexual cues as previously studied in drug addictions.[24] However, there was a significant disassociation between their brain's reaction, and their subjective enjoyment of the image, which is more consistent with compulsive behaviors.[25] An attempt to treat problematic pornography use as a compulsive disorder rather than using an addiction model showed an 85 percent reduction in pornography use and an increase in measures of quality of life.[26]

Human Trafficking, Prostitution, and Child Pornography

Human trafficking is a form of modern-day slavery affecting young children, teenagers, and adults, who are subjected to force, fraud, or coercion for sexual exploitation or forced labor.[27] Commercial sexual exploitation is a form of human trafficking, and can include prostitution and pornography as a means for the perpetrator to make money.[28] Both adults and children can be victims of these acts.[29] The U.S. Department of Justice estimates that as many as 300,000 children in the United States are at risk for commercial sexual exploitation.[30]

In cases of sexual exploitation of minors, perpetrators may engage in a "grooming" process to prepare the victim to engage in the sexual activity.[31] Grooming can include the perpetrator showering the child with gifts and compliments to gain his or her trust, or exposing the minor to adult and child pornography to normalize sexual behavior.[32]

Resolutions on Pornography in Other Jurisdictions

Since 2016, at least five other states have adopted similar resolutions declaring pornography a health crisis or hazard. Utah was the first to pass this resolution in April 2016, followed by Arkansas, Louisiana, South Dakota, and Tennessee in 2017.[33] The Canadian Parliament has also ordered a study of the effects of violent and degrading pornography on children, women, and men.[34]

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[22] The American Psychiatric Association publishes the Diagnostic and Statistical Manual of Mental Disorder, a manual classifying mental disorders, providing standardized criteria for diagnoses and treatment. It is relied upon universally in the health field and is currently on its fifth edition.

[23] Compulsions are repetitive behaviors or mental acts that an individual feels driven to perform in response to an obsession or according to rules that must be applied rigidly. THE AMERICAN PSYCHIATRIC ASSOCIATION, *Diagnostics and Statistical Manual of Mental Disorders* (5th ed., 2013) at 235.

[24] Valerie Voon et al., *Neural Correlates of Sexual Cue Reactivity in Individuals with and without Compulsive Sexual Behaviours*, 9(7) PLOS ONE (2014), *available at* http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0102419 (last visited Jan. 14, 2018).

[25] Id.

[26] Michael P. Twohig & Jesse M. Crosby, Acceptance and Commitment Therapy as a Treatment for Problematic Internet Pornography Viewing, 41(3) BEHAVIOR THERAPY (2010), *available at* https://contextualscience.org/system/files/Twohig_Crosby_2010.pdf (last visited Jan. 14, 2018).

[27] U.S. DEPARTMENT OF JUSTICE, OFFICE OF JUSTICE PROGRAMS, *OJP Fact Sheet, Fast Facts,* Dec. 2011, http://ojp.gov/newsroom/factsheets/ojpfs_humantrafficking.html (last visited Jan. 14, 2018).

[28] The federal Trafficking Victims Protection Act defines "commercial sex act" as any sex act on account of which anything of value is given to or received by any person. 22 U.S.C. s. 7102(4).

[29] S. 787.06, F.S.

[30] *Supra* note 27.

[31] Alisdair A. Gillespie, CHILD PORNOGRAPHY: LAW AND POLICY 108-109 (2011), available at https://books.google.com/books?id=uL2sAgAAQBAJ&pg=PA108#v=onepage&q&f=false (last visited Jan. 14, 2018).

[32] Id.

[33] Utah S.C.R. 9 (2016); Arkansas H.R. 1042 (2017); Louisiana H.C.R. 100 (2017); South Dakota S.C.R. 4 (2017); Tennessee S.J.R. 35 (2017).

[34] Canada. Parliament. House of Commons. Standing Committee on Health. (2017 July). *Report on the Public Health Effects of the Ease of Access and Viewing of Online Violent and Degrading Sexually Explicit Material on Children, Women, and Men*. 42nd Parliament, 1st session. Available: http://www.ourcommons.ca/DocumentViewer/en/42-1/HESA/report-11/page-5 (last visited Jan. 16, 2018).

Effect of the Resolution:

HR 157 recognizes pornography as a public health crisis and acknowledges the need for education, prevention, research, and policy change to protect the citizens of Florida.

In support of the resolution, HR 157 finds that:

- Advances in technology expose children to pornography at an alarming rate and 27 percent of young adults report first viewing pornography before the onset of puberty;
- Pornography often serves as the main source of sexual education for children and is contributing to their hypersexualization;
- Children who view pornography are at a higher risk for developing low self-esteem, an eating disorder, and a desire to engage in dangerous sexual behavior;
- Pornography objectifies women, normalizes violence and abuse of women and children, and depicts rape and abuse as harmless, thereby increasing the demand for sex trafficking, prostitution, and child pornography;
- Pornography can cause: mental and physical illnesses; difficulty forming or maintaining intimate relationships; unhealthy brain development and cognitive function; deviant, problematic, or dangerous sexual behavior; and addiction;
- Recent research indicates that pornography is potentially biologically addictive, resulting in the user consuming increasingly more shocking material to satisfy the addiction;
- Pornography is linked with a reluctance to enter into marriage, dissatisfaction in marriage, and marital infidelity; and
- Efforts to prevent exposure and addiction to pornography, to educate individuals and families of pornography's harmful effects, and to develop pornography recovery programs should be systematic and ascribe responsibility.

Legislative resolutions do not have the force of law and are not subject to the Governor's approval and veto powers.

B. SECTION DIRECTORY:

Not applicable.

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. This resolution does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

House Resolution

A resolution recognizing the public health crisis created by pornography.

WHEREAS, pornography is creating a public health crisis and contributing to the hypersexualization of children and teens, and

WHEREAS, efforts to prevent exposure and addiction to pornography, to educate individuals and families concerning pornography's harmful effects, and to develop pornography recovery programs must be systematic and ascribe responsibility, and

WHEREAS, due to advances in technology and the widespread availability of the Internet, children are exposed to pornography at an alarming rate and it often serves as their main source of education regarding human sexuality, and

WHEREAS, twenty-seven percent of young adults between the ages of 25 and 30 report that they first viewed pornography before the onset of puberty, and

WHEREAS, a child who views pornography is at a higher risk of developing low self-esteem, an eating disorder, and a desire to engage in dangerous sexual behavior, and

WHEREAS, pornography objectifies women, normalizes violence and the abuse of women and children, and depicts rape and abuse

as harmless, thereby increasing the demand for sex trafficking, prostitution, and child pornography, and

WHEREAS, pornography has potential detrimental effects on the user, including, but not limited to, mental and physical illnesses; difficulty forming or maintaining intimate relationships; unhealthy brain development and cognitive function; deviant, problematic, or dangerous sexual behaviors; and addiction, and

WHEREAS, recent research indicates that pornography is potentially biologically addictive, resulting in the user consuming increasingly more shocking material to satisfy the addiction, and

WHEREAS, pornography has a detrimental effect on families and is linked to a reluctance to enter into marriage, dissatisfaction in marriage, and marital infidelity, NOW, THEREFORE,

Be It Resolved by the House of Representatives of the State of Florida:

That the State of Florida recognizes the public health crisis created by pornography and acknowledges the need for education, prevention, research, and policy change to protect the citizens of this state.

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health & Human Services Committee

Representative Spano offered the following:

Amendment (with title amendment)

Remove everything after the resolving clause and insert:

That the State of Florida recognizes the public health risk created by pornography and acknowledges the need for education, prevention, research, and policy change to protect the citizens of this state.

T I T L E A M E N D M E N T

Remove everything before the resolving clause and insert:

House Resolution

A resolution recognizing the public health risk created by pornography.

WHEREAS, pornography is creating a public health risk and contributing to the hypersexualization of children and teens, and

WHEREAS, efforts to prevent exposure to pornography, to educate individuals and families concerning pornography's potential harmful effects, and to develop pornography recovery programs should be systematic, and

WHEREAS, due to advances in technology and the widespread availability of the Internet, children are exposed to pornography at an alarming rate and it can serve as their main source of education regarding human sexuality, and

WHEREAS, twenty-seven percent of young adults between the ages of 25 and 30 report that they first viewed pornography before the onset of puberty, and

WHEREAS, pornography depicts children and young people in a hypersexualized manner and a child who views such images is at a higher risk of developing low self-esteem, an eating disorder, and a desire to engage in dangerous sexual behavior, and

WHEREAS, pornography objectifies women, normalizes violence and the abuse of women and children, depicts rape and abuse as harmless, and is related to the increased demand for sex trafficking, prostitution, and child pornography, and

WHEREAS, pornography has potential detrimental effects on the user, and research has found correlations between pornography use and mental and physical illnesses; difficulty forming or maintaining intimate relationships; unhealthy brain development and cognitive function; and deviant, problematic, or dangerous sexual behaviors, and

WHEREAS, recent research indicates that one can develop a compulsive disorder in which excessive amounts of pornography are consumed, resulting in the user consuming increasingly more shocking material or withdrawing from daily life functions to satisfy the compulsion, and

WHEREAS, pornography can have a detrimental effect on families, including a reluctance to enter into marriage, dissatisfaction in marriage, and marital infidelity, NOW, THEREFORE,

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 281 Incarcerated Parents
SPONSOR(S): Williams, Daniels & others
TIED BILLS: **IDEN./SIM. BILLS:** SB 522

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Children, Families & Seniors Subcommittee	14 Y, 0 N	Grabowski	Brazzell
2) Appropriations Committee	29 Y, 0 N	Pridgeon	Leznoff
3) Health & Human Services Committee		MG Grabowski	Calamas

SUMMARY ANALYSIS

Chapter 39, F.S., creates Florida's child welfare system that aims to protect children and prevent abuse, abandonment, and neglect.

DCF's child welfare practice model (model) standardizes the approach to risk assessment and decision-making used to determine a child's safety. The model emphasizes parent engagement and empowerment as well as the training and support of child welfare professionals to assess child safety. It also emphasizes a family-centered practice with the goal of keeping children in their homes whenever possible.

One key element of the model is the development of a case plan, which is an outline of tasks and requirements that must be met to facilitate the permanency goal of a child. Section 39.6011, F.S., details the development of the case plan and who must be involved throughout the case planning process. This section also details what must be in the case plan, such as descriptions of the identified problems, the permanency goal, timelines, and notice requirements.

HB 281 further defines the role of incarcerated parents in the development and execution of case plans associated with their children. Section 39.6011, F.S., also requires DCF to engage incarcerated parents in the dependency case process, including case plan development, and the bill provides a set of explicit responsibilities that must be met by both DCF and incarcerated parents throughout the dependency case process.

The bill requires DCF to:

- Include incarcerated parents in case planning and develop case plans that give some consideration to limitations faced by incarcerated persons;
- Coordinate efforts with relevant correctional facilities to determine what services and resources may be available to incarcerated parents;
- Amend case plans as individuals become incarcerated or are released from incarceration; and,

The bill makes incarcerated parents responsible for complying with case plan requirements and the requirements of relevant correctional facilities.

The bill has no fiscal impact on state or local government.

The bill has an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Florida's Child Welfare System

Chapter 39, F.S., creates Florida's child welfare system that aims to protect children and prevent abuse, abandonment, and neglect.[1] The Department of Children and Families (DCF) works in partnership with local communities and the courts to ensure the timely permanency and well-being of children. During FY 2016-17, DCF and selected county sheriffs' offices contracted as child protective investigative staff conducted more than 220,000 investigations. The department ultimately served more than 38,000 children in out-of-home care during the same period. Approximately 41% of children removed from their homes achieved permanency within 12 months, based on 2016 data – which placed Florida just above the national average of 40.5%.[2]

Practice Model

DCF's child welfare practice model (model) standardizes the approach to risk assessment and decision making used to determine a child's safety.[3] The model seeks to achieve the goals of safety, permanency, and child and family well-being.[4] The model emphasizes parent engagement and empowerment as well as the training and support of child welfare professionals to assess child safety,[5] and emphasizes a family-centered practice with the goal of keeping children in their homes whenever possible.[6] DCF contracts with community-based care lead agencies to coordinate case management and services for families within the dependency system.

Dependency Case Process

When child welfare necessitates that DCF remove a child from his or her home, a series of dependency court proceedings must occur to adjudicate the child dependent and place him or her in out-of-home care, as indicated by the chart below.

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[1] S. 39.001(8), F.S.
[2] Department of Children and Families, *Child Welfare Key Indicators Monthly Report*, available at http://www.centerforchildwelfare.org/qa/cwkeyindicator/KI_Monthly_Report_Sept2017.pdf (last accessed November 5, 2017).
[3] Department of Children and Families, *2013 Year in Review*, available at: http://www.dcf.state.fl.us/admin/publications/year-in-review/2013/page19.shtml (last accessed October 31, 2017).
[4] The Department of Children and Families, *Florida's Child Welfare Practice Model*, available at: http://www.myflfamilies.com/service-programs/child-welfare/child-welfare-practice-model (last accessed October 31, 2017).
[5] Supra, FN 3.
[6] The Department of Children and Families, *2012 Year in Review*, available at: http://www.dcf.state.fl.us/admin/publications/year-in-review/2012/page9.shtml (last accessed October 31, 2017).

Proceeding	Description	Statute
Removal	The child's home is determined to be unsafe, and the child is removed	s. 39.401, F.S.
Shelter Hearing	A shelter hearing occurs within 24 hours after removal. The judge determines whether to keep the child out-of-home.	s. 39.401, F.S.
Petition for Dependency	A petition for dependency occurs within 21 days of the shelter hearing. This petition seeks to find the child dependent.	s. 39.501, F.S.
Arraignment Hearing and Shelter Review	An arraignment and shelter review occurs within 28 days of the shelter hearing. This allows the parent to admit, deny, or consent to the allegations within the petition for dependency and allows the court to review any shelter placement.	s. 39.506, F.S.
Dependency Adjudicatory Trial	An adjudicatory trial is held within 30 days of arraignment, to determine whether a child is dependent.	s. 39.507, F.S.
Disposition Hearing	Disposition occurs within 15 days of arraignment or 30 days of adjudication. The judge reviews and orders the case plan for the family and the appropriate placement of the child.	ss. 39. 506 and 39.521, F.S.
Judicial Review Hearings	The court must review the case plan and placement every 6 months, or upon motion of a party.	s. 39.701, F.S.
Petition for Termination of Parental Rights (TPR)	After 12 months, if DCF determines that reunification is no longer a viable goal, termination of parental rights is in the best interest of the child, and other requirements are met, a petition for TPR is filed.	ss. 39.802, 39.8055, 39.806, and 39.810, F.S.
Advisory Hearing	This hearing is set as soon as possible after all parties have been served with the petition for TPR. The hearing allows the parent to admit, deny, or consent to the allegations within the petition for TPR.	s. 39.808, F.S.
TPR Adjudicatory Trial	An adjudicatory trial shall be set within 45 days after the advisory hearing. The judge determines whether to terminate parental rights to the child at this trial.	s. 39.809, F.S.

Federal Requirements for Permanency

Many of the federal requirements related to the dependency process can be traced to the Adoption and Safe Families Act (ASFA) of 1997.[7] The AFSA expanded the use of detailed case planning, while emphasizing the well-being of children at all critical points during the dependency case process.[8] It further requires that states make timely decisions regarding permanency. The permanency goal is enforced primarily via a requirement that states terminate the parental rights of children who have spent 15 or more months of the past 22 months in foster care.[9]

The ASFA also required that states participate in Child & Family Services Reviews (CSFRs) to identify and remedy potential weaknesses in their existing child welfare frameworks. Among the issues noted in Florida's 2016 CSFR were the challenges involved in actively engaging parents, particularly fathers, in the case planning process.[10]

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[7] Public Law 105-89.
[8] Committee on Child Maltreatment Research, Policy, and Practice for the Next Decade: Phase II, New Directions in Child Abuse and Neglect Research (2004), available at https://www.ncbi.nlm.nih.gov/books/NBK195980/ (last accessed November 6, 2017).
[9] Id.
[10] Child and Family Services Reviews – Final Report on Florida (2016), U.S. Department of Health and Human Services, Children's Bureau, available at http://centerforchildwelfare.org/qa/CFSRTools/2016%20CFSR%20Final%20Report.pdf (last accessed November 7, 2017).

Case Plans

Throughout the dependency process, DCF must develop and refine a case plan with input from all parties to the dependency case that details the problems being addressed as well as the goals, tasks, services, and responsibilities required to ameliorate the concerns of the state.[11] The case plan follows the child from the provision of voluntary services through dependency, or termination of parental rights.[12] Once a child is found dependent, a judge reviews the case plan, and if the judge accepts the case plan as drafted, orders the case plan to be followed.[13]

Section 39.6011, F.S., details the development of the case plan and who must be involved, such as the parent, guardian ad litem, and if appropriate, the child. This section also details what must be in the case plan, such as descriptions of the identified problems, the permanency goal, timelines, and notice requirements.

Section 39.6012, F.S., details the types of tasks and services that must be provided to the parents as well as the type of care that must be provided to the child. The services must be designed to improve the conditions in the home, facilitate the child's safe return to the home, ensure proper care of the child, and facilitate permanency. The case plan must describe each task with which the parent must comply and the services provided that address the identified problem in the home and all available information that is relevant to the child's care.

When determining whether to place a child back into the home he or she was removed from, or whether to move forward with another permanency option, the court seeks to determine whether the circumstances that caused the out-of-home placement have been remedied to the extent that the safety, well-being and health of the child are not endangered by an in-home placement.[14] To support the permanency goal, the court continues to monitor a parent's efforts to comply with the tasks assigned in the case plan.[15]

Case Plans Involving Incarcerated Parents

Recent research suggests that about 7% of all children in the United States have lived with a parent who was incarcerated at some point.[16] There is a significant body of research which documents the negative impacts of parental incarceration on children. Among other insights, this research often highlights the virtues of reunification, when possible, and the importance of child welfare processes that actively engage incarcerated parents in the care of their children.[17]

Incarceration of a parent is not, in and of itself, sufficient grounds for the termination of that individual's parental rights.[18] Accordingly, DCF and the courts must engage with incarcerated parents to develop and implement case plans. However, the incarceration of one or more parents can present significant challenges to the timely and appropriate permanency of children. Among these challenges are narrow visitation schedules, communication restrictions, and limited prisoner support services.[19]

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[11] Ss, 39.6011 and 39.6012, F.S.
[12] S. 39.01(11), F.S.
[13] S. 39.521, F.S.
[14] S. 39.522, F.S.
[15] S. 39.621, F.S.
[16] David Murphey and P. Mae Cooper, Parents Behind Bars: What Happens to their Children? (October 2015), available at https://www.childtrends.org/wp-content/uploads/2015/10/2015-42ParentsBehindBars.pdf (last accessed November 3, 2017).
[17] Child Welfare Information Gateway. Child Welfare Practice With families affected by Parental Incarceration (October 2015), U.S. Department of Health and Human Services, Children's Bureau, available at https://www.childwelfare.gov/pubPDFs/parental_incarceration.pdf (last accessed November 3, 2017).
[18] Id.
[19] Annie E. Casey Foundation, When a Parent is Incarcerated: A Primer for Social Workers (2011), available at http://www.aecf.org/m//resourcedoc/aecf-WhenAParentIsIncarceratedPrimer-2011.pdf (last accessed November 1, 2017).

The Florida Department of Corrections (DOC) currently allows DCF staff access to inmates for relevant meetings and interviews. DOC also contributes by approving transfers, when appropriate, for incarcerated parents to facilities which meet the inmate's programming needs; and by allowing incarcerated parents to have routine visits with their children, when appropriate.

DOC provides inmates with access to a range of educational and vocational services that may help an incarcerated parent meet select goals attached to his/her case plan. Among the relevant resources offered by DOC are substance abuse treatment, anger management programs, and parenting classes. DOC also provides high school diploma programs, literacy programs, and occupational training in fields such as carpentry, masonry, plumbing, and automotive technology. DOC identifies which services are available at each facility in published annual reports and also on the department webpage for each facility.[20]

Effect of Proposed Changes

The bill specifically addresses the role of incarcerated parents in the case planning process. To include incarcerated parents more effectively in the development and execution of case plans, the bill requires DCF to:

- Initiate contact with the correctional facility in which a parent is being held to determine how the parent can participate in the preparation and execution of the case plan;
- Attach a list of services available at the relevant correctional facility to the case plan itself;
- Develop case plans that take into account the services and resources available to incarcerated parents in the facilities in which they reside;
- Provide flexibility within the case plan following the incarceration of a parent. If a parent becomes incarcerated after initial development of a case plan, the case plan must be amended if this incarceration may impact the permanency of the child. Such an amendment may include revisions to visitation arrangements between the child and incarcerated parent, identification of services available to the parent within the correctional facility, and modification of the stated permanency goal;
- Use the case plan to facilitate re-entry of an incarcerated parent. If an incarcerated parent is released prior to expiration of the case plan, the case plan must indicate which tasks will need to be completed post-release; and
- Document non-participation in the case plan. If an incarcerated parent does not participate in the development of the case plan, DCF must include a full explanation for this non-participation and detail any efforts made to secure the participation of the incarcerated parent.

The bill also reinforces the responsibility that lies with incarcerated parents in the development and execution of the case plan. Incarcerated parents must comply with procedures established by the relevant correctional facility and maintain contact with impacted children as provided in the case plan. The bill does not, however, create any additional obligations for relevant correctional facilities beyond those that already exist in statute.

The bill also does not prevent DCF or the court from using discretion in determining whether reunification of an incarcerated parent with his or her child is in the best interest of the child.[21]

The bill has an effective date of July 1, 2018.

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[20] Florida Department of Corrections, Annual Report for Fiscal Year 2015-2016, available at http://www.dc.state.fl.us/pub/annual/1516/FDC_AR2015-16.pdf (last accessed November 3, 2017). For instance, see information regarding Calhoun Correctional Institution at http://www.dc.state.fl.us/facilities/region1/105.html (last accessed November 6, 2017).

[21] Section 39.806(1)(d), F.S., outlines the circumstances in which the court may terminate the parental rights of an incarcerated parent. Among such considerations are the nature of the offense committed by an incarcerated parent, the length of the parent's expected incarceration, and the nature of the relationship between the incarcerated parent and the child.

B. SECTION DIRECTORY:

Section 1: Creates s. 39.6021, F.S., relating to case plan development involving an incarcerated parent.

Section 2: Provides for an effective date of July 1, 2018.

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. This bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to incarcerated parents; creating s. 39.6021, F.S.; requiring the Department of Children and Families to obtain specified information from a facility where a parent is incarcerated under certain circumstances; providing an exception; requiring that a parent who is incarcerated be included in case planning and provided with a copy of the case plan; providing requirements for case plans; specifying that the incarcerated parent is responsible for complying with facility procedures and policies to access services or maintain contact with his or her children as provided in the case plan; requiring the parties to the case plan to move to amend the case plan if a parent becomes incarcerated after a case plan has been developed and the parent's incarceration has an impact on permanency for the child; requiring that the case plan include certain information if the incarcerated parent is released before it expires; requiring the department to include certain information in the case plan if the incarcerated parent does not participate in its preparation; providing construction; providing an effective date.

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

Section 1. Section 39.6021, Florida Statutes, is created to read:

39.6021 Case planning when parents are incarcerated or become incarcerated.—

(1) In a case in which the parent is incarcerated, the department shall obtain information from the facility where the parent is incarcerated to determine how the parent can participate in the preparation and completion of the case plan and receive the services that are available to the parent at the facility. This subsection does not apply if the department has determined that a case plan for reunification with the incarcerated parent will not be offered.

(2) A parent who is incarcerated must be included in case planning and must be provided a copy of any case plan that is developed.

(3) A case plan for a parent who is incarcerated must comply with ss. 39.6011 and 39.6012 to the extent possible, and must give consideration to the regulations of the facility where the parent is incarcerated and to services available at the facility. The department shall attach a list of services available at the facility to the case plan. If the facility does not have a list of available services, the department must note the unavailability of the list in the case plan.

(4) The incarcerated parent is responsible for complying

with the facility's procedures and policies to access services or maintain contact with his or her children as provided in the case plan.

(5) If a parent becomes incarcerated after a case plan has been developed, the parties to the case plan must move to amend the case plan if the parent's incarceration has an impact on permanency for the child, including, but not limited to:

(a) Modification of provisions regarding visitation and contact with the child;

(b) Identification of services within the facility; or

(c) Changing the permanency goal or establishing a concurrent case plan goal.

(6) If an incarcerated parent is released before the case plan expires, the case plan must include tasks that must be completed by the parent and services that must be accessed by the parent upon the parent's release.

(7) If the parent does not participate in preparation of the case plan, the department must include in the case plan a full explanation of the circumstances surrounding his or her nonparticipation and must state the nature of the department's efforts to secure the incarcerated parent's participation.

(8) This section does not prohibit the department or the court from revising a permanency goal after a parent becomes incarcerated or from determining that a case plan with a goal of reunification may not be offered to a parent. This section may

not be interpreted as creating additional obligations for a facility which do not exist in the statutes or regulations governing that facility.

Section 2. This act shall take effect July 1, 2018.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 283 Cardiac Programs
SPONSOR(S): Raschein
TIED BILLS: **IDEN./SIM. BILLS:** SB 408

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	11 Y, 0 N	Langston	Crosier
2) Health Care Appropriations Subcommittee	11 Y, 0 N	Clark	Pridgeon
3) Health & Human Services Committee		Langston	Calamas

SUMMARY ANALYSIS

The Agency for Health Care Administration (AHCA) regulates hospitals, including adult cardiovascular services (ACS), under chapter 395, F.S., and the general licensure provisions of part II of chapter 408, F.S. Licensed Level I ACS programs provide diagnostic and therapeutic cardiac catheterization services, on a routine and emergency basis, but do not have on-site open-heart surgery capability. Level II ACS programs provide the same services as a Level I ACS program, but have on-site open-heart surgery capability.

A hospital seeking a Level I ACS program license must demonstrate that, for the most recent 12-month period as reported to AHCA, it:

- 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 and that it has a transfer agreement with a hospital that has a Level II ACS program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes.

HB 283 bill expands the type of patients that may be counted to meet the minimum volume threshold for treatment of ischemic heart, by counting all patients with ischemic heart disease, rather than only inpatients.

Currently, a hospital that is more than 100 road miles from the closest Level II ACS program that is able to meet all criteria except for the emergency transfer time may still qualify as a Level I ACS program.

The bill provides a new exception for such hospitals to qualify for the Level I ACS program if the hospital can demonstrate that it:

- Provided a minimum of 100 adult inpatient and outpatient diagnostic cardiac catheterizations for the most recent 12-month period; or
- Discharged or transferred at least 300 patients with a principle diagnosis of ischemic heart disease for the most recent 12-month period.

The Lower Keys Medical Center in Key West is the only diagnostic cardiac catheterization that could qualify for the exception under this bill to become a Level I ACS program.

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

The bill provides an effective date of July 1, 2018.

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 Coronary Intervention

Percutaneous coronary 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]

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[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 January 12, 2018).
[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 January 12, 2018).
[6] Id.
[7] Id.
[8] Id.

Regulation of Adult Cardiovascular Services

Adult cardiovascular services (ACS), were previously regulated through the Certificate-of-Need (CON)[9] program. In 2007, Florida eliminated CON review for adult cardiac catheterization and adult open-heart surgery services[10] 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.[11] However, those hospitals were required to meet licensure standards applicable to existing programs for every subsequent licensure period.[12]

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.[13]

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,[14] for diagnosing congenital or acquired cardiovascular diseases, or for measuring blood pressure flow.[15] It also includes the selective catheterization of the coronary ostia[16] with injection of contrast medium into the coronary arteries.[17]

AHCA regulates the operation of adult inpatient diagnostic cardiac catheterization programs through licensure. This license permits the program to perform only diagnostic procedures;[18] the license does not allow for the performance of therapeutic procedures.[19] [20] Providers of diagnostic cardiac catheterization services comply with the most recent guidelines of the American College of Cardiology and American Heart Association for cardiac catheterization and cardiac catheterization laboratories.[21]

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[9] 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.

[10] 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.

[11] 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.

[12] S. 408.0361(2), F.S.

[13] S. 408.0361(3)(a), F.S.

[14] An arteriogram is an imaging test that uses x-rays and a contrast dye to see inside the arteries of the heart.

[15] Rule 59A-3.2085(13)(b)1., F.A.C.

[16] 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.

[17] Rule 59A-3.2085(13)(b)1., F.A.C.

[18] Diagnostic procedures include left heart catheterization with coronary angiography and left ventriculography; right heart 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.

[19] 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.

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

[21] 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 January 12, 2018). 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.

As of November 1, 2017, there are 21 general acute care hospitals with an adult diagnostic cardiac catheterization program in Florida.[22]

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.[23] 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;[24] and that it has formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes. [25]

The criteria cannot be met by combining the two volume options; either the sessions volume is met or the inpatient principle diagnosis volume is met.[26] Once a hospital obtains the designation it does not need to verify volume thresholds to maintain the designation.

Licensed Level I ACS programs must comply with the guidelines that apply to diagnostic cardiac catheterization services[27] and PCI, including guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[28] Additionally, they must comply with the reporting requirements of the American College of Cardiology-National Cardiovascular Data Registry.[29]

Subsection 408.0361(3), F.S., allows a hospital that is more than 100 road miles from the closest Level II hospital that is able to meet all criteria except for the emergency transfer of patients within 60 minutes to qualify as a Level I ACS.

As of November 1, 2017, there are 56 general acute care hospitals with a Level I ACS program in Florida.[30]

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[22] 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 January 12, 2018).

[23] 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.

[24] Heart condition caused by narrowed heart arteries. This is also called "coronary artery disease" and "coronary heart disease."

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

[26] Agency for Health Care Administration, Analysis of 2018 House Bill 283, Oct. 5, 2017 (on file with Health and Human Services Committee Staff).

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

[28] 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 January 12, 2018), 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.

[29] 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.

[30] 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 January 12, 2018).

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.[31] 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.[32]

In addition to the licensure requirements for a Level I ACS program, Level II ACS programs must also comply with guidelines from the American College of Cardiology and the American Heart Association, which include standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[33]

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.[34] 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.[35]

As of November 1, 2017, there are 79 general acute care hospitals with a Level II ACS program in Florida.[36]

Effect of the Bill

The bill expands the type of patients that a hospital may count to meet the minimum volume threshold for a Level I ACS program. It amends the minimum volume threshold for treatment of ischemic heart disease to provide greater flexibility by counting experience treating any patients with ischemic heart disease, rather than only those treated as inpatients. Currently, there are no hospitals without a Level I ACS program that have fewer than 300 inpatient discharges as required by the current standard, that also have more than 300 total patient discharges as would be required under the bill.[37]

The bill also provides alternate volume thresholds for a hospital more than 100 miles from a Level II ACS program that is seeking to become a Level I ACS program. The allow such hospitals to qualify for the Level I ACS program designation if the hospital can demonstrate that it:

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[31] Rule 59A-3.2085(17)(a), F.A.C.
[32] S. 408.0361(3)(c), F.S.
[33] 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.
[34] 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.
[35] 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 January 12, 2018).
[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_II_ACS_Listing.pdf (last visited January 12, 2018). 64 of these 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 HB 119 2018 Legislative Session*, Sept. 5, 2017 (on file with Health and Human Services Committee staff).
[37] *Supra*, note 26.

- Provided a minimum of 100 adult inpatient and outpatient diagnostic cardiac catheterizations for the most recent 12-month period; or
- Discharged or transferred at least 300 patients with a principle diagnosis of ischemic heart disease for the most recent 12-month period.

The Lower Keys Medical Center in Key West is the only diagnostic cardiac catheterization that would qualify for the exemption under this bill to become a Level I ACS program.[38] Currently, there are only seven general hospitals out of 84, that are neither Level I or Level II ACS program, which are also more than 50 miles away from a Level II hospital, including the Lower Keys Medical Center; however, the Lower Keys Medical Center is the only hospital more than 100 miles away from a Level II ACS program.[39]

The Lower Keys Medical Center has provided a minimum of 100 adult inpatient and outpatient diagnostic cardiac catheterizations for the most recent 12-month period, and as a result will qualify as a Level I ACS program.[40]

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure.
Section 2: Provides an effective date of July 1, 2018.

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.

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[38] *Supra*, note 26.
[39] Id.
[40] Id. Lower Keys Medical Center has not discharged or transferred at least 300 patients with a principle diagnosis of ischemic heart disease for the most recent 12-month period; however, it is only necessary that it meet one of the two volume requirements, not both.

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

A bill to be entitled

An act relating to cardiac programs; amending s. 408.0361, F.S.; granting an exception from volume requirements for diagnostic cardiac catheterization procedures and ischemic heart disease diagnoses for certain hospitals providing adult cardiovascular services; providing an effective date.

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

Section 1. Paragraph (b) of subsection (3) of section 408.0361, Florida Statutes, is amended to read:

408.0361 Cardiovascular services and burn unit licensure.—

(3) In establishing rules for adult cardiovascular services, the agency shall include provisions that allow for:

(b)1. For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or, for the most recent 12-month period, has discharged or transferred at least 300 patients ~~inpatients~~ with the principal diagnosis of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60

minutes. ~~However,~~

2.a. A hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the diagnostic cardiac catheterization volume and ischemic heart disease diagnosis volume requirements in subparagraph 1. if the hospital demonstrates that it has, for the most recent 12-month period as reported to the agency, provided a minimum of 100 adult inpatient and outpatient diagnostic cardiac catheterizations or that, for the most recent 12-month period, it has discharged or transferred at least 300 patients with the principal diagnosis of ischemic heart disease.

b. A hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the 60-minute transfer time protocol requirement in subparagraph 1. if the hospital demonstrates that it has a formalized, written transfer agreement with a hospital that has a Level II program. The agreement must include written transport protocols to ensure the safe and efficient transfer of a patient, taking into consideration the patient's clinical and physical characteristics, road and weather conditions, and viability of ground and air ambulance service to transfer the patient.

Section 2. This act shall take effect July 1, 2018.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 313 Access to Health Care Practitioner Services
SPONSOR(S): Health Quality Subcommittee; Grant
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 0 N, As CS	Siples	McElroy
2) Health Care Appropriations Subcommittee	13 Y, 0 N	Mielke	Pridgeon
3) Health & Human Services Committee		Siples	Calamas

SUMMARY ANALYSIS

CS/HB 313 incentivizes physicians to provide pro bono health care services to certain low-income individuals and provides an opportunity for physicians from other jurisdictions and retired physicians to provide health services to low-income and medically underserved individuals in this state.

The bill requires Department of Health (DOH) to waive the renewal fee of an allopathic or osteopathic physician who demonstrates to DOH the provision of at least 160 hours of pro bono medical services to certain populations within the biennial licensure renewal period. Demonstration of 120 hours gains an exemption from the 40 hours of continuing medical education required for license renewal.

The bill authorizes both the Board of Medicine and the Board of Osteopathic Medicine to issue a limited number of restricted licenses to physicians not licensed in Florida who contract to practice for 36 months solely in the employ of the state, a federally funded community health center, a migrant health center, a free clinic, or a health provider in a health professional shortage area or medically underserved area. An applicant for a restricted license must hold an active, unencumbered license to practice medicine in another jurisdiction of the U. S. or Canada and pass a background screening. Prior to the end of the 36-month contract, the physician must take and pass the appropriate licensing exam to become fully licensed in this state. Breach of contract precludes full licensure.

The bill also creates a registration process for retired physicians to provide volunteer health care services if the physician held an active licensed status to practice and maintained such license in good standing in this state or in another jurisdiction of the U. S. or Canada for at least 20 years and contracts with a health care provider to provide free, volunteer health care services to indigent persons or medically underserved populations in a health professional shortage area or medically underserved area. Such a physician must work under the supervision of a non-retired physician who holds an active, unencumbered license, provide only medical services of the type and within the specialty performed by the physician prior to retirement, and not perform surgery or prescribe controlled substances. These physicians are exempt from any application, licensure, unlicensed activity, and renewal fees. Registration must be renewed biennially to demonstrate compliance with registration requirements.

The "Access to Health Care Act" (Act) was enacted in 1992 to encourage health care providers to provide care to low-income persons. The bill redefines low-income persons to include individuals that do not have health insurance and have a family income that does not exceed 400 percent of the federal poverty level, rather than the 200 percent in current law.

The bill may have an indeterminate positive impact and an indeterminate negative fiscal impact on DOH (see fiscal impact on state government). Current department resources are sufficient to absorb added workload. The bill will have no impact on local governments.

The bill provides an effective date of July 1, 2018

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Licensure and Regulation of Physicians

Allopathic Physicians

Chapter 458, F.S., governs licensure and regulation of the practice of medicine by the Florida Board of Medicine (allopathic board) in conjunction the Department of Health (DOH). The chapter provides, among other things, licensure requirements by examination for medical school graduates and licensure by endorsement requirements.

Allopathic Licensure by Examination

An individual seeking to be licensed by examination as an allopathic physician, must meet the following requirements:[1]

- Pay an application fee;[2]
- Be at least 21 years of age;
- Be of good moral character;
- Has not committed an act or offense that would constitute the basis for disciplining a physician, pursuant to s. 458.331, F.S.;
- Complete 2 years of post-secondary education which includes, at a minimum, courses in fields such as anatomy, biology, and chemistry prior to entering medical school;
- Meets one of the following medical education and postgraduate training requirements:
    - Is a graduate of an allopathic medical school recognized and approved by an accrediting agency recognized by the U.S. Office of Education or recognized by an appropriate governmental body of a U.S. territorial jurisdiction, and has completed at least one year of approved residency training;
    - Is a graduate of an allopathic foreign medical school registered with the World Health Organization and certified pursuant to statute as meeting the standards required to accredit U.S. medical schools, and has completed at least one year of approved residency training; or
    - Is a graduate of an allopathic foreign medical school that has not been certified pursuant to statute; has an active, valid certificate issued by the Educational Commission for Foreign Medical Graduates (ECFMG),[3] has passed that commission's examination; and has completed an approved residency or fellowship of at least 2 years in one specialty area;
- Has submitted to a background screening by the DOH; and
- Has obtained a passing score on:
    - The United States Medical Licensing Examination (USMLE);

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[1] Section 458.311(1), F.S.

[2] Pursuant to r. 64B8-3.002(5), F.A.C., the application fee for a person desiring to be licensed as a physician by examination is $500. The applicant must pay an initial license fee of $429. Section 766.314(4), F.S., assesses a fee to be paid with at time of an initial license to finance the Florida Birth-Related Neurological Injury Compensation Plan. The current assessment amount is $250 for most practitioners and $5,000 for obstetricians. If a practitioner dispenses medicinal drugs, an additional fee of $100 must be paid at the time of licensure.

[3] A graduate of a foreign medical school does not need to present an ECFMG certification or pass its exam if the graduate received his or bachelor's degree from an accredited U.S. college or university, studied at a medical school recognized by the World Health Organization, and has completed all but the internship or social service requirements, has passed parts I and II of the National Board Medical Examiners licensing examination or the ECFMG equivalent examination. (Section 458.311, F.S.)

- A combination of the USMLE, the examination of the Federation of State Medical Boards of the United States, Inc. (FLEX), or the examination of the National Board of Medical Examiners up to the year 2000; or
- The Special Purpose Examination of the Federation of State Medical Boards of the United States (SPEX), if the applicant was licensed on the basis of a state board examination, is currently licensed in at least one other jurisdiction of the United States or Canada, and has practiced for a period of at least 10 years.

Allopathic Licensure by Endorsement

An individual who holds an active license to practice medicine in another jurisdiction may seek licensure by endorsement to practice medicine in Florida.[4] The applicant must meet the same requirements for licensure by examination. To qualify for licensure by endorsement, the applicant must also submit evidence of the licensed active practice of medicine in another jurisdiction for at least 2 of the preceding 4 years, or evidence of successful completion of either a board-approved postgraduate training program within 2 years preceding filing of an application or a board-approved clinical competency examination within the year preceding the filing of an application for licensure.[5]

When the allopathic board determines that any applicant for licensure by endorsement has failed to meet, to the allopathic board's satisfaction, each of the appropriate requirements for licensure by endorsement, it may enter an order requiring one or more of the following terms:[6]

- Refusal to certify to the DOH an application for licensure, certification, or registration;
- Certification to the DOH of an application for licensure, certification, or registration with restrictions on the scope of practice of the licensee; or
- Certification to the DOH of an application for licensure, certification, or registration with placement of the physician on probation for a period of time and subject to such conditions as the allopathic board may specify, including, but not limited to, requiring the physician to submit to treatment, attend continuing education courses, submit to reexamination, or work under the supervision of another physician.

Allopathic License Renewal

Physician licenses are renewed biennially. The current fee for the timely renewal of a license is $389; this fee also applies to restricted licenses and temporary certificates for practice in areas of critical need.[7] However, if a physician holding a restricted license or temporary certificate for practice in areas of critical need submits a notarized statement from his or her employer stating that the physician will not receive monetary compensation for the provision of medical services, the renewal fees are waived.[8]

Within each biennial licensure renewal period, a physician must complete 40 hours of continuing medical education (CME) courses approved by the allopathic board. As a part of the 40 hours of CME, a licensee must also complete the following:

- A two-hour course regarding domestic violence every third biennial;[9]
- A one-hour course addressing the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome no later than upon the first biennial licensure renewal;[10] and
- Two hours of CME relating to the prevention of medical errors.[11]

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[4] Section 458.313, F.S.
[5] Section 458.313(c), F.S.
[6] Section 458.313(7), F.S.
[7] Rule 64B8-3.003, F.A.C. If a practitioner dispenses medicinal drugs, an additional fee of $100 must be paid at the time of renewal.
[8] Id.
[9] Section 456.031, F.S.
[10] Section 456.033, F.S.
[11] Section 456.013(7), F.S.

The allopathic board authorizes up to 5 hours of the required CME hours to be fulfilled by the performance of pro bono services to indigent or underserved persons or in areas of critical need.[12] The allopathic board has approved as pro bono service sites, federally funded community and migrant health centers, volunteer health care provider programs contracted to provide uncompensated care with DOH, and DOH. If pro bono services are to be provided to any other entity, the licensee must obtain prior approval for such services to apply against the CME requirement.

DOH may not renew a license until a licensee complies with all CME requirements.[13] The allopathic board may also take action against a license for failure to comply with CME requirements.

Osteopathic Physicians

Chapter 459, F.S., governs licensure and regulation of the practice of medicine by the Florida Board of Osteopathic Medicine (osteopathic board) in conjunction the Department of Health (DOH). The chapter provides, among other things, general licensure requirements, including by examination for medical school graduates and licensure by endorsement requirements.

Osteopathic General Licensure

An individual seeking to be licensed as an osteopathic physician must meet the following requirements:[14]

- Pay an application fee;[15]
- Be at least 21 years of age;
- Be of good moral character;
- Complete at least 3 years of pre-professional post-secondary education;
- Has not committed, or be under investigation in any jurisdiction for, an act or offense that would constitute the basis for disciplining an osteopathic physician, unless the osteopathic board determines such act does not adversely affect the applicant's present ability and fitness to practice osteopathic medicine;
- Has not had an application for a license to practice osteopathic medicine denied or a license to practice osteopathic medicine revoked, suspended, or otherwise acted against by the licensing authority in any jurisdiction;
- Has not received less than a satisfactory evaluation from an internship, residency, or fellowship training program;
- Has submitted to a background screening by the DOH;
- Is a graduate of a medical college recognized and approved by the American Osteopathic Association;
- Successfully completes a resident internship of at least 12 months in a hospital approved by the Board of Trustees of the American Osteopathic Association or any other internship approved by the osteopathic board; and
- Obtains a passing score, as established by rule of the osteopathic board, on the examination conducted by the National Board of Osteopathic Medical Examiners or other examination approved by the osteopathic board, no more than five years prior to applying for licensure.[16]

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[12] Rule 64B8-13.005(9), F.A.C. Indigency is persons of low-income (no greater than 150 percent of the federal poverty level) or uninsured persons.
[13] Section 456.031, F.S.
[14] Section 459.0055(1), F.S.
[15] Pursuant to r. 64B15-10.002, F.A.C., the application fee for a person desiring to be licensed as an osteopathic physician by examination is $200. The applicant must pay an initial license fee of $305. Section 766.314(4), F.S., assesses a fee to be paid with at time of an initial license to finance the Florida Birth-Related Neurological Injury Compensation Plan. The current assessment amount is $250.
[16] However, if an applicant has been actively licensed in another state, the initial licensure in the other state must have occurred no more than five years after the applicant obtained the passing score on the licensure examination.

Osteopathic Licensure by Endorsement

If an applicant for a license to practice osteopathic medicine is licensed in another state, the applicant must have actively practiced osteopathic medicine within the two years prior to applying for licensure in this state.[17] If it has been more than two years since the active practice of osteopathic medicine and more than two years since completion of a resident internship, residency, or fellowship and if the osteopathic board determines that the disruption in practice has adversely affected the osteopathic physician's present ability to practice, the osteopathic board may:[18]

- Deny the application;
- Issue the license with reasonable restrictions or conditions; or
- Issue the license upon receipt of documentation confirming the applicant has met any reasonable conditions of the osteopathic board.

Osteopathic License Renewal

Osteopathic physician licenses are renewed biennially. The current fee for the timely renewal of a license is $429; this fee also applies to restricted licenses and temporary certificates for practice in areas of critical need.[19] However, the renewal fees are waived if an osteopathic physician holding a restricted license or temporary certificate for practice in areas of critical need submits a notarized statement from his or her employer stating that the physician will not receive monetary compensation for the provision of medical services.[20]

Within each biennial licensure renewal period, an osteopathic physician must complete 40 hours of CME courses approved by the osteopathic board. As a part of the 40 hours of CME, a licensee must also complete the following:

- A two-hour course regarding domestic violence every third biennial;[21]
- A one-hour course addressing the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome no later than upon the first biennial licensure renewal;[22]
- Two hours of CME relating to the prevention of medical errors;[23]
- A one-hour course on profession and medical ethics education; and
- A one-hour course on the federal and state laws related to the prescribing of controlled substances.[24]

The osteopathic board authorizes up to 10 hours of the required CME hours to be fulfilled by the performance of pro bono medical services to indigent or underserved persons or in areas of critical need.[25] The osteopathic board has approved federally-funded community and migrant health centers, volunteer health care provider programs contracted to provide uncompensated care with DOH, and DOH as pro bono sites. If pro bono services are to be provided to any other entity, the licensee must obtain prior approval for such services to apply to the CME requirement.

DOH may not renew a license until a licensee complies with all CME requirements.[26] The osteopathic board may also take action against a license for failure to comply with CME requirements.[27]

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[17] Section 459.0055(2), F.S.
[18] Id.
[19] Rule 64B8-3.003, F.A.C. If a practitioner dispenses medicinal drugs, an additional fee of $100 must be paid at the time of renewal.
[20] Id.
[21] Section 456.031, F.S.
[22] Section 456.033, F.S.
[23] Section 456.013(7), F.S.
[24] Rule 64B15-13.001, F.A.C.
[25] Rule 64B15-13.005, F.A.C. Indigency refers to persons of low-income (no greater than 150 percent of the federal poverty level) or uninsured persons.
[26] Section 456.0361, F.S.
[27] Section 456.0361(2). F.S.

Financial Responsibility

Both allopathic and osteopathic physicians must carry malpractice insurance or demonstrate proof of financial responsibility as a condition of licensure or renewal of licensure. A physician may meet this requirement by:

- Maintaining financial liability coverage in an amount of at least $100,000 per claim, with a minimum annual aggregate of at least $300,000 if the licensee does not have hospital privileges;
- Maintaining financial liability coverage in an amount of at least $250,000 per claim, with a minimum annual aggregate of at least $750,000 if the licensee has hospital privileges;
- Maintaining an unexpired, irrevocable letter of credit or an escrow account in an amount of at least $100,000 per claim, with a minimum aggregate availability of at least $300,000 if the licensee does not have hospital privileges;
- Maintaining an unexpired, irrevocable letter of credit or an escrow account in an amount of at least $250,000 per claim, with a minimum aggregate availability of at least $750,000 if the licensee has hospital privileges; or
- Not obtaining malpractice insurance or demonstrating financial ability but agreeing to satisfy any adverse judgments and prominently posting a notice in the reception area to notify all patients of such decision.[28]

Physician Licensure for Volunteer and Low-Income Practice

Allopathic Restricted Licenses

Current law authorizes the allopathic board to issue restricted licenses to practice medicine in this state, without examination, for physicians who contracts to practice for 24 months solely in the employ of the state or a federally funded community health center or migrant health center. An applicant for a restricted license must also: [29]

- Meet the requirements for licensure by examination; and
- Have actively practiced medicine in another jurisdiction for at least two years of the immediately preceding four years or has completed board-approved postgraduate training within the year preceding submission of the application.

A restricted licensee must take and pass the licensure examination prior to completion of the 24-month practice period.[30] A restricted licensee who breaches the terms of his or her contract is prohibited from being licensed as a physician in this state.[31]

The allopathic board may issue up to 100 restricted licenses annually.[32]

Osteopathic Limited Licenses

Current law authorizes the osteopathic board to issue limited licenses to certain osteopathic physicians who will only practice in areas of critical need or in medically underserved areas. A limited license may be issued to an individual who: [33]

- Submits the licensure application and required application fee of $100;

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[28] Sections 458.320, F.S., and 459.0085, F.S.
[29] Section 458.310, F.S.
[30] Section 458.310(3), F.S.
[31] Section 458.310(4), F.S.
[32] Section 458.310(2), F.S.
[33] Section 459.0075, F.S., and r. 64B15-12.005, F.A.C.

- Provides proof that he or she has been licensed to practice osteopathic medicine in any jurisdiction of the United States in good standing for at least 10 years;
- Has completed at least 40 hours of continuing education within the preceding two year period; and
- Will only practice in the employ of public agencies, nonprofit entities, or agencies or institutions in areas of critical need or in medically underserved areas.

If it has been more than three years since the applicant has actively practiced osteopathic medicine, the full-time director of the local county health department must supervise the applicant for at least six months after issuance of the limited license.[34]

The osteopathic board must review the practice of each physician who holds a limited license at least biennially to ensure that he or she is in compliance with the practice act and rules adopted thereunder.[35]

Temporary Certificate for Practice in Areas of Critical Need

The boards may issue a temporary certificate to practice in areas of critical need to an allopathic or osteopathic physician who will practice in an area of critical need. An applicant for a temporary certificate must: [36]

- Be actively licensed to practice medicine in any jurisdiction of the U.S.;
- Be employed by or practice in a county health department, correctional facility, Department of Veterans' Affairs clinic, federally-funded community health care center, or any other agency or institution designated by the State Surgeon General and provides health care to underserved populations; or
- Practice for a limited time to address critical physician-specialty, demographic, or geographic needs for this state's workforce as determined by the Surgeon General.

The allopathic and osteopathic boards are authorized to administer an abbreviated oral examination to determine a physician's competency, but a written examination is not required.[37] The boards may deny the application, issue the temporary certificate with reasonable restrictions, or require the applicant to meet any reasonable conditions of the allopathic or osteopathic board prior to issuing the temporary certificate if it has been more than three years since the applicant has actively practiced and the board determines the applicant lacks clinical competency, adequate skills, necessary medical knowledge, or sufficient clinical decision-making.[38]

Fees for the temporary certificate for practice in areas of critical need include a $300 application fee and $429 initial licensure fee; however, these fees may be waived if the individual is not compensated for his or her practice.[39] The temporary certificate is only valid for as long as the Surgeon General determines that critical need remains an issue in this state.[40] However, the allopathic and osteopathic boards must review the temporary certificate holder at least annually to ensure that he or she is in compliance with the practice act and rules adopted thereunder.[41] The allopathic board may revoke or restrict the temporary certificate for practice in areas of critical need, if noncompliance is found.[42]

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[34] Section 459.0075(2), F.S.
[35] Section 459.0075(5), F.S.
[36] Sections 458.315, and 459.0076, F.S.
[37] Id.
[38] Sections 458.315(3)(b), and 459.0076(3)(b), F.S.
[39] Rules 64B8-3.003, and 64B15-10.002, F.A.C.
[40] Sections 458.315(3), and 459.0076(3), F.S.
[41] Sections 458.315(3)(c), and 459.0076(3)(c), F.S.
[42] Id.

Florida Volunteer Protection Act

The Florida Volunteer Protection Act (FVPA), s. 768.1355, F.S., limits the civil liability for volunteers. Under the FVPA, any person who volunteers to perform any service for any nonprofit organization, without compensation from the nonprofit organization, regardless of whether the person is receiving compensation from another source, is an agent of the nonprofit organization when acting within the scope of any official duties.[43] The FVPA exempts volunteers from civil liability for any act or omission which results in personal injury or property damage if:[44]

- The volunteer was acting in good faith within the scope of any official duties;
- The volunteer was acting as an ordinary reasonably prudent person would have acted under the same or similar circumstances; and
- The injury or damage was not caused by any wanton or willful misconduct of the volunteer in the performance of such duties.

If a volunteer is determined not to be liable pursuant to these provisions, the nonprofit organization for which the volunteer was performing services when the damages were caused is liable for the damages to the same extent as the nonprofit organization would have been liable if the liability limitation under the Act had not been provided.[45]

Access to Health Care Act

The "Access to Health Care Act" (Act), s. 766.1115, F.S., was enacted in 1992 to encourage health care providers to provide care to low-income persons.[46] Low-income persons include:

- A person who is Medicaid-eligible;
- A person who is without health insurance and whose family income does not exceed 200 percent of the federal poverty level;[47] or
- Any eligible client of DOH who voluntarily chooses to participate in a program offered or approved by the department.

Health care providers under the Act include, among others, allopathic and osteopathic physicians.[48] DOH administers the Act through the Volunteer Health Services Program, which works with DOH entities and community and faith-based health care providers to promote access to quality health care for the medically underserved and uninsured in this state.[49]

The Act grants sovereign immunity[50] to health care providers who execute a contract with a governmental contractor[51] and who, as agents of the state, provide volunteer, uncompensated health

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[43] Section 766.1355, F.S. Compensation does not include reimbursement for actual expenses, a stipend under the Domestic Service Volunteer Act of 1973 (i.e. Americorps and SeniorCorps), or other financial assistance that is valued at less than two-thirds of the federal minimum wage.
[44] Section 768.1355(1), F.S.
[45] Section 768.1355(3), F.S.
[46] Section 766.115, F.S.
[47] A single individual whose annual income does not exceed $24,120 or a family of four whose household or family income does not exceed $49,200 is at 200 percent of the federal poverty level. U.S. Department of Health and Human Services, *HHS Poverty Guidelines for 2017*, (January 26, 2017), available at https://aspe.hhs.gov/poverty-guidelines (last visited November 21, 2017).
[48] Section 766.1115(3)(d), F.S.,
[49] DOH, *Volunteer Health Services*, available at http://www.floridahealth.gov/provider-and-partner-resources/getting-involved-in-public-health/volunteer-health-services-opportunities/index.html (last visited November 21. 2017).
[50] The legal doctrine of sovereign immunity prevents a government from being sued in its own courts without its consent. According to United States Supreme Court Justice Oliver Wendell Holmes, citing the noted 17th century Hobbes work, *Leviathan*, "a sovereign is exempt from suit, not because of any formal conception or obsolete theory, but on the logical and practical ground that there can be no legal right as against the authority that makes the law on which the right depends." State governments in the United States, as sovereigns, inherently possess sovereign immunity. Article X, section 13 of the Florida Constitution recognizes the concept of sovereign immunity and gives the Legislature the power to waive immunity in part or in full by general law. Section 768.28, F.S., contains the limited waiver of sovereign immunity applicable to the state. Under this statute, officers, employees, and agents of the state will not be

care services to low-income individuals. These health care providers are considered agents of the state under s. 768.28(9), F.S., so have sovereign immunity while acting within the scope of duties required under the Act.[52] Therefore, the state will defend a health care provider covered under the Act in any action alleging harm or injury, and any recovery would be limited to $200,000 for one incident and a total of $300,000 for all recoveries related to one incident.

A contract under the Act must pertain to volunteer, uncompensated services for which the provider may not receive compensation from the governmental contractor for any services provided under the contract and must not bill or accept compensation from the recipient or any public or private third-party payor for the specific services provided to the low-income recipients covered by the contract.[53]

The Act establishes several contractual requirements for government contractors and health care providers. The contract must require the government contractor to retain the right of dismissal or termination of any health care provider delivering services under the contract[54] and to have access to the patient records of any health care provider delivering services under the contract.[55] The health care provider must, under the contract, report adverse incidents and information on treatment outcomes to the governmental contractor.[56] The governmental contractor or the health care provider must make patient selection and initial referrals.[57] The health care provider is subject to supervision and regular inspection by the governmental contractor.[58]

The governmental contractor must provide written notice to each patient, or the patient's legal representative, receipt of which must be acknowledged in writing, that the provider is covered under s. 768.28, F.S., for purposes of legal actions alleging medical negligence.[59]

In Fiscal Year 2016-2017, 13,538 licensed health care professionals (plus an additional 12,446 clinic staff volunteers) provided 442,608 health care services under the Act.[60]

Since February 15, 2000, 10 claims have been filed against the Volunteer Health Services Program.[61]

Effect of Proposed Changes

Restricted Licenses to Practice Medicine or Osteopathic Medicine

The bill amends the criteria for the allopathic board to issue restricted licenses to practice allopathic medicine, and authorizes the osteopathic board to issue restricted licenses to practice osteopathic medicine to physicians who contract to practice for 36 months in certain settings. The contract must be for employment by:

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held personally liable in tort or named as a party defendant in any action for any injury or damage suffered as a result of any act, event, or omission of action in the scope of her or his employment or function. However, personal liability may result from actions committed in bad faith or with malicious purpose or in a manner exhibiting wanton and willful disregard of human rights, safety, or property. When an officer, employee, or agency of the state is sued, the state steps in as the party litigant and defends against the claim. A person may recover no more than $200,000 for one incident and the total for all recoveries related to one incident is limited to $300,000. The sovereign immunity recovery caps do not prevent a plaintiff from obtaining a judgment in excess of the caps, but the plaintiff cannot recover the excess damages without action by the Legislature. *See* Black's Law Dictionary, 3rd Pocket Edition, 2006; *Kawananakoa v Polyblank*, 205 U.S. 349, 353 (1907); Fla. Jur. 2d, Government Tort Liability, Sec. 1.; Section 768.28, F.S.

[51] A governmental contractor is the DOH, a county health department, a special taxing district having health care responsibilities, or a hospital owned and operated by a governmental entity. Section 766.1115(3)(c), F.S.

[52] Section 766.1115(4), F.S.

[53] Section 766.1115(3)(a), F.S.

[54] Section 766.1115(4)(a), F.S

[55] Section 766.1115(4)(b), F.S

[56] Section 766.1115(4)(c), F.S

[57] Section 766.1115(4)(d), F.S

[58] Section 766.1115(4)(f), F.S.

[59] Section 766.1115(5), F.S.

[60] E-mail correspondence with DOH staff dated November 27, 2017, (on file with the Health Quality Subcommittee).

[61] E-mail correspondence with DOH staff dated November 29, 2017, (on file with the Health Quality Subcommittee).

- This state;
- A federally funded community health center;
- A migrant health center:
- A free clinic that only delivers medical diagnostic services or nonsurgical medical treatment free of charge to all low-income residents; or
- A health provider in a health professional shortage area or medical underserved areas, as designated by the U.S. Department of Health and Human Services.[62]

Each board may issue no more than 300 restricted licenses; however, the boards may issue an unlimited number of restricted licenses to physicians who hold active unencumbered licenses in Canada. To obtain a restricted license, an applicant must:

- Submit a completed application, along with a nonrefundable fee not to exceed $50;
- Be at least 21 years old;
- Be of good moral character;
- Have not committed an act or offense that would constitute the basis for disciplining a physician pursuant to s. 458.331, F.S., or an osteopathic physician pursuant to ch. 459, F.S.;
- Submit to a background screening by DOH; however, a Canadian applicant must also provide the applicable board with a printed or electronic copy of his or her national, fingerprint-based Canadian criminal history records check, which must have been completed within six months of the date of application;
- Submit evidence of the active licensed practice of medicine or osteopathic medicine, as appropriate in another jurisdiction for at least two of the immediately preceding four years, or completion of postgraduate training approved by the appropriate board within the year preceding the filing of an application;
- Enter into a contract to practice for 36 months solely in the employ of the state, a federally funded community health center, a migrant health center, a free clinic, or a health provider in a health professional shortage area or medical underserved areas, as designated by the U.S. Department of Health and Human Services.

Additionally, an osteopathic physicians applying for a restricted license must demonstrate completion of at least three years of pre-professional postsecondary education, that he or she is not under investigation in any jurisdiction that would constitute a violation of the osteopathic medicine practice act, and that he or she has not had an application for a license to practice osteopathic medicine denied or a license to practice osteopathic medicine revoked, suspended, or otherwise acted against, by the licensing authority in any jurisdiction.

Prior to the conclusion of the contracted practice period, an allopathic or osteopathic physician must take the appropriate licensure examination to become fully licensed in this state. However, a physician who breaches the terms of the employment contract may not be licensed as a physician in this state.

The bill also repeals the authority of the Board of Medicine to adopt rules related to the criteria for the issuance of restricted licenses. However, both the allopathic and osteopathic boards have broad grants of rulemaking authority to adopt rules implementing statutes related to the licensure and regulation of physicians.[63] Therefore, the boards may adopt any rules necessary to implement the restricted licenses.

The bill maintains current law authorizing limited licenses for osteopathic physicians.

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[62] As of November 2017, Florida has 641 health professional shortage areas and 128 medically underserved areas. *See* https://datawarehouse.hrsa.gov/topics/shortageAreas.aspx (last visited November 21, 2017) (hover over Florida on the map to get the number of health professional shortage areas and click on the State Summary of Medically Underserved Areas/Populations to obtain the number of medically underserved areas).

[63] *See* s. 458.309 and 459.005, F.S.

Volunteer Retired Physician Registration

The bill creates a registration program to allow retired physicians to practice medicine under contact with a health care provider to provide free, volunteer health care services to indigent persons or medically underserved populations in a health professional shortage area or medically underserved area, as designated by the U.S. Department of Health and Human Services.

The bill authorizes a retired physician to register as a volunteer retired physician if the physician:

- Submits an application to the board within two years of changing the license to practice from active status to retired status for an allopathic physician, of if he or submits an application to board no more than six months before the license permanently expires and no later than two years after such expiration for an osteopathic physician;
- Provides proof of active practice medical practice for at least three of the five years immediately preceding the date on which the license changed from active status to retired status for an allopathic physician;
- Has held an active licensed status to practice and maintained such license in good standing in this state or in another jurisdiction or the United States or Canada for at least 20 years;
- Works under the supervision of a non-retired allopathic physician or osteopathic physician, as applicable, who holds an active unencumbered license;
- Only provides medical services of the type and within the specialty performed by the physician prior to retirement; and
- Does not perform surgery or prescribe controlled substances.

DOH must waive all application, licensure, unlicensed activity, and renewal fees for retired physicians who qualify for registration under the provisions of the bill. Registration must be renewed biennially to demonstrate compliance with registration requirements. A board may deny, revoke, or impose restrictions or conditions on a registration if there is a violation of the practice act or the core licensing statute (ch. 456, F.S.) A board may also revoke or deny a registration for failure to comply with registration requirements.

Licensure Renewals

The bill requires DOH to waive the licensure renewal fee of an allopathic or osteopathic physician who demonstrates to DOH, in a manner provided by board rule, that he or she has provided at least 160 hours of pro bono medical services to indigent persons or medically underserved populations within the biennial renewal period.

If an allopathic or osteopathic physician provides documentation to DOH that he or she has provided at least 120 hours of pro bono medical services within the biennial licensure period, he or she is exempt from the 40 hours of continuing medical education required for license renewal. This exemption would also apply to any of the specific courses, such as the courses on domestic violence and prevention of medical errors, that are calculated as a part of as a part of the required 40 hours of continuing medical education.

A physician may receive both the waiver of the licensure renewal fee and an exemption from the continuing medical education requirements if the required number of pro bono hours are provided.

Physician Licensure by Examination

Currently, allopathic physicians who hold an active unencumbered license to practice medicine in Canada who have practiced at least 10 years may use a passing score the Special Purpose Examination of the Federation of State Medical Boards of the United States to qualify for licensure in this state. The bill clarifies the requirement that allopathic physicians licensed in Canada must practice

for 10 years to use the Special Purpose Examination of the Federation of State Medical Boards of the United States to qualify for licensure in this state.

Access to Health Care Act

The bill increases the eligibility for services under the Act by amending the definition of low-income to mean a person without health insurance and whose family income does not exceed 400 percent of the federal poverty level, rather than the 200 percent in current law.

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 456.013, F.S., relating to department; general licensing provisions.
Section 2: Amends s. 458.310, F.S., relating to restricted licenses.
Section 3: Creates s. 458.3105, F.S., relating to registration of volunteer retired physicians.
Section 4: Amends s. 458.311, F.S., relating to licensure by examination; requirements; fees.
Section 5: Amends s. 458.319, F.S., relating to renewal of license.
Section 6: Creates s. 459.00751, F.S., relating to restricted licenses.
Section 7: Creates s. 459.00752, F.S., relating to registration of volunteer retired osteopathic physicians.
Section 8: Amends s. 459.008, F.S., relating to renewal of licenses and certificates.
Section 9: Amends s. 766.1115, F.S., relating to health care providers; creation of agency relationship with governmental contractors.
Section 10: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill may have an indeterminate positive fiscal impact on DOH associated with the new application fees for osteopathic physician restricted licenses.[64] It is unknown how many may apply, but is not likely to be significant.

2. Expenditures:

   The bill may have an insignificant negative fiscal impact on DOH associated with the loss of application, licensure, unlicensed activity, and/or renewal fees for those physicians who qualify for the waiver of such fees. It is unknown how many may apply, but is not likely to be significant.

   DOH may experience an insignificant, negative nonrecurring fiscal impact for rulemaking activities and an insignificant, negative recurring fiscal impact for labor costs associated with processing the restricted licenses and registrations authorized under the provisions of the bill. However, current resources are sufficient to absorb such costs.[65]

   DOH may experience an indeterminate, nonrecurring negative fiscal impact for modifications to its Licensing and Enforcement Information Database to accommodate requirements of the bill.[66] DOH estimates that current resources are sufficient to absorb these costs.[67]

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[64] DOH, *2018 Agency Legislative Bill Analysis: House Bill 313*, (October 25, 2017), on file with the Health Quality Subcommittee.
[65] Id.
[66] Id.
[67] Id.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Physicians performing pro bono medical services may not have to pay licensure renewal fees or pay for continuing education courses.

Entities providing continuing education courses may experience reduced enrollment if physicians provide at least 120 hours of pro bono medical services and take advantage of the continuing education exemption.

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:

Both the allopathic and osteopathic boards have broad grants of rulemaking authority to adopt rules under their respective practice acts; therefore, no additional rulemaking authority is needed

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On December 6, 2017, the Health Quality Subcommittee adopted an amendment that did the following:

- Required the Canadian background screening for a restricted license be a fingerprint-based, national criminal history check performed within six months of the date of application;
- Clarified that DOH must waive all application, licensure, and renewal fees for registered volunteer retired physicians; and
- Made other technical, non-substantive changes.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.

A bill to be entitled

An act relating to access to health care practitioner services; amending s. 456.013, F.S.; exempting physicians who provide a certain number of hours of pro bono services from continuing education requirements; amending s. 458.310, F.S.; revising the eligibility criteria for a restricted license; prohibiting licensure if a restricted licensee breaches the terms of an employment contract; creating s. 458.3105, F.S.; establishing a registration program for volunteer retired physicians; providing eligibility criteria for such registration; requiring biennial registration renewal; requiring the Department of Health to waive certain fees; authorizing the Board of Medicine to deny, revoke, or impose restrictions or conditions on a registration for certain violations; amending s. 458.311, F.S.; revising the physician licensure criteria applicable to Canadian applicants; amending s. 458.319, F.S.; requiring the department to waive a physician's license renewal fee under certain circumstances; deleting an obsolete date; creating s. 459.00751, F.S.; providing legislative intent; authorizing the Board of Osteopathic Medicine to issue a restricted license to qualified applicants; providing eligibility

criteria for such license; prohibiting licensure if a restricted licensee breaches the terms of an employment contract; creating s. 459.00752, F.S.; establishing a registration program for volunteer retired osteopathic physicians; providing eligibility criteria for such registration; requiring biennial registration renewal; requiring the Department of Health to waive certain fees; authorizing the Board of Osteopathic Medicine to deny, revoke, or impose restrictions or conditions on a registration for certain violations; amending s. 459.008, F.S.; requiring the department to waive an osteopathic physician's license renewal fee under certain circumstances; deleting an obsolete date; amending s. 766.1115, F.S.; revising the definition of the term "low-income" for purposes of the Access to Health Care Act; providing an effective date.

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

Section 1. Subsection (6) of section 456.013, Florida Statutes, is republished, and subsection (9) of that section is amended, to read:

456.013 Department; general licensing provisions.—

(6) As a condition of renewal of a license, the Board of

Medicine, the Board of Osteopathic Medicine, the Board of Chiropractic Medicine, and the Board of Podiatric Medicine shall each require licensees which they respectively regulate to periodically demonstrate their professional competency by completing at least 40 hours of continuing education every 2 years. The boards may require by rule that up to 1 hour of the required 40 or more hours be in the area of risk management or cost containment. This provision shall not be construed to limit the number of hours that a licensee may obtain in risk management or cost containment to be credited toward satisfying the 40 or more required hours. This provision shall not be construed to require the boards to impose any requirement on licensees except for the completion of at least 40 hours of continuing education every 2 years. Each of such boards shall determine whether any specific continuing education requirements not otherwise mandated by law shall be mandated and shall approve criteria for, and the content of, any continuing education mandated by such board. Notwithstanding any other provision of law, the board, or the department when there is no board, may approve by rule alternative methods of obtaining continuing education credits in risk management. The alternative methods may include attending a board meeting at which another licensee is disciplined, serving as a volunteer expert witness for the department in a disciplinary case, or serving as a member of a probable cause panel following the expiration of a

board member's term. Other boards within the Division of Medical Quality Assurance, or the department if there is no board, may adopt rules granting continuing education hours in risk management for attending a board meeting at which another licensee is disciplined, for serving as a volunteer expert witness for the department in a disciplinary case, or for serving as a member of a probable cause panel following the expiration of a board member's term.

(9) Any board that currently requires continuing education for renewal of a license, or the department if there is no board, shall adopt rules to establish the criteria for continuing education courses. The rules may provide that up to a maximum of 25 percent of the required continuing education hours can be fulfilled by the performance of pro bono services to the indigent or to underserved populations or in areas of critical need within the state where the licensee practices. However, a physician licensed under chapter 458 or chapter 459 who submits to the department documentation proving that he or she has completed at least 120 hours of pro bono services within a biennial licensure period is exempt from the continuing education requirements established by board rule under subsection (6). The board, or the department if there is no board, must require that any pro bono services be approved in advance in order to receive credit for continuing education under this subsection. The standard for determining indigency

shall be that recognized by the Federal Poverty Income Guidelines produced by the United States Department of Health and Human Services. The rules may provide for approval by the board, or the department if there is no board, that a part of the continuing education hours can be fulfilled by performing research in critical need areas or for training leading to advanced professional certification. The board, or the department if there is no board, may make rules to define underserved and critical need areas. The department shall adopt rules for administering continuing education requirements adopted by the boards or the department if there is no board.

Section 2. Subsections (2) and (3) of section 458.310, Florida Statutes, are amended to read:

458.310 Restricted licenses.—

(2) The board ~~of Medicine~~ may annually~~, by rule, develop criteria and, without examination,~~ issue restricted licenses authorizing the practice of medicine in this state to not more than 300 persons and to an unlimited number of physicians who hold active unencumbered licenses to practice medicine in Canada if such applicants ~~annually to up to 100 persons to practice medicine in this state who~~:

(a) Submit to the department a completed application form and a nonrefundable application fee not to exceed $50;

(b)~~(a)~~ Meet the requirements of s. 458.311(1)(b), (c), (d), and (g). A Canadian applicant must also provide the board

with a printed or electronic copy of his or her fingerprint-based, national Canadian criminal history records check, conducted within 6 months after the date of application;

(c) ~~(b)~~ Show evidence of the active licensed practice of medicine in another jurisdiction for at least 2 years of the immediately preceding 4 years, or completion of board-approved postgraduate training within the year preceding the filing of an application; and

(d) ~~(c)~~ Enter into a contract to practice for a period of up to 36 ~~24~~ months ~~solely~~ in the employ of the state, ~~or~~ a federally funded community health center, or a migrant health center; a free clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to all low-income residents; or a health care provider in a health professional shortage area or medically underserved area designated by the United States Department of Health and Human Services~~, at the current salary level for that position~~. The board may ~~of Medicine shall~~ designate other areas of critical need in the state where these restricted licensees may practice.

(3) Before the end of the contracted ~~24-month~~ practice period, the physician must take and successfully complete the licensure examination under s. 458.311 to become fully licensed in this state.

Section 3. Section 458.3105, Florida Statutes, is created to read:

458.3105 Registration of volunteer retired physicians.—

(1) A physician may register under this section to practice medicine as a volunteer retired physician if the physician:

(a) Submits an application to the board on a form developed by the department within 2 years after the date on which the physician's license changed from active status to retired status;

(b) Provides proof to the department that the physician actively practiced medicine for at least 3 of the 5 years immediately preceding the date on which his or her license changed from active status to retired status;

(c) Has held an active license to practice medicine and maintained such license in good standing in this state or in at least one other jurisdiction of the United States or Canada for at least 20 years;

(d) Contracts with a health care provider to provide free, volunteer health care services to indigent persons or medically underserved populations in health professional shortage areas or medically underserved areas designated by the United States Department of Health and Human Services;

(e) Works under the supervision of a nonretired physician who holds an active unencumbered license; and

(f) Only provides medical services of the type and within the specialty performed by the physician before retirement and

does not perform surgery or prescribe a controlled substance as defined in s. 893.02(4).

(2) The registrant shall apply biennially to the board for renewal of his or her registration by demonstrating to the board compliance with this section.

(3) The department shall waive all application, licensure, unlicensed activity, and renewal fees for qualifying applicants under this section.

(4) The board may deny, revoke, or impose restrictions or conditions on a registration for any violation of this chapter or chapter 456 or the rules adopted under this chapter or chapter 456.

(5) The board may deny or revoke registration for noncompliance with this section.

Section 4. Paragraph (h) of subsection (1) of section 458.311, Florida Statutes, is amended to read:

458.311 Licensure by examination; requirements; fees.—

(1) Any person desiring to be licensed as a physician, who does not hold a valid license in any state, shall apply to the department on forms furnished by the department. The department shall license each applicant who the board certifies:

(h) Has obtained a passing score, as established by rule of the board, on the licensure examination of the United States Medical Licensing Examination (USMLE); or a combination of the United States Medical Licensing Examination (USMLE), the

examination of the Federation of State Medical Boards of the United States, Inc. (FLEX), or the examination of the National Board of Medical Examiners up to the year 2000; or for the purpose of examination of any applicant who was licensed on the basis of a state board examination and who is currently licensed in at least one other jurisdiction of the United States ~~or Canada,~~ and who has practiced pursuant to such licensure for a period of at least 10 years, or for the purpose of examination of any applicant who holds an active unencumbered license to practice medicine in Canada and who has practiced pursuant to such licensure for a period of at least 10 years, use of the Special Purpose Examination of the Federation of State Medical Boards of the United States (SPEX) upon receipt of a passing score as established by rule of the board. However, for the purpose of examination of any applicant who was licensed on the basis of a state board examination before ~~prior to~~ 1974, who is currently licensed in at least three other jurisdictions of the United States or Canada, and who has practiced pursuant to such licensure for a period of at least 20 years, this paragraph does not apply.

Section 5. Subsection (1) of section 458.319, Florida Statutes, is amended to read:

458.319 Renewal of license.—

(1) The department shall renew a license upon receipt of the renewal application, evidence that the applicant has

actively practiced medicine or has been on the active teaching faculty of an accredited medical school for at least 2 years of the immediately preceding 4 years, and a fee not to exceed $500; provided, however, that if the licensee is either a resident physician, assistant resident physician, fellow, house physician, or intern in an approved postgraduate training program, as defined by the board by rule, the fee shall not exceed $100 per annum. If the licensee demonstrates to the department in a manner set by department rule that he or she has provided at least 160 hours of pro bono medical services to indigent persons or medically underserved populations within the biennial renewal period, the department shall waive the renewal fee. If the licensee has not actively practiced medicine for at least 2 years of the immediately preceding 4 years, the board shall require that the licensee successfully complete a board-approved clinical competency examination before ~~prior to~~ renewal of the license. "Actively practiced medicine" means that practice of medicine by physicians, including those employed by any governmental entity in community or public health, as defined by this chapter, including physicians practicing administrative medicine. An applicant for a renewed license must also submit the information required under s. 456.039 to the department on a form and under procedures specified by the department, along with payment in an amount equal to the costs incurred by the Department of Health for the statewide criminal

background check of the applicant. The applicant must submit a set of fingerprints to the Department of Health on a form and under procedures specified by the department, along with payment in an amount equal to the costs incurred by the department for a national criminal background check of the applicant for the initial renewal of his or her license ~~after January 1, 2000~~. If the applicant fails to submit either the information required under s. 456.039 or a set of fingerprints to the department as required by this section, the department shall issue a notice of noncompliance, and the applicant will be given 30 additional days to comply. If the applicant fails to comply within 30 days after the notice of noncompliance is issued, the department or board, as appropriate, may issue a citation to the applicant and may fine the applicant up to $50 for each day that the applicant is not in compliance with the requirements of s. 456.039. The citation must clearly state that the applicant may choose, in lieu of accepting the citation, to follow the procedure under s. 456.073. If the applicant disputes the matter in the citation, the procedures set forth in s. 456.073 must be followed. However, if the applicant does not dispute the matter in the citation with the department within 30 days after the citation is served, the citation becomes a final order and constitutes discipline. Service of a citation may be made by personal service or certified mail, restricted delivery, to the subject at the applicant's last known address. If an applicant has

submitted fingerprints to the department for a national criminal history check upon initial licensure and is renewing his or her license for the first time, then the applicant need only submit the information and fee required for a statewide criminal history check.

Section 6. Section 459.00751, Florida Statutes, is created to read:

459.00751 Restricted licenses.—

(1) It is the intent of the Legislature to provide medical services to all residents of this state at an affordable cost.

(2) The board may annually issue restricted licenses authorizing the practice of osteopathic medicine in this state to not more than 300 persons and to an unlimited number of osteopathic physicians who hold active unencumbered licenses to practice medicine in Canada if such applicants:

(a) Submit to the department a completed application form and a nonrefundable application fee not to exceed $50;

(b) Meet the requirements of s. 459.0055(1)(b), (c), (d), (e), (f), (g), and (j). A Canadian applicant must also provide the board with a printed or electronic copy of his or her fingerprint-based, national Canadian criminal history records check, conducted within 6 months after the date of application;

(c) Provide proof to the department that the osteopathic physician has held an active license to practice osteopathic medicine and maintained such license in good standing in this

state or in at least one other jurisdiction of the United States or Canada for at least 2 of the immediately preceding 4 years, or completed board-approved postgraduate training within the year immediately preceding the filing of an application; and

(d) Enter into a contract to practice osteopathic medicine for a period of up to 36 months in the employ of the state, a federally funded community health center, or a migrant health center; a free clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to all low-income residents; or a health care provider in a health professional shortage area or medically underserved area designated by the United States Department of Health and Human Services. The board may designate other areas of critical need in the state where these restricted licensees may practice.

(3) Before the end of the contracted practice period, the osteopathic physician must take and successfully complete the licensure examination under s. 459.0055 to become fully licensed in this state.

(4) If the restricted licensee breaches the terms of the employment contract, he or she may not be licensed as an osteopathic physician in this state under any licensing provisions.

Section 7. Section 459.00752, Florida Statutes, is created to read:

459.00752 Registration of volunteer retired osteopathic

physicians.—

(1) An osteopathic physician may register under this section to practice medicine as a volunteer retired osteopathic physician if the osteopathic physician:

(a) Submits an application to the board on a form developed by the department no earlier than 6 months before the date on which the osteopathic physician's license permanently expires and no later than 2 years after such expiration;

(b) Has held an active license to practice osteopathic medicine and maintained such license in good standing in this state or in at least one other jurisdiction of the United States or Canada for at least 20 years;

(c) Contracts with a health care provider to provide free, volunteer health care services to indigent persons or medically underserved populations in health professional shortage areas or medically underserved areas designated by the United States Department of Health and Human Services;

(d) Works under the supervision of a nonretired osteopathic physician who holds an active unencumbered license; and

(e) Only provides medical services of the type and within the specialty performed by the osteopathic physician before retirement and does not perform surgery or prescribe controlled substances as defined in s. 893.02(4).

(2) The registrant shall apply biennially to the board for

renewal of his or her registration by demonstrating to the board compliance with this section.

(3) The department shall waive all application, licensure, unlicensed activity, and renewal fees for qualifying applicants under this section.

(4) The board may deny, revoke, or impose restrictions or conditions on a registration for any violation of this chapter or chapter 456 or the rules adopted under this chapter or chapter 456.

(5) The board may deny or revoke registration for noncompliance with this section.

Section 8. Subsection (1) of section 459.008, Florida Statutes, is amended to read:

459.008 Renewal of licenses and certificates.—

(1) The department shall renew a license or certificate upon receipt of the renewal application and fee. If the licensee demonstrates to the department that he or she has provided at least 160 hours of pro bono osteopathic medical services to indigent persons or medically underserved populations within the biennial renewal period, the department shall waive the renewal fee. An applicant for a renewed license must also submit the information required under s. 456.039 to the department on a form and under procedures specified by the department, along with payment in an amount equal to the costs incurred by the department ~~of Health~~ for the statewide criminal background check

of the applicant. The applicant must submit a set of fingerprints to the Department of Health on a form and under procedures specified by the department, along with payment in an amount equal to the costs incurred by the department for a national criminal background check of the applicant for the initial renewal of his or her license ~~after January 1, 2000~~. If the applicant fails to submit either the information required under s. 456.039 or a set of fingerprints to the department as required by this section, the department shall issue a notice of noncompliance, and the applicant will be given 30 additional days to comply. If the applicant fails to comply within 30 days after the notice of noncompliance is issued, the department or board, as appropriate, may issue a citation to the applicant and may fine the applicant up to $50 for each day that the applicant is not in compliance with the requirements of s. 456.039. The citation must clearly state that the applicant may choose, in lieu of accepting the citation, to follow the procedure under s. 456.073. If the applicant disputes the matter in the citation, the procedures set forth in s. 456.073 must be followed. However, if the applicant does not dispute the matter in the citation with the department within 30 days after the citation is served, the citation becomes a final order and constitutes discipline. Service of a citation may be made by personal service or certified mail, restricted delivery, to the subject at the applicant's last known address. If an applicant has

submitted fingerprints to the department for a national criminal history check upon initial licensure and is renewing his or her license for the first time, then the applicant need only submit the information and fee required for a statewide criminal history check.

Section 9. Paragraph (e) of subsection (3) of section 766.1115, Florida Statutes, is amended to read:

766.1115 Health care providers; creation of agency relationship with governmental contractors.—

(3) DEFINITIONS.—As used in this section, the term:

(e) "Low-income" means:

1. A person who is Medicaid-eligible under Florida law;

2. A person who is without health insurance and whose family income does not exceed 400 ~~200~~ percent of the federal poverty level as defined annually by the federal Office of Management and Budget; or

3. Any client of the department who voluntarily chooses to participate in a program offered or approved by the department and meets the program eligibility guidelines of the department.

Section 10. This act shall take effect July 1, 2018.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 429 Donation and Transfer of Human Tissue
SPONSOR(S): Health Quality Subcommittee; Pigman
TIED BILLS: **IDEN./SIM. BILLS:** SB 514

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N, As CS	Langston	McElroy
2) Health & Human Services Committee		Langston	Calamas

SUMMARY ANALYSIS

Organ and tissue donation is the process of surgically removing an organ or tissue from one person (the donor) and transplanting it into another person (the recipient). Transplantation in such cases is necessary because the recipient's organ has failed or has been damaged by disease or injury.

It is important to determine if the potential donor has an infection that could be transmitted to recipients through the transplanted organs and tissues. Currently, between one and two percent of recipients acquire an unexpected disease transmission, including malignancies, as a result of transplant. Section 381.0041, F.S., requires every donation of blood, plasma, organs, skin, or other human tissue be tested for HIV and other communicable diseases prior to transfusion or transplantation.

CS/HB 429 requires DOH to develop and publish on its website an educational pamphlet on the risks and benefits of human cells, tissue, and cellular and tissue-based product transplants. At a minimum, the pamphlet must include:

- An overview of the risk of infectious disease transmission;
- An overview of the standards for donor testing and screening;
- An overview of sterilization and inactivation processes intended to increase viral safety of donated human cells, tissue, or cellular or tissue-based product;
- The importance of providing limited recipient transplant information to the supplier of the human cells, tissue, or cellular or tissue-based product; and
- Information about the generosity of the human donor who provided the human cells, tissue, or cellular or tissue-based product.

DOH must electronically notify physicians of the availability of this pamphlet.

The bill with have an insignificant negative fiscal impact on DOH, which can be absorbed within existing resources. The bill does not have a fiscal impact on local governments.

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

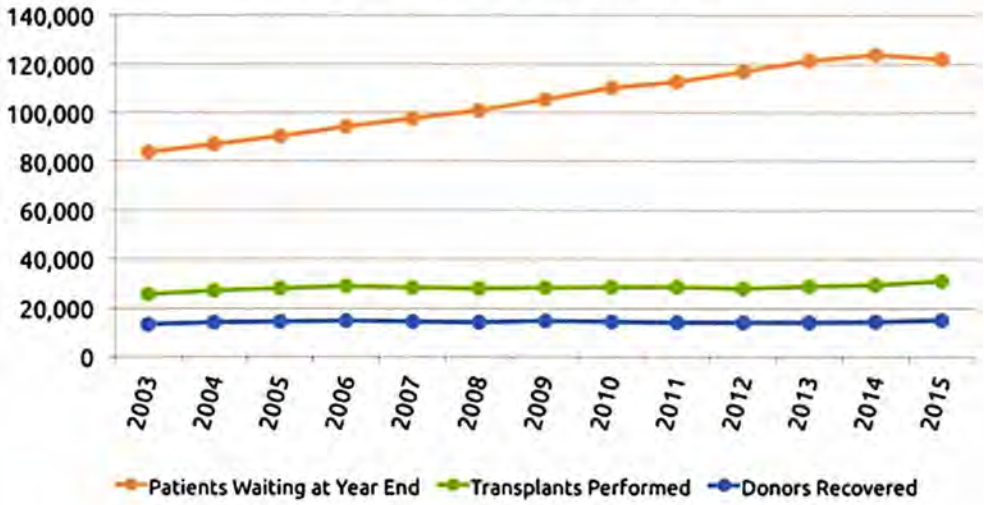
Tissue Donation and Transfer

Organ and tissue donation is the process of surgically removing an organ or tissue from one person (the donor) and transplanting it into another person (the recipient). Transplantation in such cases is necessary because the recipient's organ has failed or has been damaged by disease or injury. Transplantable organs include the kidneys, liver, heart, lungs, pancreas and intestine.[1] Transplantable tissue include skin used as a temporary dressing for burns, serious abrasions and other exposed areas; heart valves used to replace defective valves; tendons used to repair torn ligaments on knees or other joints; veins used in cardiac by-pass surgery; corneas used to restore sight; and bone used in orthopedic surgery to facilitate healing of fractures or prevent amputation.[2]

A single person can save up to eight lives through organ donation, and dozens more lives may be improved through tissue donation.[3] While most organ and tissue donations occur after the donor has died, some organs, including a kidney or part of a liver or lung, and tissues can be donated while the donor is alive.[4] There are about as many living donors every year as there are deceased donors.[5]

Despite advances in medicine and technology, and increased awareness of organ donation and transplantation, more donors are needed to meet the demand for transplants.[6]

National Organ Shortage 2003-2015[7]



[1] DONATE LIFE FLORIDA, *Frequently Asked Questions,* https://www.donatelifeflorida.org/categories/donation/ (last visited January 12, 2018).
[2] Id.
[3] Id.
[4] U.S. GOVERNMENT INFORMATION ON ORGAN DONATION AND TRANSPLANTATION, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, *How Organ Donation Works,* https://organdonor.gov/about/process.html (last visited January 12, 2018).
[5] Id.
[6] ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, https://optn.transplant.hrsa.gov/ (last visited January 12, 2018).
[7] Id.

Today, there are nearly 120,000 children and adults are waiting for organ transplants, including 5,000 in Florida.[8]

The Organ Procurement and Transplantation Network (OPTN) regulates how donor organs are matched and allocated to patients on the waiting list.[9] Non-profit, federally designated organ procurement organizations (OPOs) work closely with OPTN, hospitals, and transplant centers to facilitate the organ donation and transplantation process,[10] including conducting a thorough medical and social history of the potential donor to help determine the suitability of his or her organs for transplantation.[11]

Risk of Infectious Disease Transmission

Currently, between one and two percent of recipients acquire an unexpected disease transmission, including malignancies, through organ and tissue transplants.[12] Possible transmissions include virus transmissions, such as Hepatitis B and C, the human immunodeficiency virus (HIV), and West Nile Virus; bacteria transmissions; fungus transmissions; and parasite transmissions.[13]

Screening and Testing

It is important to determine if the potential donor has an infection that could be transmitted to recipients through the transplanted organs and tissues.[14] This is accomplished through donor interviews and testing.

OPTN policy requires OPOs[15] to conduct a medical and social history interview of the living donor or the deceased donor's next-of-kin to gather information about behaviors that may have exposed the potential donor to certain diseases.[16] OPTN also requires OPOs and living donor recovery centers to test potential donors for:

- HIV
- Hepatitis B
- Hepatitis C
- Syphilis
- Cytomegalovirus
- Epstein Barr Virus
- Tuberculosis (living kidney donors only)

The U.S. Food and Drug Administration (FDA) requires tissue and eye banks to conduct donor screening interviews similar to those required by the OPTN.[17] The FDA also requires donors be tested

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[8] *Supra*, note 3.
[9] U.S. GOVERNMENT INFORMATION ON ORGAN DONATION AND TRANSPLANTATION, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, *The Organ Transplant Process*, https://organdonor.gov/about/process/transplant-process.html (last visited January 12, 2018).
[10] DONATE LIFE FLORIDA, *Organ Procurement Organizations and Transplant Centers*, https://www.donatelifeflorida.org/local-resources/transplant-centers/ (last visited January 12, 2018).
[11] ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, *The Basic Path of Donation*, https://optn.transplant.hrsa.gov/learn/about-donation/the-basic-path-of-donation/ (last visited January 12, 2018).
[12] CENTERS FOR DISEASE CONTROL AND PREVENTION, *Transplant Safety: Outbreak Investigations*, https://www.cdc.gov/transplantsafety/outbreak_investigations.html (last visited January 12, 2018).
[13] Id.
[14] CENTERS FOR DISEASE CONTROL AND PREVENTION, *Transplant Safety: Donor Screening and Testing*, https://www.cdc.gov/transplantsafety/screening_testing.html (last visited January 12, 2018).
[15] U.S. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Vaccines, Blood & Biologics: Tissue Guidances*, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/default.htm
[16] *Supra*, note 14.
[17] Id. The FDA recommends that blood collection centers screen all donations using a screening test authorized for use under an FDA investigational new drug application or use an FDA-approved pathogen-reduction device for plasma and certain platelet products. *Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components: Guidance for Industry*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH,

for HIV, Hepatitis B and C, and syphilis,[18] and tissues that may contain live white blood cells, such as skin, be tested for human T-lymphotropic virus and cytomegalovirus.[19]

Section 381.0041, F.S., requires every donation of blood, plasma, organs, skin, or other human tissue be tested for HIV and other communicable diseases,[20] prior to transfusion[21] or transplantation. Additionally, the institution or physician responsible for overseeing the procedure warn the prospective recipient as to the risks of contracting HIV prior to the transplant of an organ or artificial insemination.[22]

Sterilization and Inactivation

Once screened, OPOs, tissue banks, and donor recovery centers take additional steps to rid tissue of pathogens that might be present on or within the tissue.[23] Corneas are stored in a solution to reduce bacterial growth.[24] Some tissues, such as corneas, blood vessels, heart valves and skin cannot be sterilized because the treatment could damage the tissue; however, other tissues go through a disinfection process.[25] Various sterilization techniques have been used to prevent infection include gamma irradiation,[26] ethylene oxide gas,[27] thermal treatment with moist heat,[28] beta-propiolactone, chemical processing, and antibiotic soaks.[29]

Recipient Follow-Up

It is important that other recipients of organs and tissues from the same donor be quickly traced when a donor-derived disease transmission is suspected or confirmed in a recipient.[30] OPTN requires reporting of suspected donor-derived disease transmission in a recipient or new information regarding a donor that indicates risk of disease transmission to recipients.[31] OPTN requires OPOs to notify the United Network for Organ Sharing (UNOS), who then notifies transplant centers and requests follow up with

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(Aug. 2016), *available at,* https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM518213.pdf (last visited January 12, 2018).

[18] *Supra*, note 14.

[19] Id.

[20] Other communicable diseases must be specified in Department of Health (DOH) rules. S. 381.004(1), F.S. DOH requires donated blood, organs and tissue to tested for infectious diseases identified in 21 CFR s. 610.40 (which also includes hepatitis B and C) and in the Federal Health Resources and Services Administration's Organ Procurement and Transplantation Network Policy 2.2, as revised 9-1-2012. Rule 64D-2.005(1), F.A.C.

[21] A blood transfusion is a safe, common procedure in which blood is given to you through an intravenous (IV) line in one of your blood vessels. Blood transfusions are typically done to replace blood lost during surgery or due to a serious injury. NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, U.S,. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *What is a Blood Transfusion?*, https://www.nhlbi.nih.gov/health/health-topics/topics/bt (last visited January 12, 2018).

[22] S. 381.0041(12), F.S.

[23] *Supra*, note 14.

[24] Id.

[25] Id.

[26] Radiation sterilization is one of the most widespread and successful applications of radiation. Radiation is an acceptable method for sterilization and is based on the ability of ionizing radiation to kill microorganisms. There are two mechanisms for the cell damage and inactivation of bacteria, fungi and viruses due to the direct effect and indirect effect of gamma radiation.

[27] Ethylene oxide is a chemical sterilization method which provides both bactericidal and virucidal effects at appropriate concentrations that is widely used commercially for sterilization of health care products. Ethylene oxide is thus not a suitable method of sterilization for tissue allografts; however; peracetic acid-ethanol sterilization procedure has been used for sterilization of bone grafts. Although the peracetic acid treatment is an established sterilization method of bone, dermis and amniotic membrane transplants with no evidence to impair the transplants properties, it has caused significantly reduced biomechanical strength and decreased remodeling activity in anterior cruciate ligament reconstruction tendon grafts.

[28] Thermodisinfection has been used for femoral heads excised during hip joint surgery. Thermodisinfection of cancellous bone was found to preserve tensile strength necessary for clinical purposes. Additionally, the process of microwave sterilization was found to be effective for sterilization of bone allografts processed from femoral heads contaminated with Gram-positive and Gram-negative bacteria.

[29] Rita Singh, Durgeshwer Singh, and Antaryami Singh, *Radiation sterilization of tissue allografts: A review*, WORLD JOURNAL OF RADIOLOGY, (Apr. 28, 201), *available at,* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4840193/ (last visited January 12, 2018).

[30] CENTERS FOR DISEASE CONTROL AND PREVENTION, *Transplant Safety: Investigating, Tracking and Reporting Findings*, https://www.cdc.gov/transplantsafety/tracking_infections.html (last visited January 12, 2018).

[31] CENTERS FOR DISEASE CONTROL AND PREVENTION, *Transplant Safety: CDC's Transplant-Transmitted Infection Toolkit*, https://www.cdc.gov/transplantsafety/TTI-toolkit.html (last visited January 12, 2018).

potentially impacted recipients.[32] These reports are reviewed by UNOS's Disease Transmission Advisory Committee to determine the likelihood of transplant transmission, educate the transplant community, and inform policy.[33] Additionally, UNOS notifies the Centers for Disease Control and Prevention (CDC)[34] and requests that the reporting transplant center or OPO notify local public health authorities.[35] Early identification and treatment improves recipient outcomes.[36] Additionally, the ability to easily trace unused tissue to storage locations for immediate quarantine can prevent further transplantation of potentially infected tissues.[37]

Effect of the Bill

CS/HB 429 requires DOH to develop and publish on its website an educational pamphlet relating to the risks and benefits of human cells, tissue, and cellular and tissue-based product transplants. At a minimum, the pamphlet must include:

- An overview of the risk of infectious disease transmission;
- An overview of the standards for donor testing and screening;
- An overview of sterilization and inactivation processes intended to increase viral safety of donated human cells, tissue, or cellular or tissue-based product;
- The importance of providing limited recipient transplant information to the supplier of the human cells, tissue, or cellular or tissue-based product; and
- Information about the generosity of the human donor who provided the human cells, tissue, or cellular or tissue-based product.

DOH must electronically notify physicians of the availability of the pamphlet.

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.0041, F.S., relating to donation and transfer of human tissue; testing requirements.
Section 2: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill with have an insignificant negative fiscal impact on DOH related to the cost of publishing the pamphlet on its website, which can be absorbed within existing resources.[38]

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[32] Id.
[33] Id.
[34] UNOS staff notifies CDC for cases that involve disease clusters, unknown diseases, or nationally notifiable diseases. CDC works first to establish recipient safety and then to determine residency of all involved; relevant health departments are notified promptly should a donor or recipient be within their jurisdiction.
[35] *Supra*, note 31.
[36] *Supra*, note 30.
[37] Id.
[38] Email from Paul Runk, Director, Office of Legislative Planning, Florida Department of Health, RE: HB 429 – Amendment Fiscal, (Jan. 16, 2018) (on file with Health and Human Services Committee staff).

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. This 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 December 6, 2017, the Health Quality Subcommittee adopted an amendment that requires DOH to develop and publish on its website an educational pamphlet relating to the risks and benefits of human cells, tissue, and cellular and tissue-based product transplants.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.

A bill to be entitled

An act relating to donation and transfer of human tissue; amending s. 381.0041, F.S.; requiring the Department of Health to develop and publish on its website an educational pamphlet relating to certain tissue transplants; requiring the educational pamphlet to include specified information relating to the risks and benefits of human cell, tissue, and cellular and tissue-based product transplants; providing an effective date.

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

Section 1. Subsection (13) is added to section 381.0041, Florida Statutes, to read:

381.0041 Donation and transfer of human tissue; testing requirements.—

(13) The department shall develop and publish on its website an educational pamphlet relating to the risks and benefits of human cell, tissue, and cellular and tissue-based product transplants. The department shall electronically notify physicians of the availability of the pamphlet. At a minimum, the pamphlet shall include:

(a) An overview of the risk of infectious disease transmission.

(b) An overview of the standards for donor testing and screening.

(c) An overview of sterilization and inactivation processes intended to increase the viral safety of donated human cells, tissue, or cellular or tissue-based products.

(d) The importance of providing limited recipient transplant information to the supplier of the human cells, tissue, or cellular or tissue-based products.

(e) The generosity of the human donor who provided the human cells, tissue, or cellular or tissue-based products.

Section 2. This act shall take effect July 1, 2018.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 429 (2018)

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health & Human Services Committee

Representative Pigman offered the following:

Amendment

Remove lines 28-30 and insert:

(c) An overview of processing methods intended to reduce the risk of disease or bacterial transmission in donated human cells, tissue, or cellular or tissue-based products.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 513 Distributing Pharmaceutical Drugs and Devices
SPONSOR(S): Rommel
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N	Langston	McElroy
2) Health & Human Services Committee		Langston	Calamas

SUMMARY ANALYSIS

Third-party logistics providers act as an intermediary between the manufacturer or distributor of prescription drugs and the consumer by providing supply chain logistics services and transportation. These entities do not take title to or have responsibility to direct the sale or disposition of the prescription drug.

The Florida Drug and Cosmetic Act, requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics. Most of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require various entities in the distribution chain, such as prescription drug manufacturers and wholesale distributors, medical device manufacturers, and third-party logistics providers to obtain permits.

The Board of Pharmacy recognizes six types of pharmacy permits, including Special Pharmacy – End Stage Renal Dialysis (ESRD). An ESRD permit is required for any person who provides dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address. Section 465.027(2), F.S., provides an exemption from pharmacy permitting requirements, including ESRD permits, for a manufacturer, or its agent, holding an active permit as a manufacturer under ch. 499, F.S., who is engaged solely in manufacturing or distributing dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure.

Third-party logistics providers must obtain a third-party logistics provider permit from DBPR to operate in Florida. Third-party logistics providers that provide dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home must also obtain an ESRD permit from the Board of Pharmacy.

HB 513 expands the exemption from permitting requirements in s. 465.027(2), F.S., to third-party logistics providers who are engaged in the distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure.

The bill also removes the requirement that a manufacturer or its agent be engaged solely in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure to qualify for the 465.027(2), F.S., exemption.

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

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Kidney Disease and Renal Dialysis

Chronic kidney disease is a condition in which a person gradually loses kidney function over time, and includes conditions that damage the kidneys and decrease their ability to process waste.[1] Renal dialysis is a common treatment for individuals with chronic kidney failure, and is used to:[2]

- Remove waste, salt, and extra water to prevent build up in the body;
- Maintain a safe level of certain chemicals in the blood, such as potassium, sodium, and bicarbonate; and
- Control blood pressure.

Renal dialysis can be performed in a hospital, in a dialysis unit that is not part of a hospital, or in a person's home.[3] Additionally, there are two types of dialysis, hemodialysis and peritoneal dialysis.

In hemodialysis, an artificial kidney, called a hemodialyzer, is used to remove waste and extra chemicals and fluid from the blood.[4] Blood is pumped out of the body and into the hemodialyzer to be cleaned. The dialyzer, or filter, has two parts, separated by a thin membrane: one for blood and one for a washing fluid, called dialysate.[5] Blood cells and proteins remain in the blood because they are too large to pass through the membrane; however, smaller waste products, such as urea, creatinine, potassium and extra fluid pass through the membrane and are washed away.[6] The filtered blood is returned to the body when the process is complete.[7]

In peritoneal dialysis the inside lining of the stomach acts as a natural filter and wastes are taken out with dialysate, which is washed in and out of the stomach in cycles.[8] A catheter is surgically inserted into the stomach and is used to transfer the dialysate into and out of the stomach.[9] There are two kinds of peritoneal dialysis, continuous ambulatory peritoneal dialysis and automated peritoneal dialysis.[10] These are the same basic treatment; however, the former is manual and done while the person receiving treatment goes about normal daily activities, and the latter is a machine cycler that is usually done overnight, while the person is asleep.[11]

Regulation of Pharmacies and Pharmacists

Pursuant to ch. 465, F.S., the Florida Board of Pharmacy, within the Department of Health, licenses and regulates the practice of pharmacy. The term "pharmacy" includes a community pharmacy,[12] an

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[1] National Kidney Foundation, *About Chronic Kidney Disease*, available at https://www.kidney.org/kidneydisease/aboutckd (last visited January 12, 2018).
[2] National Kidney Foundation, *Dialysis*, https://www.kidney.org/atoz/content/dialysisinfo (last visited January 12, 2018).
[3] Id.
[4] National Kidney Foundation, *Hemodialysis*, https://www.kidney.org/atoz/content/hemodialysis (last visited January 12, 2018).
[5] National Kidney Foundation, *Peritoneal Dialysis: What You Need to Know*, https://www.kidney.org/atoz/content/peritoneal (last visited January 12, 2018).
[6] *Supra*, note 4.
[7] *Supra*, note 5.
[8] Id.
[9] Id.
[10] Id.
[11] Id.
[12] A community pharmacy includes every location where medicinal drugs are compounded, dispensed, stored, or sold, or where prescriptions are filled or dispensed on an outpatient basis. S.465.003(11)(a)1., F.S.

institutional pharmacy,[13] a nuclear pharmacy,[14] a special pharmacy,[15] and an internet pharmacy.[16] The board regulates the operation of pharmacies and disciplines pharmacies for failure to comply with state and federal regulations.[17]

Special Pharmacy – End Stage Renal Dialysis Permit

The Board of Pharmacy recognizes six types of pharmacy permits, including Special Pharmacy – End Stage Renal Dialysis (ESRD).[18] An ESRD permit is required for any person who provides dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address.[19] To obtain an ESRD permit, an applicant must:[20]

- Complete an application and pay a $250 initial payment fee;
- Submit a legible set of fingerprint cards and $48 fee for each person having an ownership interest of at least 5 percent and any person who, directly or indirectly, manages, oversees, or controls the operation of the pharmacy, including officers and members of the board of directors, if the applicant is a corporation;
- Pass an on-site inspection;
- Provide written policies and procedures for preventing and controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships; and
- Designate a prescription department manager or consultant pharmacist of record.

Florida law provides an exemption to pharmacy permitting requirements, including ESRD permits, under limited circumstances. Specifically, s.465.027(2), F.S., exempts a manufacturer, or its agent, holding an active permit as a manufacturer under ch. 499, F.S., who is engaged solely in the manufacturer or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure from pharmacy permitting requirements if the dialysate, drugs, or devices are:

- Approved by the federal Food and Drug Administration, and
- Delivered in the original, sealed packaging to the patient for self-administration, to a health care practitioner, or an institution.

Currently, the Board of Pharmacy has seven pharmacies permitted as a Special Pharmacy – ESRD.[21]

Regulation of Drugs, Devices, and Cosmetics in Florida

Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act, requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics.[22] Most of the regulations

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[13] An institutional pharmacy includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold. S. 465.003(11)(a)2., F.S.
[14] A nuclear pharmacy includes every location were radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold, but does not include hospitals or the nuclear medicine facilities of hospitals. S. 465.003(11)(a)3., F.S.
[15] A special pharmacy includes every location where medicinal drugs are compounded, dispensed, stored, or sold, if not otherwise classified as a community pharmacy, institutional pharmacy, nuclear pharmacy, or internet pharmacy. S. 465.003(11)(a)4., F.S.
[16] An internet pharmacy includes locations not otherwise licensed or issued a permit pursuant to statute, within or outside of this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy. S. 465.003(11)(a)5., F.S.
[17] *See* ss. 465.022 and 465.023, F.S.
[18] Rule 64B16-28.100(5)(d), F.A.C.
[19] Rule 64B16-28.850(1), F.A.C.
[20] Rule 64b16-28.100(1) and (5), F.A.C.
[21] Email from Paul Runk, Director, Office of Legislative Planning, Florida Department of Health, RE: HB 513 Question, (Jan. 16, 2018) (on file with Health and Human Services Committee staff).
[22] S. 27, ch. 2010-161, Laws of Fla., shifted responsibility for operation and enforcement of the Florida Drugs, Devices, and Cosmetics Act from the Department of Health to the Department of Business and Professional Regulation.

relate to the distribution of prescription drugs into and within Florida. The chapter also regulates manufacturing and distributing medical devices. In particular, the regulations require various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors, to obtain permits. Florida has 18 distinct permits for these entities.[23]

Manufacturer Permits

DBPR offers nine different manufacturer and repackager permits for prescription drugs, over-the-counter drugs, cosmetics, and medical devices.

Prescription drug manufacturer permits are required for anyone that manufactures a prescription drug and manufactures or distributes that prescription drugs in Florida.[24] If someone manufactures prescription drugs outside of Florida, but distributes their prescription drugs in Florida, a nonresident prescription drug manufacturer permit is required, unless that person is permitted as a third party logistics provider.[25] Virtual permits are available for those manufacture prescription drugs but do not make or take physical possession of any prescription drugs.[26] An over-the-counter drug manufacturer permit is required for anyone manufacturing or repackaging over-the-counter drugs[27] and a cosmetic manufacturer permit is required for anyone manufacturing or repackaging cosmetics in Florida.[28]

A device manufacturer permit is required for anyone manufacturing, repackaging, or assembling medical devices for human use unless the person only manufactures, repackages, or assembles medical devices or components: [29]

- Pursuant to a practitioner's order for a specific patient; or,
- That are registered with the federal Food and Drug Administration and satisfy specified statutory requirements.

Regulation of Third-Party Logistics Providers

Third-party logistics providers act as an intermediary between the manufacturer or distributor of prescription drugs and the consumer by providing supply chain logistics services and transportation. A third party logistics provider contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf a manufacturer, wholesale distributor, or dispenser, but does not take title to or have responsibility to direct the sale or disposition of the prescription drug.[30]

Third-party logistic providers must obtain a DBPR permit before operating in Florida and out-of-state third-party logistics providers must also be licensed in the state or territory from where it distributes the prescription drug.[31] Third-party logistics providers that provide dialysis products and supplies to

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[23] A permit is required for a prescription drug manufacturer; a prescription drug repackager; a nonresident prescription drug manufacturer; a prescription drug wholesale distributor; an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment. S. 499.01(1), F.S.

[24] S. 499.01(2)(a), F.S.

[25] S. 499.01(2)(c), F.S.

[26] S. 499.01(2)(a)1., F.S. and S. 499.01(2)(c), F.S.

[27] S. 499.01(2)(n), F.S.

[28] S. 499.01(2)(p), F.S. Someone that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a cosmetic manufacturer permit.

[29] S. 499.01(2)(o), F.S.

[30] S. 499.01(2)(q), F.S.

[31] Id. If the state or territory from which the third party logistics provider originates does not require a license to operate as a third party logistics provider, the third party logistics provider must be licensed as a third party logistics provider as required under federal law.

persons with chronic kidney failure for self-administration at the person's home must also obtain an ESRD permit from the Board of Pharmacy.[32]

Currently, DBPR has 177 active permitted third-party logistics providers.[33] None of the 177 third-party logistics providers permitted by DBPR also hold an ESRD permit from the Board of Pharmacy.[34]

Effect of Proposed Changes:

HB 513 expands the eligibility for the exemption from pharmacy permitting requirements in s. 465.027(2), F.S., to include third-party logistics providers who are distribute of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure. Third-party logistics provides will no longer be required to obtain an ESRD permit from the Board of Pharmacy, but will still have to obtain a third-party logistics permit from DBPR.

The bill also removes the requirement that a manufacturer be engaged *solely* in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure in order to qualify for the pharmacy permit exemption.

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 465.027, F.S., relating to exceptions.
Section 2: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None. Because none of third-party logistics providers permitted by DBPR also hold an ESRD permit from the Board of Pharmacy, there will be no loss of permitting revenues from third-party logistics providers that will no longer be required to hold an ESRD permit.

2. Expenditures:

   None. Because none of third-party logistics providers permitted by DBPR also hold an ESRD permit from the Board of Pharmacy, there will be no reduction in workload for the Board of Pharmacy related fewer ESRD permits.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

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[32] Rule 64B16-28.100(5)(d)4., F.A.C.
[33] Email from Colton L. Madill, Deputy Legislative Affairs Director, Office of Legislative Affairs, Department of Business and Professional Regulation, RE: Agency Bill Analysis Request, (Jan. 16, 2018) (on file with Health and Human Services Committee staff).
[34] *Supra*, note 21.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Third-party logistics providers made exempt from ch. 465, F.S., under the bill will no longer be required to pay an ESRD permitting fee, and as a result will realize a savings.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This 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

A bill to be entitled

An act relating to distributing pharmaceutical drugs and devices; amending s. 465.027, F.S.; revising an exception to pharmacy regulations for certain manufacturers and distributors of dialysis drugs or supplies; providing an effective date.

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

Section 1. Subsection (2) of section 465.027, Florida Statutes, is amended to read:

465.027 Exceptions.—

(2) This chapter does ~~shall~~ not apply to a manufacturer, or its agent, holding an active manufacturer or third-party logistics provider permit ~~as a manufacturer~~ under chapter 499, to the extent the manufacturer, or its agent, is ~~and~~ engaged ~~solely~~ in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure, if the dialysate, drugs, or devices are:

(a) Approved or cleared by the United States Food and Drug Administration; and

(b) Delivered in the original, sealed packaging after receipt of a physician's order to dispense to:

1. A patient with chronic kidney failure, or the patient's

designee, for the patient's self-administration of the dialysis therapy; or

2. A health care practitioner or an institution for administration or delivery of the dialysis therapy to a patient with chronic kidney failure.

Section 2. This act shall take effect July 1, 2018.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 721 Mental Health and Substance Abuse Services
SPONSOR(S): Silvers
TIED BILLS: **IDEN./SIM. BILLS:** SB 960

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Children, Families & Seniors Subcommittee	13 Y, 0 N	Langston	Brazzell
2) Health Care Appropriations Subcommittee	12 Y, 0 N	Fontaine	Pridgeon
3) Health & Human Services Committee		Langston	Calamas

SUMMARY ANALYSIS

Forensic clients are individuals who have been committed to the Department of Children and Families (DCF) pursuant to ch. 916, F.S., because they have been charged with committing a felony but been adjudicated incompetent, adjudicated not guilty by reason of insanity, or determined to be incompetent to proceed.

Currently, jail physicians must provide a current psychotropic medication order at the time a forensic client is transferred to the state mental health treatment facility or upon request of the admitting physician after the client is evaluated. However, there is no timeframe within which a jail physician must respond to a request by DCF for such medication information, nor is there any requirement for jail physicians to provide other medical information about individuals being transferred to DCF. Some individuals have medical needs that require immediate care or treatment upon transfer to DCF.

When forensic clients are released from state mental health treatment facilities, most are returned to the county jail of the committing jurisdiction to await resolution of their court cases. Some individuals are maintained by county jails on the same psychotropic medication regimen prescribed and administered at the state mental health treatment facility, while others individuals are not. Changing medications may result in individuals losing competency and returning to a state mental health treatment facility.

Prevention coalitions are local partnerships between multiple sectors of the community that respond to community conditions by developing and implementing comprehensive plans that lead to measurable, population-level reductions in drug use and related problems. Florida is the only state that requires prevention coalitions to be certified.

HB 721 requires county jails to continue to administer the psychotropic medications prescribed at mental health treatment facilities upon a facility client's discharge and return to the county jail, unless the jail physician determines that there is a compelling medical reason to change or discontinue the medication for the health and safety of the individual. The bill also requires county jails to send all medical information for individuals in their custody who will be admitted to state mental health treatment facilities. DCF must request this information within two business days of receipt of a completed commitment packet. Upon receipt of such a request, the county jail must provide the requested information within three business days.

The bill also repeals the requirement for DCF to develop a certification process by rule for community substance abuse prevention coalitions.

The bill will have an indeterminate fiscal impact on state and local governments. *See Fiscal Analysis & Economic Impact Statement.*

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Mental Illness and Substance Abuse of Offenders in the Criminal Justice System

Mental illness affects millions of people in the United States each year. Only about 17% of adults in the United States are considered to be in a state of optimal mental health.[1] This leaves the majority of the population with less than optimal mental health: [2]

- One in five adults (43.8 million people) experiences mental illness in a given year;
- Approximately 6.9 percent (16 million people) had at least one major depressive episode in the past year; and
- Approximately 18.1 percent of adults live with anxiety disorders, such as obsessive-compulsive disorder, posttraumatic stress disorder, and specific phobias.

Many people are diagnosed with more than one mental illness. For example, people who suffer from a depressive illness (major depression, bipolar disorder, or dysthymia) often have a co-occurring mental illness such as anxiety.[3]

An estimated 17,000 prison inmates, 15,000 jail detainees, and 40,000 individuals under correctional supervision are experiencing serious mental illness each day in Florida.[4] Annually, up to125,000 adults with a mental illness or substance use disorder requiring immediate treatment are arrested and booked into Florida jails.[5] Between 2002 and 2010, the population of inmates with mental illness or substance use disorder in Florida increased from 8,000 to 17,000 inmates.[6] By 2020, the number of inmates with these types of disorders is expected to reach at least 35,000.[7]

Most individuals with serious mental illness or substance use disorder who become involved with the criminal justice system are charged with minor misdemeanor and low-level felony offenses that are often a direct result of their untreated condition.[8] These individuals are often poor, uninsured, and homeless.[9]

Florida's Substance Abuse and Mental Health Program

The Florida Department of Children and Families (DCF) administers a statewide system of safety-net services for substance abuse and mental health (SAMH) prevention, treatment, and recovery. It serves

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[1] *Mental Health Basics*, Centers for Disease Control and Prevention. http://www.cdc.gov/mentalhealth/basics.htm (last visited January 12, 2018). Mental illness can range in severity from no or mild impairment to significantly disabling impairment. Serious mental illness is a mental disorder that has resulted in a functional impairment which substantially interferes with or limits one or more major life activities. *Any Mental Illness (AMI) Among Adults*, National Institute of Mental Health, available at http://www.nimh.nih.gov/health/statistics/prevalence/any-mental-illness-ami-among-adults.shtml (last viewed on January 12, 2018).

[2] *Mental Health by the Numbers,* National Alliance on Mental Illness, available at http://www.nami.org/Learn-More/Mental-Health-By-the-Numbers (last visited January 12, 2018).

[3] *Mental Health Disorder Statistics,* John Hopkins Medicine, available at http://www.hopkinsmedicine.org/healthlibrary/conditions/mental_health_disorders/mental_health_disorder_statistics_85,P00753/ (last visited January 12, 2018).

[4] The Florida Senate, *Forensic Hospital Diversion Pilot Program, Interim Report 2011-106*, (Oct. 2010), p. 1, available at https://www.flsenate.gov/UserContent/Session/2011/Publications/InterimReports/pdf/2011-106cf.pdf (last visited January 12, 2018).

[5] Id.

[6] Id. at 1.

[7] Id.

[8] Id. at 2.

[9] Id.

children and adults who are otherwise unable to obtain these services (such as individuals who are not covered under Medicaid or private insurance and do not have the financial ability to pay for the services themselves). SAMH programs include a range of prevention, acute interventions (such as crisis stabilization or detoxification), residential, transitional housing, outpatient treatment, and recovery support services. Services are provided based upon state and federally-established priority populations.[10] DCF also administers the state's forensic services, described below.

State Forensic System -- Mental Health Treatment for Criminal Defendants

Chapter 916, F.S., governs the state forensic system, which is a network of state facilities and community services for persons who have mental health issues and are involved with the criminal justice system. The forensic system serves defendants who are determined incompetent to proceed or not guilty by reason of insanity.

The Due Process Clause of the 14th Amendment prohibits states from trying and convicting defendants who are incompetent to stand trial.[11] States must have procedures in place that adequately protect the defendant's right to a fair trial, which includes his or her participation in all material stages of the process.[12] Defendants must be able to appreciate the range and nature of the charges and penalties that may be imposed, understand the adversarial nature of the legal process, and disclose to counsel facts pertinent to the proceedings. Defendants also must manifest appropriate courtroom behavior and be able to testify relevantly.[13] A defendant is determined incompetent to proceed if he or she does not have sufficient present ability to consult with his or her lawyer with a reasonable degree of rational understanding or if the defendant has no rational, as well as factual, understanding of the proceedings against him or her.[14]

If a defendant is suspected of being incompetent, the court, counsel for the defendant, or the state may file a motion for examination to have the defendant's cognitive state assessed.[15] If the motion is well-founded, the court will appoint experts to evaluate the defendant's cognitive state. The defendant's competency is then determined by the judge in a subsequent hearing.[16] If the defendant is found to be competent, the criminal proceeding resumes.[17] If the defendant is found to be incompetent to proceed, the proceeding may not resume unless competency is restored.[18] Competency restoration services help defendants learn about legal process, their charges, the court dispositions they might face, and their legal rights so as to prepare them to participate meaningfully in their own defense.[19]

Defendants may be adjudicated not guilty by reason of insanity pursuant to s. 916.15, F.S. DCF must admit such defendants who are committed to DCF[20] to an appropriate facility or program for treatment and must retain and treat the defendant.[21]

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[10] These priority populations include, among others, persons diagnosed with co-occurring substance abuse and mental health disorders, persons who are experiencing an acute mental or emotional crisis, children who have or are at risk of having an emotional disturbance and children at risk for initiating drug use.

[11] See *Pate v. Robinson*, 383 U.S. 375, (1966); *Bishop v. U.S.*, 350 U.S. 961, (1956); *Jones v. State*, 740 So.2 d 520 (Fla. 1999).

[12] *Id.* See also Rule 3.210(a)(1), Fla.R.Crim.P.

[13] *Id.* See also s. 916.12, 916.3012, and 985.19, F.S.

[14] S. 916.12(1), F.S.

[15] Rule 3.210, Fla.R.Crim.P.

[16] *Id.*

[17] Rule 3.212, Fla.R.Crim.P.

[18] *Id.*

[19] Office of Program Policy Analysis & Government Accountability, *Juvenile and Adult Incompetent to Proceed Cases and Costs*, Report. No. 13-04, Feb. 2013, p. 1.

[20] The court may also order outpatient treatment at any other appropriate facility or service or discharge the defendant. Rule 3.217, Fla.R.Crim.P.,

[21] S. 916.15(3), F.S.

Offenders who are charged with a felony and adjudicated incompetent to proceed and offenders who are adjudicated not guilty by reason of insanity may be involuntarily committed to state civil[22] and forensic[23] treatment facilities by the circuit court,[24] or in lieu of such commitment, may be released on conditional release by the circuit court if the person is not serving a prison sentence.[25]

State Treatment Facilities

State treatment facilities are the most restrictive settings for forensic services. DCF oversees two state-operated forensic facilities, Florida State Hospital[26] and North Florida Evaluation and Treatment Center,[27] and two privately-operated, maximum security forensic treatment facilities.[28] The forensic facilities provide assessment, evaluation, and treatment to the individuals who have mental health issues and who are involved with the criminal justice system.[29] In addition to general psychiatric treatment approaches and environment, specialized services include:

- Psychosocial rehabilitation;
- Education;
- Treatment modules such as competency, anger management, mental health awareness, medication and relapse prevention;
- Sexually transmitted disease education and prevention;
- Substance abuse awareness and prevention;
- Vocational training;
- Occupational therapies; and
- Full range of medical and dental services.[30]

DCF must admit defendants committed to its care for forensic involuntary hospitalization within 15 days of commitment.[31] In FY 2015-2016, it took an average of 12 days to admit forensic individuals into state mental health treatment facilities.[32]

Forensic clients are individuals who have been committed to DCF, pursuant to ch. 916, F.S., because they have been charged with committing a felony but been adjudicated incompetent, adjudicated not guilty by reason of insanity, or determined to be incompetent to proceed.

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[22] A "civil facility" is a mental health facility established within the Department of Children and Families (DCF) or by contract with DCF to serve individuals committed pursuant to chapter 394, F.S., and defendants pursuant to chapter 916, F.S., who do not require the security provided in a forensic facility; or an intermediate care facility for the developmentally disabled, a foster care facility, a group home facility, or a supported living setting designated by the Agency for Persons with Disabilities (APD) to serve defendants who do not require the security provided in a forensic facility. S. 916.106(4), F.S.

[23] A "forensic facility" is a separate and secure facility established within DCF or APD to service forensic clients. A separate and secure facility means a security-grade building for the purpose of separately housing persons who have mental illness from persons who have intellectual disabilities or autism and separately housing persons who have been involuntarily committed pursuant to chapter 916, F.S., from non-forensic residents. S. 916.106(10), F.S.

[24] Ss. 916.13, 916.15, and 916.302, F.S. "Court" is defined to mean the circuit court. s. 916.106(5), F.S.

[25] S. 916.17(1), F.S.

[26] Florida State Hospital has capacity for 959 individuals, of which 469 may receive forensic services. Up to an additional 245 individuals with forensic commitments (but do not require the security of a forensic setting) may occupy the hospital's civil beds. *See* Department of Children and Families, *Forensic Facilities*, 2014, available at http://www.myflfamilies.com/service-programs/mental-health/forensic-facilities (last visited January 12, 2018).

[27] Id. The North Florida Evaluation and Treatment Center has 193 beds.

[28] Id. South Florida Evaluation and Treatment Center has a capacity to serve 238 individuals, and Treasure Coast Treatment Center has a contracted capacity of 208 beds.

[29] Florida Department of Children and Families, *About Adult Forensic Mental Health (AFMH)*, 2014, available at http://www.myflfamilies.com/service-programs/mental-health/about-adult-forensic-mental-health (last visited January 12, 2018).

[30] *Id.*

[31] S. 916.107(1)(a), F.S.

[32] Department of Children and Families, *Exhibit D-3A, Expenditures by Issue and Appropriation Category, Budget Period 2017-2018*, p. 354.

Medical Information Sharing Between County Jails and DCF

Forensic clients committed to DCF's state mental health treatment facilities are transferred to the facilities directly from the county jails, and some may have medical conditions that require on-going or immediate medical treatment.[33] Current law requires jail physicians to provide a current psychotropic medication[34] order at the time a forensic client is transferred to the state mental health treatment facility or upon request of the admitting physician after the client is evaluated.[35] However, there is no timeframe within which a jail physician must respond to a request by DCF for such information, nor is there any requirement for jail physicians to provide other medical information about individuals being transferred to DCF. While DCF currently requests medical information from the county jails when a commitment packet is received from the courts, there is no time requirement within which DCF must make the request. According to DCF, lack of continuity of care and lack of information on the individual's medical status can result in life-threatening situations.[36]

Continuation of Psychotropic Medications

When forensic clients are released from state mental health treatment facilities, most are returned to the county jail of the committing jurisdiction to await resolution of their court cases. Some individuals are maintained by county jails on the same psychiatric medication regimen prescribed and administered at the state mental health treatment facility, while others individuals are not.

Continuation of a forensic client's psychotropic medication treatment upon transfer from a county jail to a state mental health treatment facility may prevent negative health outcomes, including loss of competency.[37] If an individual loses competency, then the jail must return him or her to a secure forensic facility, as he or she once again becomes unable to stand trial or proceed with resolution of his or her court case.[38]

DCF defines a recidivist as an individual who is recommended as competent to the court, returned to the jail from the forensic facility, and then readmitted to the forensic facility as incompetent to proceed on the same charge for which they were originally found competent.[39] Over the last three years, there has been an increase from eight to 12 percent.[40] DCF does not collect information on the reason for the recidivism, so DCF cannot identify how often recidivism is caused by the jail's failure to maintain the forensic client's psychotropic medication treatment.

Certification of Community Substance Abuse Prevention Coalitions

Prevention coalitions are local partnerships between multiple sectors of the community that respond to community conditions by developing and implementing comprehensive plans that lead to measurable, population-level reductions in drug use and related problems. Generally, prevention coalitions have community wide involvement including parents, youth, teachers, police, faith-based leaders and business partners.[41]

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[33] Department of Children and Families, Agency Bill Analysis for 2018 House Bill 0721, (Nov. 30, 2017) (On file with Children, Families, and Seniors Subcommittee Staff).

[34] Psychotropic medication is a broad term referring to medications that affect mental function, behavior, and experience; these medications include anxiolytic/hypnotic medications, such as benzodiazepines, antidepressant medications, such as selective serotonin reuptake inhibitors (SSRIs), and antipsychotic medications. Pamela L. Lindsey, *Psychotropic Medication Use among Older Adults: What All Nurses Need to Know*, J. GERONTOL NURS., (Sept. 200), *available at*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3128509/ (last visited January 12, 2018).

[35] S. 916.107(3)(a)2.a., F.S.

[36] *Supra*, note 33.

[37] Id.

[38] Id.

[39] Email from Lindsey Zander, Deputy Director of Legislative Affairs, Department of Children and Families, RE: Recidivist Data, (Dec. 17, 2017) (on file with Health and Human Services Committee staff)

[40] Id.

[41] *Supra*, note 33.

Section 397.321, F.S., requires DCF to license and regulate all substance abuse providers in the state. It also requires DCF to develop a certification process by rule for community substance abuse prevention coalitions (prevention coalitions), and DCF is currently in the rulemaking process.[42]

Prevention coalitions do not provide licensable substance abuse clinical treatment services, and certification is not a requirement for eligibility to receive federal or state substance abuse prevention funding. However, to receive funding from DCF, a coalition must follow a comprehensive process that includes a detailed needs assessment and plan for capacity building, development, implementation, and sustainability to ensure that data-driven, evidence–based practices are employed for addressing substance misuse for state-funded coalitions.

Some prevention coalitions choose to receive certification from nationally-recognized credentialing entities through an application process. Additionally, the Florida Certification Board, a non-profit professional credentialing entity, offers certifications for Certified Prevention Specialists and Certified Prevention Professionals, for those individuals who desire professional credentialing.

Florida is the only state that requires prevention coalitions to be certified.[43]

Effect of Proposed Changes

Sharing Medical Information Between County Jails and DCF

HB 721 amends s. 916.13(2), F.S., and s. 916.15(3), F.S., to require county jails to send all medical information for individuals in their custody who will be admitted to state mental health treatment facilities. The bill requires DCF to request this information within two business days of receipt of a completed commitment packet which is provided by the court. Upon receipt of such a request, the bill requires the county jail to provide the requested information within three business days.

Continuation of Psychotropic Medications

The bill also amends s. 916.13(2)(b), F.S., and s. 916.15(5), F.S., to require the county jails to administer the same psychotherapeutic medications to individuals returning to the jail from a state mental health treatment facility as prescribed by the treating physician upon discharge by the state mental health treatment facility, unless the jail physician determines that there is a compelling medical reason to change or discontinue the medication for the health and safety of the individual.

Repeal of Prevention Coalition Certification

The bill repeals the requirement that DCF develop a certification process by rule for community substance abuse prevention coalitions. As a result, prevention coalitions will no longer be required to be certified.

B. SECTION DIRECTORY:

Section 1: Amends s. 397.321, F.S., relating to duties of the department.
Section 2: Amends s. 916.13, F.S., relating to involuntary commitment of defendant adjudicated incompetent.
Section 3: Amends s. 916.15, F.S., relating to involuntary commitment of defendant adjudicated not guilty by reason of insanity.
Section 4: Provides an effective date of July 1, 2018.

[42] *Supra*, note 33.
[43] Only one other state, Ohio, has established a certification program for prevention coalitions, and it is voluntary.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill may have an indeterminate positive fiscal impact on DCF resulting from reduced expenditures for recidivists. If fewer individuals who are restored to competency are subsequently returned to state mental health facilities, DCF's overall caseload will be reduced, freeing bed space to serve new patients in state mental health treatment facilities. Additionally, if DCF has additional medical information for individuals transferred from jails to state mental health treatment facilities, it may reduce expenditures for addressing medical and mental health crises brought about from a lack of such information.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   The bill may have an indeterminate insignificant negative fiscal impact on county jails that may be required to cover the cost of a specific psychotropic medication that they would not have previously covered.

   The bill may also have an indeterminate positive fiscal impact on county jails resulting from fewer expenditures for recidivists who, as a result of being maintained on a specific psychotropic medication, remain competent upon return from a state mental health treatment facility and are able to stand trial in timely manner, and thus spend less time in jail awaiting trial.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   The county/municipality mandates provision of Art. VII, section 18, of the Florida Constitution may apply because this bill may require county jails to spend funds to continue psychotropic medications; however, an exemption applies because the bill amends criminal procedures and may have an insignificant fiscal impact.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to mental health and substance abuse services; amending s. 397.321, F.S.; deleting a requirement that the Department of Children and Families develop a certification process by rule for community substance abuse prevention coalitions; amending ss. 916.13 and 916.15, F.S.; requiring the department to request medical information from jails pertaining to certain defendants within a specified timeframe; requiring jails to provide such information to the department within a specified timeframe; requiring the continued administration of psychotropic medication to certain defendants upon their discharge and transfer to jails under certain conditions; providing an effective date.

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

Section 1. Subsection (16) of section 397.321, Florida Statutes, is amended to read:

397.321 Duties of the department.—The department shall:

~~(16) Develop a certification process by rule for community substance abuse prevention coalitions.~~

Section 2. Subsection (2) of section 916.13, Florida Statutes, is amended to read:

916.13 Involuntary commitment of defendant adjudicated incompetent.—

(2) A defendant who has been charged with a felony and who has been adjudicated incompetent to proceed due to mental illness, and who meets the criteria for involuntary commitment under this chapter, may be committed to the department, and the department shall retain and treat the defendant. Within 2 business days after receipt of a commitment order and other documents as required by rule, the department must request from the jail any and all medical information pertaining to the defendant. Within 3 business days after receipt of such a request, the jail shall provide such information to the department.

(a) Within 6 months after the date of admission and at the end of any period of extended commitment, or at any time the administrator or designee determines that the defendant has regained competency to proceed or no longer meets the criteria for continued commitment, the administrator or designee shall file a report with the court pursuant to the applicable Florida Rules of Criminal Procedure.

(b) A competency hearing shall be held within 30 days after the court receives notification that the defendant is competent to proceed or no longer meets the criteria for continued commitment. The defendant must be transported to the committing court's jurisdiction for the hearing. If the

defendant is receiving psychotropic medication at the mental health facility at the time he or she is discharged and transferred to the jail, the administration of such medication shall continue unless the jail physician determines there is a compelling medical reason to change or discontinue such medication for the health or safety of the defendant.

Section 3. Subsections (3) and (5) of section 916.15, Florida Statutes, are amended to read:

916.15 Involuntary commitment of defendant adjudicated not guilty by reason of insanity.—

(3) Every defendant acquitted of criminal charges by reason of insanity and found to meet the criteria for involuntary commitment may be committed and treated in accordance with the provisions of this section and the applicable Florida Rules of Criminal Procedure. The department shall admit a defendant so adjudicated to an appropriate facility or program for treatment and shall retain and treat such defendant. No later than 6 months after the date of admission, prior to the end of any period of extended commitment, or at any time the administrator or designee shall have determined that the defendant no longer meets the criteria for continued commitment placement, the administrator or designee shall file a report with the court pursuant to the applicable Florida Rules of Criminal Procedure. Within 2 business days after receipt of a commitment order and other

documents as required by rule, the department shall request from the jail any and all medical information pertaining to the defendant. Within 3 business days after receipt of such a request, the jail shall provide such information to the department.

(5) The commitment hearing shall be held within 30 days after the court receives notification that the defendant no longer meets the criteria for continued commitment. The defendant must be transported to the committing court's jurisdiction for the hearing. If the defendant is receiving psychotropic medication at the mental health facility at the time he or she is discharged and transferred to the jail, the administration of such medication shall continue unless the jail physician determines there is a compelling medical reason to change or discontinue such medication for the health or safety of the defendant.

Section 4. This act shall take effect July 1, 2018.

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	____	(Y/N)
ADOPTED AS AMENDED	____	(Y/N)
ADOPTED W/O OBJECTION	____	(Y/N)
FAILED TO ADOPT	____	(Y/N)
WITHDRAWN	____	(Y/N)
OTHER		

Committee/Subcommittee hearing bill: Health & Human Services Committee

Representative Silvers offered the following:

Amendment (with title amendment)

Remove lines 50-91 and insert:

committing court's jurisdiction for the hearing. If the defendant is receiving psychotropic medication at the mental health facility at the time he or she is discharged and transferred to the jail, the administration of such medication shall continue unless the jail physician documents the need to change or discontinue such medication. The jail physician and the department physician shall collaborate to ensure that any medication changes will not adversely affect the defendant's mental health status and ability to continue with court proceedings, with the final authority regarding the

administration of medication to an inmate in jail resting with the jail physician.

Section 3. Subsections (3) and (5) of section 916.15, Florida Statutes, are amended to read:

916.15 Involuntary commitment of defendant adjudicated not guilty by reason of insanity.—

(3) Every defendant acquitted of criminal charges by reason of insanity and found to meet the criteria for involuntary commitment may be committed and treated in accordance with the provisions of this section and the applicable Florida Rules of Criminal Procedure. The department shall admit a defendant so adjudicated to an appropriate facility or program for treatment and shall retain and treat such defendant. No later than 6 months after the date of admission, prior to the end of any period of extended commitment, or at any time the administrator or designee shall have determined that the defendant no longer meets the criteria for continued commitment placement, the administrator or designee shall file a report with the court pursuant to the applicable Florida Rules of Criminal Procedure. Within 2 business days after receipt of a commitment order and other documents as required by rule, the department shall request from the jail any and all medical information pertaining to the defendant. Within 3 business days after receipt of such a

request, the jail shall provide such information to the department.

(5) The commitment hearing shall be held within 30 days after the court receives notification that the defendant no longer meets the criteria for continued commitment. The defendant must be transported to the committing court's jurisdiction for the hearing. If the defendant is receiving psychotropic medication at the mental health facility at the time he or she is discharged and transferred to the jail, the administration of such medication shall continue unless the jail physician documents the need to change or discontinue such medication. The jail physician and the department physician shall collaborate to ensure that any medication changes will not adversely affect the defendant's mental health status and ability to continue with court proceedings, with the final authority regarding the administration of medication to an inmate in jail resting with the jail physician.

T I T L E A M E N D M E N T

Remove line 14 and insert:
and transfer to jails under certain conditions;
specifying that final authority regarding the administration of such medication rests with the jail physician;

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HM 817 Renewal of Title IV-E Waivers for Child Welfare Services
SPONSOR(S): Harrell
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Local, Federal & Veterans Affairs Subcommittee	14 Y, 0 N	Darden	Miller
2) Health & Human Services Committee		Grabowski	Calamas
3) Government Accountability Committee			

SUMMARY ANALYSIS

HM 817 is a memorial to the U.S. Congress requesting legislation under which Florida's existing Title IV-E waiver for child welfare services could be renewed in lieu of a return to traditional federal Title IV-E funding.

Title IV-E of the federal Social Security Act provides entitlement funding for out-of-home services for certain children eligible due to family income, placement setting, and vulnerability to maltreatment as well as for certain related purposes. However, Florida currently has a waiver to allow it instead to receive Title IV-E funding as a capped allocation and distribute it to community-based care lead agencies providing child welfare services, which may then use that funding for a wider array of services than otherwise specified in law. This waiver expires September 30, 2018, and federal law bars the operation of any Title IV-E waiver projects after September 30, 2019, which means Florida will have to revert to meeting more restrictive federal requirements for Title IV-E funding in the near future.

The memorial presents the rationale for continuing the existing Title IV-E waiver beyond September 30, 2019. The waiver allows the state to provide an expanded range of community-based services and supports to children and families that might otherwise be jeopardized by a reversion to the traditional Title IV-E funding model.

HM 817 also directs that copies of the memorial be provided to the President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, and to each member of the Florida delegation to the United States Congress.

Legislative memorials are not subject to the Governor's veto power and are not presented to the Governor for review. Memorials have no force of law, as they are mechanisms for formally petitioning the federal government to act on a particular subject.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Child Welfare System

The child welfare system identifies families whose children are in danger of suffering or have suffered abuse, abandonment, or neglect and works with those families to address the problems that are endangering children, if possible. If the problems cannot be ameliorated, the child welfare system finds safe out-of-home placements for such children, such as relative and non-relative caregivers, foster families, or adoptive families.

To serve families and children, the Department of Children and Families (DCF) contracts for foster care and related services with lead agencies, also known as community-based care organizations (CBCs). The transition to outsourced provision of child welfare services was intended to increase local community ownership of service delivery and design.[1] DCF, through the CBCs, administers a system of care for children to:[2]

- Prevent children's separation from their families;
- Intervene to allow children to remain safely in their own homes;
- Reunify families who have had children removed from their care, if possible and appropriate;
- Ensure safety and normalcy for children who are separated from their families;
- Enhance the well-being of children through educational stability and timely health care;
- Provide permanency; and
- Develop their independence and self-sufficiency.

As of October 31, 2017, 11,911 children were receiving services in their home, while 24,318 children were in out-of-home care.[3] Out-of-home placements range from temporary placement with a family member to a family foster home to a residential child-caring agency to a permanent adoptive placement with a family previously unknown to the child.[4]

Florida uses funds from a variety of sources for child welfare services, such as the Social Services Block Grant, the Temporary Assistance to Needy Families block grant, Title XIX Medicaid administration, Title IV-B, Title IV-E, various other child welfare grants, and general revenue.

Title IV-E Funding for Child Welfare

While states bear primary responsibility for child welfare, Congress appropriates funds to states through a variety of funding streams for services to children who have suffered maltreatment. One of these funding streams is Title IV-E of the Social Security Act. Title IV-E provides federal reimbursement to states for a portion of the cost of foster care, adoption assistance, and (in states electing to provide this kind of support) kinship guardianship assistance on behalf of each child who meets federal eligibility criteria. Title IV-E also authorizes funding to support services to youth who "age out" of foster care, or are expected to age out without placement in a permanent family. While Title IV-E funding is an entitlement, eligibility is limited to those children who:

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[1] DEPARTMENT OF CHILDREN AND FAMILIES, *Community-Based Care*, http://www.myflfamilies.com/service-programs/community-based-care (last accessed Dec. 20, 2017).
[2] Section 409.145(1), F.S.
[3] DEPARTMENT OF CHILDREN AND FAMILIES, *Child Welfare Key Indicators Monthly Report*, November 2017, p. 29, available at http://centerforchildwelfare.fmhi.usf.edu/qa/cwkeyindicator/KI_Monthly_Report_Nov2017.pdf (last accessed Dec. 20, 2017).
[4] Section 409.175, F.S.

- Are from a home with very low income (less than 50% of federal poverty level in most states),
- Have been determined by a judge to need to be in care,
- Are living in a licensed family foster home or a "child care institution", and
- Be under 18 years old, unless the state has included older youth in its Title IV-E plan.

A Congressional Research Service analysis estimates that less than half of the children in foster care met Title IV-E foster care eligibility criteria in 2015.[5]

Eligible Title IV-E expenditures include:

- Foster care maintenance payments (for the child's room and board);
- Caseworker time to perform required activities on behalf of eligible children in foster care or children at imminent risk of entering foster care (e.g., finding a foster care placement for a child and planning services necessary to ensure a child does not need to enter care, is reunited with his or her parents, has a new permanent home, or is otherwise prepared to leave foster care);
- Program-related data system development and operation, training, and recruitment of foster care providers; and
- Other program administration costs.

The federal government pays a share of these costs ranging from 50-83%, depending on the nature of the expenditure. Regarding foster care maintenance payments, an additional consideration is the state's per capita income.[6]

Title IV-E Waivers

In 1994, Congress authorized the U.S. Department of Health and Human Services (HHS) to approve state demonstration projects made possible by waiving certain provisions of Title IV-E. This provided states flexibility in using federal funds for services promoting safety, well-being, and permanency for children in the child welfare system.[7] HHS may waive compliance with standard Title IV-E requirements and instead allow states to establish projects that allow them to serve children and provide services that are not typically eligible. To do so, states must enter into an agreement with the federal government outlining the terms and conditions to which the state will adhere in using the federal funds. The states also agree to evaluate the projects.[8] Currently 26 states have approved projects, including Florida.[9]

Florida's Title IV-E Waivers

Florida's original Title IV-E waiver was effective on October 1, 2006, and was to extend for five years. Key features of the original waiver were:

- A capped allocation of funds, similar to a block grant, distributed to community-based care lead agencies for service provision;
- Flexibility to use funds for a broader array of services beyond out-of-home care; and
- Ability to serve children who did not meet Title IV-E criteria.[10]

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[5] Emelie Stoltzfus, *Child Welfare: An Overview of Federal Programs and their Current Funding*, CONGRESSIONAL RESEARCH SERVICE, January 10, 2017, p. 13-15, *available at* https://fas.org/sgp/crs/misc/R43458.pdf (last accessed Dec. 20, 2017).
[6] *Id.*
[7] Amy C. Vargo et al., *Final Evaluation Report, IV-E Waiver Demonstration Evaluation, SFY 11-12*, March 15, 2012, p. 5, *available at* http://www.centerforchildwelfare.org/kb/LegislativeMandatedRpts/IV-EWaiverFinalReport3-28-12.pdf (last accessed Dec. 20, 2017).
[8] 42 U.S.C. §1320a–9(f).
[9] Stoltzfus, *supra* note 6, at 15.
[10] Vargo, *supra* note 7, at 5-6.

The original waiver tested the hypotheses that under this approach:

- An expanded array of community-based care services would become available,
- Fewer children would need to enter out-of-home care,
- Child outcomes would improve, and
- Out-of-home care costs would decrease while expenditures for in-home and preventive services would increase.

Results indicated that the waiver generally achieved these goals, though evaluators noted areas of improvement available regarding the ongoing assessment of fathers' needs; assessment of children's dental, educational, and physical health needs and provision of needed services; frequency of case manager visits with parents; and engagement of fathers in services. [11]

The federal government extended Florida's original waiver to 2014, then approved a renewal retroactively beginning October 1, 2013. The renewal is authorized until September 30, 2018. The renewal waiver's terms and conditions include the following goals:

- Improving child and family outcomes through flexible use of Title IV-E funds;
- Providing a broader array of community-based services and increasing the number of children eligible for services; and
- Reducing administrative costs associated with the provision of child welfare services by removing current restrictions on Title IV-E eligibility and on the types of services that may be paid for using Title IV-E funds. [12]

Like the original waiver, the renewal waiver also involves a capped allocation of funds, flexibility to use funds for a wider array of services, and expanded eligibility for children.[13] The renewal waiver also required that the state procure an independent evaluation of the processes and outcomes under the waiver. The University of South Florida was chosen to complete these evaluations, which are available on the DCF website.[14] Florida was projected to expend an estimated $182 million in Title IV-E waiver funds in 2016-17, about 15% of total child welfare spending.[15]

Sunset of Waiver and Non-Renewal

As stated above, Florida's waiver is due to end September 30, 2018. Federal law prohibits the federal government from establishing new waivers or allowing current waivers to operate after September 30, 2019.[16] Thus Florida will revert to more restrictive Title IV-E federal funding requirements beginning in 2018, or in 2019 if the waiver is renewed for an additional year.

Child and Family Services Review

HHS, through the Children's Bureau, conducts periodic Child and Family Services Reviews in each state. As authorized by federal law, these reviews assess states' compliance with the federal requirements for child welfare systems in Title IV-B and Title IV-E of the Social Security Act. In particular, the Children's Bureau examines whether desired child outcomes are being achieved and whether the child welfare system is structured appropriately and its processes operate effectively.

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[11] *Id.* at 2-3.

[12] *Demonstration Project Terms and Conditions*, p. 4, *available at* http://www.centerforchildwelfare.org/kb/GenIVE/WaiverTErms2013-2018.pdf (last accessed Dec. 20, 2017).

[13] *Waiver Authority*, p.1, *available at* http://www.centerforchildwelfare.org/kb/GenIVE/WaiverTErms2013-2018.pdf (last accessed Dec. 20, 2017).

[14] Department of Children and Families, *IV-E Waiver Evaluation Reports, available at* http://centerforchildwelfare.fmhi.usf.edu/IVEReport.shtml (last accessed Dec. 20, 2017).

[15] Department of Children and Families, *Child Welfare Funding Basics for Florida in Light of Our Title IV-E Demonstration Waiver and the Family First Prevention Services Act of 2016 - HR 5456,* presented at the Florida Coalition for Children Foundation's 2016 Annual Conference, on file with Local, Federal & Veterans Affairs Subcommittee staff.

[16] 42 U.S.C. s. 1320a–9(d)(2).

In two previous rounds of reviews[17], no state was assessed as meeting all requirements.[18] The third round began in 2015 and involves a comprehensive analysis of the child welfare system comprising a statewide assessment, interviews, focus groups, and reviews of 80 cases. Through this analysis, the Children's Bureau rates whether a state is in "substantial conformity" with each outcome or systemic factor. For a state to be in substantial conformity with a particular outcome, 95% or more of the cases reviewed must be rated as having substantially achieved the outcome. The substantial conformity assessment for the systemic factors considers information from the statewide assessment, interviews, and focus groups.[19]

The report summarizing Florida's results was issued in late 2016. The report indicated that Florida was not in substantial conformity of any of the 7 outcomes but was in substantial conformity with 3 of 7 systemic factors, including:

- Quality assurance system,
- Staff and provider training, and
- Agency responsiveness to the community.[20]

As the reviews are currently in progress, 24 states and the District of Columbia have a Final State Report for Round 3 posted to the Children's Bureau website.[21] Once a state's review is complete, the state formulates a Performance Improvement Plan to address those outcomes and systemic factors not in substantial conformity.[22] Florida's current Performance Improvement Plan is available on the DCF website.[23]

Effect of the Memorial

The memorial requests that Congress amend federal law to allow for the extension of the existing Title IV-E waiver beyond September 30, 2019. An extension on the existing waiver program would give Florida the flexibility to continue alternative funding models and preserve the expanded array of services and supports that have been developed statewide. In the absence of an extension for the existing waiver, maintaining current service levels may require additional appropriations of state funds.

HM 817 also directs that copies of the memorial be provided to the President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, and to each member of the Florida delegation to the United States Congress.

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[17] U.S. Department of Health and Human Services, *Children's Bureau Fact Sheet: Child and Family Services Reviews, available at* https://www.acf.hhs.gov/sites/default/files/cb/cfsr_general_factsheet.pdf (last accessed Dec. 20, 2017). Note that because of differences in how the third round of reviews is being conducted, state performance cannot be compared across the reviews. *See* http://www.centerforchildwelfare.org/qa/CFSRTools/2016%20CFSR%20Final%20Report.pdf (last accessed Dec. 20, 2017).

[18] Id. The outcomes address safety (children are, first and foremost, protected from abuse and neglect and safely maintained in their homes whenever possible and appropriate), permanency (children have permanency and stability in their living situations, and the continuity of family relationships and connections is preserved for families), and family and child well-being (families have enhanced capacity to provide for their children's needs, and children receive appropriate services to meet their educational needs and adequate services to meet their physical and mental health needs). The systemic factors include the effectiveness of the statewide child welfare information system; the case review system; the quality assurance system; staff and provider training; the service array and resource development; the agency's responsiveness to the community; and foster and adoptive parent licensing, recruitment, and retention.

[19] U.S. Department of Health and Human Services, Administration for Children and Families, Administration on Children, Youth, and Families, Children's Bureau, *Child and Family Services Reviews, Florida Final Report, 2016*, p. 2, at http://www.centerforchildwelfare.org/qa/CFSRTools/2016%20CFSR%20Final%20Report.pdf (last accessed Dec. 20, 2017).

[20] *Id* at 3.

[21] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Reports and Results of the Child and Family Services Reviews (CFSRs)*, https://library.childwelfare.gov/cwig/ws/cwmd/docs/cb_web/SearchForm (last accessed Dec. 20, 2017).

[22] *Supra* note 17.

[23] FLORIDA'S CENTER FOR CHILD WELFARE, *Child and Family Services Review*, http://www.centerforchildwelfare.org/CFSRHome.shtml (last accessed Dec. 20, 2017).

Legislative memorials are not subject to the Governor's veto power and are not presented to the Governor for review. Memorials have no force of law, as they are mechanisms for formally petitioning the federal government to act on a particular subject.

B. SECTION DIRECTORY:

Not applicable.

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. This memorial does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The memorial does not provide rulemaking authority or require executive branch rulemaking.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

House Memorial

A memorial to the Congress of the United States, urging Congress to allow renewal of Title IV-E waivers for child welfare services.

WHEREAS, one of the most important roles of government is ensuring the safety and well-being of society's most vulnerable members, including children, and

WHEREAS, children enter the child welfare system for many reasons, such as parental substance abuse, domestic violence, mental illness, and generational poverty, and the complexity of cases is growing due to the interplay of these factors, and

WHEREAS, preventing child abuse, abandonment, and neglect saves children from trauma and avoids costs for more intensive treatment services, juvenile justice interventions, public benefits expenditures, and other social services, and

WHEREAS, with the federal funding flexibility provided by Florida's Title IV-E waiver for child welfare services, professionals working closely with children and families can tailor services to best meet individual needs, regardless of the level of involvement in the child welfare system, thus making the most effective and efficient use of funding, and

WHEREAS, Florida has been a national leader in innovative child welfare service provision through a community-based system of care and flexible funding streams, providing communities with

the responsibility, authority, and resources to care for their own children, and

WHEREAS, while the federal Child and Family Services Review found that Florida exceeds national standards with respect to certain indicators and systemic factors, the state still faces challenges in meeting other requirements and would benefit from continued flexibility in federal funding to most effectively meet these challenges, and

WHEREAS, Florida's Title IV-E waiver will expire September 30, 2018, and federal law requires all waiver operations to terminate by September 30, 2019, such that Florida will soon revert to more restrictive funding limitations unless Congress takes action, and

WHEREAS, widespread support exists nationally to transform the current Title IV-E funding approach to emphasize prevention and greater provision of a wider array of services tailored to meet individual families' needs so that children may be safe while avoiding the trauma of placement outside the home when possible, which is what Florida's waiver currently allows, and

WHEREAS, meeting traditional Title IV-E obligations will force significant changes to Florida's child welfare system, requiring professionals to spend time revising policies and processes instead of working to meet the needs of children and families, NOW, THEREFORE,

Be It Resolved by the Legislature of the State of Florida:

That the Legislature of the State of Florida requests the Congress of the United States to amend federal law to allow the Secretary of the Department of Health and Human Services to renew existing Title IV-E waivers to extend beyond September 30, 2019, giving Florida the flexibility to continue providing an expanded array of community-based programs and support to children who are in or who are at risk of entering out-of-home placement and their families.

BE IT FURTHER RESOLVED that copies of this memorial be dispatched to the President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, and to each member of the Florida delegation to the United States Congress.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 855 Genetic Information Used for Insurance
SPONSOR(S): Brodeur
TIED BILLS: **IDEN./SIM. BILLS:** SB 1106

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N	Grabowski	McElroy
2) Health & Human Services Committee		Grabowski	Calamas

SUMMARY ANALYSIS

The availability and use of genetic tests has increased dramatically in recent years. The resulting genetic information is generally used by individuals or their physicians to determine whether any action should be taken to improve long-term wellbeing.

Since the advent of genetic testing, there have been concerns about the use of personal genetic information by third parties. In particular, there is a concern that insurers may discriminate against individuals who have genetic markers indicating a heightened risk of developing certain diseases or health conditions.

The federal Health Insurance Portability and Accountability Act of 1996 prohibits health insurers from making coverage decisions solely based on personal genetic information. The federal Genetic Information Nondiscrimination Act of 2008 extended this concept by prohibiting health insurers from using genetic information in the underwriting process, and in the setting of premiums.

Florida law also prohibits health insurers from considering genetic information, both when issuing insurance policies and when setting applicable premium rates. This prohibition, however, does not extend to issuers of life insurance, disability income insurance, and long-term care insurance policies.

HB 855 expands existing prohibitions on the use of genetic information by insurers to include entities that issue policies for life insurance, long-term care insurance, and disability income insurance. Specifically, the bill prohibits issuers of life insurance, long-term care insurance, and disability income insurance from canceling, limiting, or denying coverage and from setting differential premium rates based on personal genetic information. This prohibition is not applicable in situations where there has been a diagnosis of a condition directly related to an individual's personal genetic information.

The bill also prohibits life insurers and long-term care insurers from requiring or soliciting genetic information and from using genetic information for insurance purposes.

The bill has no fiscal impact on state or local government.

The bill has an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Regulation of Insurance in Florida

The Office of Insurance Regulation (OIR) is responsible for all activities concerning insurers and other risk bearing entities, as provided under the insurance code. OIR regulates life insurers under parts III and V of ch. 627, F.S.

OIR regulates health insurers under part VI of ch. 627, F.S., and health maintenance organizations (HMOs) under part I of ch. 641, F.S. The Agency for Health Care Administration (AHCA) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from OIR, an HMO must receive a Health Care Provider Certificate from AHCA.[1] Long-term care insurance is coverage for medical and personal care services provided in a setting other than in an acute care unit of a hospital.[2] OIR regulates long-term care insurance under part XVIII of ch. 627, F.S.

Genetic Testing

The availability and use of genetic tests has increased dramatically in recent years. As of March 2017, there were nearly 70,000 genetic testing products on the market, with an average of 10.6 new testing products entering the market *a day* since 2015.[3] A 2016 survey indicated that 5.5% of adults in the U.S. had had genetic testing. Over half of those tested did so based on a concern about future health problems for them or their children, while 18% were tested to learn more about family heritage.[4] The U.S. Centers for Disease Control and Prevention (CDC) recognizes the development of genomic tests for thousands of diseases and health conditions, while also acknowledging that such tests are not necessarily a conclusive indication that an individual will develop a particular disease or condition.[5]

A wide range of health-related DNA screenings are available. The National Institutes for Health (NIH) categorizes these tests as follows.

- ***Diagnostic testing*** - identifies a genetic condition or disease that is making or in the future will make a person ill. The results of diagnostic testing can help in treating and managing the disorder.
- ***Predictive and pre-symptomatic genetic testing*** - identifies genetic variations that increase a person's chance of developing specific diseases. This type of genetic testing may help provide information about a person's risk of developing a disease, and can help in decisions about lifestyle and health care.

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[1] S. 641.21(1) and 641.48, F.S.

[2] S. 627.9404, F.S. Long-term care services may encompass a wide array of medical, social, and personal care services required by an individual with a chronic disability. American Academy of Actuaries, *The Use of Genetic Information in Disability Income and Long-Term Care Insurance*, Issue Brief, Spring 2002, available at https://www.actuary.org/files/publications/genetic_25apr02.pdf (last visited January 7, 2018).

[3] *The Current Landscape of Genetic Testing*, Concert Genetics, March 2017, available at https://www.concertgenetics.com/wp-content/uploads/2017/05/10_ConcertGenetics_CurrentLandscapeofGeneticTesting_2017Update.pdf (last viewed Jan. 8, 2018).

[4] Harvard University T.H. Chan School of Public Health, *The Public and Genetic Editing, Testing, and Therapy*, Jan. 2016, available at https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2016/01/STAT-Harvard-Poll-Jan-2016-Genetic-Technology.pdf (last viewed Jan. 8, 2018). Genetic testing has also given rise to a novel industry aimed at providing individuals with customized data related to family ancestry, including companies like 23andMe, Ancestry.com, FamilyTree DNA, and Living DNA.

[5] U.S. Centers for Disease Control and Prevention, *Genomic Testing*, last updated July 19, 2017, available at https://www.cdc.gov/genomics/gtesting/ (last visited January 7, 2018).

- ***Carrier testing*** – identifies whether a person "carries" a genetic change that can cause a disease. Carriers usually show no signs of the disorder; however, they can pass on the genetic variation to their children, who may develop the disorder or become carriers themselves.
- ***Prenatal testing*** - identifies fetuses that have certain diseases.
- ***Pre-implantation genetic testing*** – identifies whether embryos for implantation carry genes that could cause disease. This is often done in conjunction with *in vitro* fertilization.
- ***Newborn screening*** - is used to test babies one or two days after birth to determine if those newborns have certain diseases known to cause problems with health and development.
- ***Pharmacogenetic testing*** - provides information about how certain medicines are processed in a person's body. This type of testing can help a healthcare provider choose the medicines that work best with a person's genetic makeup. For example, genetic testing is now available to guide treatments for certain cancers.
- ***Research genetic testing*** – helps scientists learn more about how genes contribute to health and disease, as well as develop gene-based treatments. Sometimes the results do not directly help the research participant, but they may benefit others in the future by helping researchers expand their understanding of the human body.[6]

One often-cited use of genetic testing involves screening of female patients for a gene mutation that can be an early predictor of breast cancer. *BRCA 1* and *BRCA 2* gene mutations are relatively rare, but women having these mutations develop breast cancer at much higher rates than those without.[7] *BRCA* testing has become increasingly prevalent among women in families with histories of breast cancer.[8]

Use of Personal Genetic Information in Insurance Markets

The now-widespread availability of genetic tests has given rise to questions and concerns over the appropriate use of genetic information. While an individual may voluntarily submit to genetic testing in an effort to gain insights into his or her own genetic history, third parties may seek to obtain this same information for other purposes, such as for use in insurance markets.

For example, insurers might use genetic information to exclude high-risk individuals from established risk pools. Insurers might also charge higher premium rates to an individual whose genetic information indicates is at an increased risk of developing a degenerative health condition.[9] Conversely, exclusion of higher-risk insureds could reduce premium inflation for those left in the risk pool.

Similarly, consumers could use personal genetic information to the detriment of insurers. For example, an individual may discover through genetic testing that he or she is likely to develop a serious health condition, and only then purchase life insurance. An insurer is at a disadvantage and cannot accurately gauge the risk posed by covering an individual in this situation.[10] Adverse selection of this nature could destabilize insurance markets if access to personal genetic information leads to widespread changes in consumer behavior.[11] Specifically, the risk-spreading ability of insurance could be compromised if only those who are likely to become ill purchase insurance.[12]

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[6] U.S. Department of Health and Human Services, National Institutes for Health, *Genetic Testing: How it is Used for Healthcare*, available at https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=43 (last visited January 7, 2018).
[7] McCarthy, Anne Marie and Armstrong, Katrina, "The Role of Testing for *BRCA1* and *BRCA2* Mutations in Cancer Prevention." *JAMA Intern Med.* 2014;174(7):1023–1024. doi:10.1001/jamainternmed.2014.1322, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4169670/ (last visited January 7, 2018).
[8] Id.
[9] Klitzman, Robert, Appelbaum, Paul S., Chung, Wendy K, "Should Life Insurers Have Access to Genetic Test Results?". *JAMA.* 2014;312(18):1855–1856. doi:10.1001/jama.2014.13301, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4259574/ (last visited January 7, 2018).
[10] Id.
[11] American Academy of Actuaries, *The Use of Genetic Information in Disability Income and Long-Term Care Insurance*, Issue Brief, Spring 2002, available at https://www.actuary.org/files/publications/genetic_25apr02.pdf (last visited January 7, 2018).
[12] Id.

Federal Laws

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) includes the first federal regulations on the use of personal genetic information.[13] HIPAA prohibits health insurers from utilizing "preexisting condition" exclusions based solely on an individual's genetic information. Under HIPAA, insurers can make coverage decisions using information reflecting diagnosed health conditions, but not based on genetic indicators alone.[14]

The Genetic Information Nondiscrimination Act of 2008 (GINA) extended federal patient protections by preventing health insurers from using genetic information in the underwriting of health insurance products.[15] Health insurers may not charge higher premiums or make coverage decisions based solely on an individual's genetic information. However, the prohibitions outlined in GINA do not extend to other types of insurance, such as life insurance and long-term care insurance. There are currently no federal limitations on the use of genetic information by these insurers.

State Laws

States have adopted various regulations related to the use of genetic information by insurers. In general, states address patient privacy for personal genetic information by: [16]

1. Requiring informed consent before performing genetic testing;
2. Restricting the use of genetic data by health insurance, employers or providers of long-term life care or insurance; and,
3. Limiting disclosure of the personal genetic information without the consent of the individual or defining genetic data as the 'property' of the individual.

Most states have enacted laws that prohibit genetic discrimination by health insurers.[17] A number of states have taken actions to limit or prohibit the use of genetic information in other lines of insurance as well.[18] For example, Arizona, California, Massachusetts and New Jersey restrict use of genetic information by life insurers, and Kansas, Maryland and Massachusetts restrict use by long-term care insurers. Similarly, Arizona, California, Idaho, Kansas, Massachusetts and New Jersey restrict use by disability[19] insurers.[20]

Florida Law

Section 760.40, F.S., makes the results of genetic testing the exclusive personal property of the person tested, and makes it a first degree misdemeanor to sharing test results without the informed consent of the person tested.

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[13] Hall, Mark A. and Rich, Stephen S., "Laws Restricting Health Insurers' Use of Genetic Information: Impact on Genetic Discrimination." *AJHG* 2000: 66(1): 293-307, available at https://doi.org/10.1086/302714 (last visited January 7, 2018).
[14] Id.
[15] U.S. Equal Employment Opportunity Commission, *The Genetic Information Nondiscrimination Act of 2008*, available at https://www.eeoc.gov/laws/statutes/gina.cfm (last visited January 7, 2018).
[16] Miller, Amalia R. and Tucker, Catherine E., "Privacy Protection, Personalized Medicine and Genetic Testing" (July 31, 2014), available at https://ssrn.com/abstract=2411230 (last visited January 7, 2018).
[17] Rothstein, Mark A., "Putting the Genetic Nondiscrimination Act in context." *Genetics in Medicine* 2008: 10: 655-656, available at https://www.nature.com/articles/gim200899 (last visited January 7, 2018).
[18] The National Human Genome Human Research Institute maintains a searchable database of legislation related to genetic information that has either been enacted or considered by state legislatures. U.S. Department of Health and Human Services, National Institutes of Health – National Human Genome Human Research Institute, *Genome Statute and Legislation Database*, available at https://www.genome.gov/policyethics/legdatabase/pubsearch.cfm?CFID=22285441&CFTOKEN=7fc536f1b99bbd21-2342A48B-03C6-03BE-03FEEF39A8695C0F (last visited January 7, 2018).
[19] Disability income insurance protects earned income against potential loss due to disabling injury or illness. American Academy of Actuaries, *The Use of Genetic Information in Disability Income and Long-Term Care Insurance*, Issue Brief, Spring 2002, available at https://www.actuary.org/files/publications/genetic_25apr02.pdf (last visited January 7, 2018).
[20] *Supra* note 20.

Section 627.4301, F.S., prohibits health insurers from considering genetic information, both when issuing insurance policies and when setting applicable premium rates.[21] Insurers cannot require or solicit genetic information, or employ underwriting based on the results of any genetic testing that an individual may choose to complete, and cannot use such results for any purpose. This prohibition is currently limited to self-insured health plans, fully-insured health plans, health maintenance organizations (HMOs), prepaid limited health service organizations, prepaid health clinics, fraternal benefit societies, or any other health care arrangement where risk is assumed. This section of law expressly exempts several forms of insurance from the prohibition: life insurance, and policies for disability income, long-term care, accident-only, hospital indemnity or fixed indemnity, dental, and vision.

Effect of Proposed Changes

HB 855 amends s. 627.4301, F.S., to expand existing prohibitions on the use of genetic information by including life insurance, long-term care insurance, and disability income insurance. Specifically, the bill prohibits issuers of life insurance, long-term care insurance, and disability income insurance from canceling, limiting, or denying coverage and from setting differential premium rates based on personal genetic information. This prohibition is not applicable in situations where there has been a diagnosis of a condition directly related to an individual's personal genetic information.

The bill also prohibits life insurers and long-term care insurers from requiring or soliciting genetic information and from using genetic information for insurance purposes.

The bill has an effective date of July 1, 2018 and would apply to insurance policies entered into or renewed on or after January 1, 2019.

B. SECTION DIRECTORY:

Section 1: Amends s. 627.4301, F.S., relating to the use of genetic information for insurance purposes.

Section 2: Establishes that the bill's requirements are applicable to insurance policies entered into or renewed on or after January 1, 2019.

Section 3: Provides an effective date of July 1, 2018.

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.

[21] See also S. 626.9706, F.S., which prohibits insurers from refusing coverage or charging higher premiums to individuals determined to carry the sickle-cell trait.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

It is unclear whether or how, insurers of life insurance, long-term care insurance, and disability income insurance are currently using personal genetic information, so the economic impact of the bill's prohibition on its use is unknown.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to genetic information used for insurance; amending s. 627.4301, F.S.; providing definitions; prohibiting the use of genetic information in the issuance of life insurance policies, long-term care policies, and disability income policies; providing applicability; providing an effective date.

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

Section 1. Section 627.4301, Florida Statutes, is amended to read:

627.4301 Genetic information for insurance purposes.—

(1) DEFINITIONS.—As used in this section, the term:

(a) "Genetic information" means information derived from genetic testing to determine the presence or absence of variations or mutations, including carrier status, in an individual's genetic material or genes that are scientifically or medically believed to cause a disease, disorder, or syndrome, or are associated with a statistically increased risk of developing a disease, disorder, or syndrome, which is asymptomatic at the time of testing. Such testing does not include routine physical examinations or chemical, blood, or urine analysis, unless conducted purposefully to obtain genetic

information, or questions regarding family history.

(b) "Health insurer" means an authorized insurer offering health insurance as defined in s. 624.603, a self-insured plan as defined in s. 624.031, a multiple-employer welfare arrangement as defined in s. 624.437, a prepaid limited health service organization as defined in s. 636.003, a health maintenance organization as defined in s. 641.19, a prepaid health clinic as defined in s. 641.402, a fraternal benefit society as defined in s. 632.601, or any health care arrangement whereby risk is assumed.

(c) "Life insurer" has the same meaning as in s. 624.602 and includes the granting of additional benefits in the event of the insured's disability.

(d) "Long-term care insurer" means an insurer that issues long-term care insurance policies as described in s. 627.9404.

(2) USE OF GENETIC INFORMATION.—

(a) In the absence of a diagnosis of a condition related to genetic information, no health insurer, life insurer, or long-term care insurer authorized to transact insurance in this state may cancel, limit, or deny coverage, or establish differentials in premium rates, based on such information.

(b) Health insurers, life insurers, and long-term care insurers may not require or solicit genetic information, use genetic test results, or consider a person's decisions or actions relating to genetic testing in any manner for any

insurance purpose.

(c) This section does not apply to the underwriting or issuance of an ~~a life insurance policy, disability income policy, long-term care policy,~~ accident-only policy, hospital indemnity or fixed indemnity policy, dental policy, or vision policy or any other actions of an insurer directly related to an ~~a life insurance policy, disability income policy, long-term care policy,~~ accident-only policy, hospital indemnity or fixed indemnity policy, dental policy, or vision policy.

Section 2. This act applies to policies entered into or renewed on or after January 1, 2019.

Section 3. This act shall take effect July 1, 2018.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 973 Performance of Physician Assistants and Advanced Registered Nurse Practitioners
SPONSOR(S): Daniels and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 708

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	15 Y, 0 N	Siples	McElroy
2) Health & Human Services Committee		Siples	Calamas

SUMMARY ANALYSIS

Advanced registered nurse practitioners (ARNPs) are licensed registered nurses with post-graduate education in nursing that prepares them to perform advanced or specialized nursing. ARNPs may perform nursing or medical acts that are authorized pursuant to a written protocol with a physician. ARNPs may only sign those documents that are directly related to the performance of the nursing or medical acts authorized pursuant to a protocol, unless otherwise prohibited by law.

Physician assistants (PAs) complete specialized education that prepares them to perform medical services and practice as a part of a health care team. PAs practice under the delegated authority of a supervising physician. A PA may sign only those documents that are directly related to the performance of medical services performed as delegated by a supervising physician and do not, by law, require a physician's signature.

ARNPs and PAs provide comprehensive health care to patients within the scope of their education, certification, and delegated authority. Currently, ARNPs and PAs are prohibited from signing various documents associated with the care that an ARNP or PA provides. Instead, a physician's signature is required on these documents even if the physician did not provide care to the patient. Such documents include the disability certification for certain tax exemptions, a death certificate, and a certificate to initiate an involuntary examination under the Baker Act.

HB 973 authorizes allopathic and osteopathic physicians to delegate authority to ARNPs and PAs to sign, certify, stamp, verify, or endorse any document required by law to be signed by a physician. However, the bill specifically prohibits a PA or an ARNP who is not a psychiatric nurse from approving the release of an individual from a Baker Act receiving facility.

The bill has no fiscal impact on state or local government.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Advanced Registered Nurse Practitioners

Nurses are licensure are licensed by DOH and regulated by the Board of Nursing pursuant to part I of ch. 464, F.S. Licensure requirements to practice nursing include completion of an approved educational course of study, passage of an examination approved by DOH, and acceptable criminal background screening results.[1]

A nurse actively licensed to practice professional nursing may be certified as an Advanced Registered Nurse Practitioner (ARNP), under s. 464.012, F.S., if the nurse meets one or both of the following requirements:

- Certification by a specialty board; or
- Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills.

Current law defines three categories of ARNPs: certified registered nurse anesthetists, certified nurse midwives, and nurse practitioners.[2] All ARNPs, regardless of practice category, may only practice within the framework of an established protocol and under the supervision of an allopathic or osteopathic physician or dentist.[3] ARNPs may carry out treatments as specified in statute, including:[4]

- Prescribing, dispensing, administering, or ordering any drug;[5]
- Initiating appropriate therapies for certain conditions;
- Ordering diagnostic tests and physical and occupational therapy;
- Ordering any medication for administration patients in certain facilities; and
- Performing additional functions as determined by rule.[6]

In addition to the above-allowed acts, an ARNP may also perform other acts as authorized by statute and within his or her specialty.[7] Currently, there are 27,588 ARNPs who hold active licenses to practice in Florida.[8]

An ARNP may sign only those documents that are directly related to the performance of authorized nursing or medical acts performed pursuant to a physician's protocol and which do not, by law, require a physician's signature. Under current law, an ARNP may not sign, among other things, a certificate to

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[1] Sections 464.008 and 464.009, F.S. As an alternative to licensure by examination, a nurse may also be eligible for licensure by endorsement.
[2] Section 464.012(2), F.S.
[3] Section 464.012(3), F.S.
[4] Id.
[5] An ARNP may only prescribe controlled substances if he or she has graduated from a program leading to a master's or doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills. An ARNP is limited to prescribing a 7-day supply of Schedule II controlled substances. Only a psychiatric nurse may prescribe psychotropic controlled substances for the treatment of mental disorders and psychiatric mental health controlled substances for children younger than 18.
[6] Section 464.003(2), F.S., defines "advanced or specialized nursing practice" to include additional activities that an ARNP may perform as approved by the Board of Nursing.
[7] Section 464.012(4), F.S.
[8] Email correspondence with the Department of Health, dated December 14, 2017 (on file with the Health Quality Subcommittee).

initiate an involuntary examination of a person under the Baker Act,[9] a death certificate,[10] or a certification of a disability for certain tax exemptions.[11] Only an ARNP who qualifies as a psychiatric nurse[12] acting within the framework of an established protocol with a psychiatrist may execute a certificate for an involuntary examination under the Baker Act[13] or authorize the release of a patient from a receiving facility.[14] If the involuntary examination was performed by psychiatrist, a psychiatric nurse may not approve the release of a patient unless it is approved by the initiating psychiatrist.[15]

Physician Assistants

Physician assistants are governed by the physician practice acts for medical doctors and doctors of osteopathic medicine. PAs are regulated by the Florida Council on Physician Assistants (Council) in conjunction with either the Board of Medicine for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S. As of December 2017, there are 9,118 PAs who hold active licenses to practice in Florida.[16]

An applicant for a PA license must apply to the Department of Health (DOH). DOH must issue a license to a person certified by the Council as having met all of the following requirements:[17]

- Complete an approved PA training program;
- Obtain a passing score on the National Commission on Certification of Physician Assistant exam;
- Acknowledge any prior felony convictions;
- Submit to a background screening and have no disqualifying offenses;[18]
- Acknowledge any previous revocation or denial of licensure in any state; and
- Provide a copy of course transcripts and a copy of the course description from a PA training program describing the course content in pharmacotherapy if the applicant is seeking prescribing authority.

PAs may only practice under the direct or indirect supervision of a medical doctor or doctor of osteopathic medicine with whom they have a clinical relationship.[19] A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[20] The supervising physician is responsible and liable for any acts or omissions of the PA and may not supervise more than four PAs at any time.[21]

The Boards have established by rule that "responsible supervision" of a PA means the ability of the supervising physician to exercise control and provide direction over the services or tasks performed by the PA. Whether the supervision of a PA is adequate, is dependent upon the:

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[9] The Baker Act authorizes the involuntary examination of certain individuals who, without care or treatment, pose a real and present danger to their well-being or may cause serious bodily injury to themselves or others in the near future, as evidenced by recent behavior (s. 394.463(1), F.S.)
[10] Section 382.008, F.S.
[11] Section 196.101, F.S.
[12] Section 394.455(35), F.S., defines a psychiatric nurse as an ARNP who has a master's degree or a doctorate in psychiatric nursing, holds a national advanced practice certification as a psychiatric mental health advance practice nurse, and has two years of post-master's clinical experience under the supervision of a physician.
[13] Section 394.463(2)(a)1., F.S.
[14] Section 394.463(2)(f), F.S. A receiving facility is a facility designated by the Department of Children and Families to provide the initial examination and short-term treatment of individuals who meet the criteria under the Baker Act.
[15] Id.
[16] Email correspondence with the Department of Health, dated December 14, 2017 (on file with the Health Quality Subcommittee).
[17] Sections 458.347(7) and 459.022(7), F.S.
[18] Section 456.0135, F.S.
[19] Sections 458.347(2)(f) and 459.022(2)(f), F.S., define supervision as responsible supervision and control which requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.
[20] Rules 64B8-30.012 and 64B15-6.010, F.A.C.
[21] Sections 458.347(15) and 459.022(15), F.S.

- Complexity of the task;
- Risk to the patient;
- Background, training and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.[22]

A supervising physician decides whether to permit a PA to perform a task or procedure under direct or indirect based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.[23] A supervising physician may delegate the authority for a PA to:

- Prescribe or dispense any medicinal drug used in the supervising physician's practice unless such medication is listed in the formulary established by the Council;[24]
- Order any medication for administration to the supervising physician's patient in a hospital or other facility licensed under chapter 395, F.S., or a nursing homes licensed under part II of chapter 400, F.S.;[25] and
- Any other services that are not expressly prohibited in ch. 458, F.S., ch. 459, F.S., or the rules adopted thereunder.[26]

A PA may sign only those documents that are directly related to the performance of medical services performed as delegated by a supervising physician and which do not, by law, require a physician's signature. Under current law, a PA may not sign, among other things, a certificate to initiate an involuntary examination of a person under the Baker Act,[27] a death certificate,[28] or a certification of a disability for certain tax exemptions.[29]

Effect of Proposed Changes

HB 973 authorizes allopathic and osteopathic physicians to delegate authority to ARNPs and PAs to sign, certify, stamp, verify, or endorse any document that requires the signature, certification, stamp, verification, or endorsement of a physician. This includes, among other things, signing a disability certification, initiation of an involuntary examination of a person under the Baker Act, or a death certificate. However, the bill specifically prohibits a PA or an ARNP who is not a psychiatric nurse from approving the release of an individual from a Baker Act receiving facility.

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 458.347, F.S., relating to physician assistants.

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[22] Rules 64B8-30.001, F.A.C., and 64B15-6.001, F.A.C.

[23] "Direct supervision" refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed. "Indirect supervision" refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication. *Supra* note 22.

[24] Sections 458.347(4)(f), F.S., and 459.022(e), F.S., directs the Council to establish a formulary listing the medical drugs that a PA may not prescribe. The formulary in Rules 64B8-30.008, F.A.C., and 64B15-6.0038, F.A.C., prohibits PAs from prescribing; general, spinal or epidural anesthetics; radiographic contrast materials; and psychiatric mental health controlled substances for children younger than 18 years of age. It also restricts the prescribing of Schedule II controlled substances to a 7-day supply. However, the rules authorize physicians to delegate to PAs the authority to order controlled substances in hospitals and other facilities licensed under ch. 395, F.S.

[25] Chapter 395, F.S., provides for the regulation and the licensure of hospitals and trauma centers, part II of ch. 400, F.S., provides for the regulation and licensure of nursing home facilities.

[26] Sections 458.347(4) and 459.022(e), F.S.

[27] *Supra* note 9.

[28] *Supra* note 10.

[29] *Supra* note 11.

Section 2: Amends s. 459.022, F.S., relating to physician assistants.
Section 3: Amends s. 464.012, F.S., relating to certification of advanced registered nurse practitioners; fees; controlled substance prescribing.
Section 4: Provides an effective date of July 1, 2018.

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:

If a document requires a physician's signature, patients will have additional options for selecting a health care provider.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. There 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

A bill to be entitled

An act relating to performance of physician assistants and advanced registered nurse practitioners; amending ss. 458.347 and 459.022, F.S.; authorizing a physician assistant to sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician; providing an exception; amending s. 464.012, F.S.; authorizing an advanced registered nurse practitioner to sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician within the framework of an established protocol and under supervision; providing an exception; providing an effective date.

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

Section 1. Paragraph (i) is added to subsection (4) of section 458.347, Florida Statutes, to read:

458.347 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(i) A supervisory physician may delegate to a licensed physician assistant the authority to sign, certify, stamp, verify, or endorse a document that requires the signature,

certification, stamp, verification, or endorsement of a physician, except that the supervisory physician may not delegate the authority to issue a written approval to release a patient from a receiving facility or its contractor under s. 394.463(2)(f).

Section 2. Paragraph (h) is added to subsection (4) of section 459.022, Florida Statutes, to read:

459.022 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(h) A supervisory physician may delegate to a licensed physician assistant the authority to sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician, except that the supervisory physician may not delegate the authority to issue a written approval to release a patient from a receiving facility or its contractor under s. 394.463(2)(f).

Section 3. Subsection (3) of section 464.012, Florida Statutes, is amended to read:

464.012 Certification of advanced registered nurse practitioners; fees; controlled substance prescribing.—

(3) An advanced registered nurse practitioner shall perform those functions authorized in this section within the framework of an established protocol which must be maintained on site at the location or locations at which an advanced

registered nurse practitioner practices. In the case of multiple supervising physicians in the same group, an advanced registered nurse practitioner must enter into a supervisory protocol with at least one physician within the physician group practice. A practitioner currently licensed under chapter 458, chapter 459, or chapter 466 shall maintain supervision for directing the specific course of medical treatment. Within the established framework, an advanced registered nurse practitioner may:

(a) Prescribe, dispense, administer, or order any drug; however, an advanced registered nurse practitioner may prescribe or dispense a controlled substance as defined in s. 893.03 only if the advanced registered nurse practitioner has graduated from a program leading to a master's or doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills.

(b) Initiate appropriate therapies for certain conditions.

(c) Perform additional functions as may be determined by rule in accordance with s. 464.003(2).

(d) Order diagnostic tests and physical and occupational therapy.

(e) Order any medication for administration to a patient in a facility licensed under chapter 395 or part II of chapter 400, notwithstanding any provisions in chapter 465 or chapter 893.

(f) Sign, certify, stamp, verify, or endorse a document

that requires the signature, certification, stamp, verification, or endorsement of a physician, except that the supervisory physician may not delegate the authority to issue a written approval to release a patient from a receiving facility or its contractor under s. 394.463(2)(f).

Section 4. This act shall take effect July 1, 2018.

HB 6049

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 6049 Medical Marijuana Growers
SPONSOR(S): Jones
TIED BILLS: **IDEN./SIM. BILLS:** SB 1134

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	15 Y, 0 N	Royal	McElroy
2) Health & Human Services Committee		Royal	Calamas

SUMMARY ANALYSIS

On November 8, 2016, Florida voters approved an amendment to the Florida Constitution (Fla. Const. art. X, s. 29) which allows the medical use of marijuana by patients with an enumerated debilitating medical condition. The amendment authorizes entities known as Medical Marijuana Treatment Centers (MMTCs) to be marijuana providers. During the 2017A Special Session, the legislature passed SB8-A which implements Fla. Const. art. X, s. 29.

Current law requires the Department of Health (DOH) to grant MMTC licenses to dispensing organizations licensed by July 3, 2017. Current law also requires DOH to grant ten additional MMTC licenses by October 3, 2017. Among these, one of the licenses must be awarded to an applicant that is a recognized class member of *Pigford v. Glickman,* 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011), and is a Florida member of the Florida Black Farmers and Agriculturalists Association (Recognized Class Member License).

HB 6049 repeals the requirement that a Recognized Class Member License applicant be a member of the Florida Black Farmers and Agriculturalists Association. An applicant must only be a recognized class member of *Pigford v. Glickman,* 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011) to be eligible for the Recognized Class Member License.

The bill also repeals the requirement that the license be awarded by October 3, 2017.

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

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Compassionate Medical Cannabis Act

The Compassionate Medical Cannabis Act (CMCA) was enacted in 2014.[1] The CMCA legalized a low-THC and high-CBD form of low-THC cannabis[2] for medical use[3] by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms. In 2016, the legislature also amended the Right to Try Act (RTTA) to allow eligible patients with a terminal condition to receive a form of cannabis with no THC limit or CBD mandate referred to as medical cannabis.[4]

Under the CMCA, the Department of Health (DOH) was required to approve by January 1, 2015, five dispensing organizations to cultivate, process, transport, and dispense low-THC cannabis or medical cannabis with one dispensing organization in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida.

The CMCA also required DOH to approve three additional dispensing organizations upon the registration of 250,000 active qualified patients in the compassionate use registry.[5] The CMCA required one of these additional dispensing organizations to be owned and operated by a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011), and be a member of the Black Farmers and Agriculturalists Association.

Amendment 2

On November 8, 2016, Florida voters approved Amendment 2, Use of Marijuana for Debilitating Medical Conditions as Art. X, Sec. 29 of the Florida Constitution. The amendment authorizes patients with an enumerated debilitating medical condition to obtain medical marijuana from MMTCs.

The amendment requires DOH to register MMTCs to provide medical marijuana and related supplies to patients or their caregivers. MMTCs may acquire, cultivate, possess process, transfer, transport, sell, distribute, dispense, or administer marijuana and products containing marijuana. MMTCs may also provide related supplies and educational materials.

The amendment requires DOH to establish procedures for the registration of MMTCs that include procedures for the issuance, renewal, suspension and revocation of registration. The amendment also requires DOH to establish regulatory standards for security, record keeping, testing, labeling, inspection, and safety.

The amendment states that the legislature may enact laws consistent with the amendment.

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[1] *See* ch. 2014-157, L.O.F., ch. 2016-123, L.O.F. and s. 381.986, F.S.

[2] The act defined "low-THC cannabis," as the dried flowers of the plant *Cannabis* which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight, or the seeds, resin, or any compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. *See* s. 381.986(1)(b), F.S.(2014)

[3] Section 381.986(1)(c), F.S. (2014), defined "medical use" as "administration of the ordered amount of low-THC cannabis. The term does not include the possession, use, or administration by smoking. The term also does not include the transfer of low-THC cannabis to a person other than the qualified patient for whom it was ordered or the qualified patient's legal representative on behalf of the qualified patient." Section 381.986(1)(e), F.S. (2014), defined "smoking" as "burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer."

[4] Section 499.0295, F.S. (2016)

[5] Section 381.986(5)(c), F.S. (2016)

SB 8-A

During the 2017A Special Session, the legislature passed SB8-A which implements Fla. Const. art. X, s. 29 by significantly amending the CMCA.

Current law requires DOH to grant MMTC licenses to dispensing organizations previously licensed under the CMCA by July 3, 2017.[6] Current law also requires DOH to grant ten additional MMTC licenses.[7] Among these, licenses were to be awarded by August 1, 2017, to any dispensing organization applicant denied under the CMCA whose application was scored by DOH and had one or more administrative or legal challenges pending as of January 1, 2017, or had a final ranking within one point of the highest final ranking applicant in its region, and proves to DOH that it has the infrastructure and ability to begin cultivating marijuana within 30 days after registration as a MMTC.[8] The remaining licenses were to be awarded by October 3, 2017, one of which must be awarded to an applicant that is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011), and is a Florida member of the Florida Black Farmers and Agriculturalists Association (Recognized Class Member License).[9]

DOH must grant 4 additional MMTC licenses when the patient population reaches 100,000 and 4 additional MMTC licenses for every additional 100,000 patients thereafter.[10]

On September 22, 2017, Columbus Smith (Smith) filed a lawsuit challenging the requirement that a Recognized Class Member License applicant be a member of the Florida Black Farmers and Agriculturalists Association.[11] Smith is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011) but is not a member of the Florida Black Farmers and Agriculturalists Association. Smith sought an injunction to enjoin DOH from awarding a Recognized Class Member License. On January 9, 2018, the injunction was granted. DOH has not granted any of the 10 additional MMTC licenses that it was required to grant by October 3, 2017, due to this lawsuit.

Effect of the Bill

HB 6049 repeals the requirement that a Recognized Class Member License applicant be a member of the Florida Black Farmers and Agriculturalists Association. An applicant must only be a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011) to be eligible for the Recognized Class Member License.

Members of the Florida Black Farmers and Agriculturalists Association can still apply for the remaining MMTC licenses.[12]

The bill also repeals the requirement that the license be awarded by October 3, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.986, F.S., relating to Medical Marijuana Treatment Centers.
Section 2: Provides an effective date of July 1, 2018.

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[6] Section 381.986(8)(a)1, F.S.
[7] Section 381.986(8)(a)2, F.S.
[8] Section 381.986(8)(a)2.a, F.S.
[9] Section 381.986(8)(a)2.b, F.S
[10] Section 381.986(8)(a)4, F.S.
[11] Smith v. Florida Department of Health, case number 17-CA-1972, in the Circuit Court for the Second Judicial Circuit of Florida.
[12] Florida Black Farmers and Agriculturalists Association members that apply for the remaining MMTC licenses will not be eligible for the exemptions granted to the Recognized Class Member License applicants. Recognized Class Member License applicants are exempt from the requirements to have been a registered Florida business for the previous five years and hold a nurseryman certificate from the Department of Agriculture and Consumer Services. See Section 381.986(8)(a)2.b, F.S.

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:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to medical marijuana growers; amending s. 381.986, F.S.; deleting a requirement that the Department of Health grant a medical marijuana treatment center license to a member of a specified association; providing an effective date.

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

Section 1. Paragraph (a) of subsection (8) of section 381.986, Florida Statutes, is amended to read:

381.986 Medical use of marijuana.—

(8) MEDICAL MARIJUANA TREATMENT CENTERS.—

(a) The department shall license medical marijuana treatment centers to ensure reasonable statewide accessibility and availability as necessary for qualified patients registered in the medical marijuana use registry and who are issued a physician certification under this section.

1. As soon as practicable, but no later than July 3, 2017, the department shall license as a medical marijuana treatment center any entity that holds an active, unrestricted license to cultivate, process, transport, and dispense low-THC cannabis, medical cannabis, and cannabis delivery devices, under former s. 381.986, Florida Statutes 2016, before July 1, 2017, and which meets the requirements of this section. In addition to the

authority granted under this section, these entities are authorized to dispense low-THC cannabis, medical cannabis, and cannabis delivery devices ordered pursuant to former s. 381.986, Florida Statutes 2016, which were entered into the compassionate use registry before July 1, 2017, and are authorized to begin dispensing marijuana under this section on July 3, 2017. The department may grant variances from the representations made in such an entity's original application for approval under former s. 381.986, Florida Statutes 2014, pursuant to paragraph (e).

2. The department shall license as medical marijuana treatment centers 10 applicants that meet the requirements of this section, under the following parameters:

a. As soon as practicable, but no later than August 1, 2017, the department shall license any applicant whose application was reviewed, evaluated, and scored by the department and which was denied a dispensing organization license by the department under former s. 381.986, Florida Statutes 2014; which had one or more administrative or judicial challenges pending as of January 1, 2017, or had a final ranking within one point of the highest final ranking in its region under former s. 381.986, Florida Statutes 2014; which meets the requirements of this section; and which provides documentation to the department that it has the existing infrastructure and technical and technological ability to begin cultivating marijuana within 30 days after registration as a medical

marijuana treatment center.

b. As soon as practicable, ~~but no later than October 3, 2017,~~ the department shall license one applicant that is a recognized class member of Pigford v. Glickman, 185 F.R.D. 82 (D.D.C. 1999), or In Re Black Farmers Litig., 856 F. Supp. 2d 1 (D.D.C. 2011) ~~and is a member of the Black Farmers and Agriculturalists Association-Florida Chapter~~. An applicant licensed under this sub-subparagraph is exempt from the requirements of subparagraphs (b)1. and 2.

c. As soon as practicable, but no later than October 3, 2017, the department shall license applicants that meet the requirements of this section in sufficient numbers to result in 10 total licenses issued under this subparagraph, while accounting for the number of licenses issued under sub-subparagraphs a. and b.

3. For up to two of the licenses issued under subparagraph 2., the department shall give preference to applicants that demonstrate in their applications that they own one or more facilities that are, or were, used for the canning, concentrating, or otherwise processing of citrus fruit or citrus molasses and will use or convert the facility or facilities for the processing of marijuana.

4. Within 6 months after the registration of 100,000 active qualified patients in the medical marijuana use registry, the department shall license four additional medical marijuana

treatment centers that meet the requirements of this section. Thereafter, the department shall license four medical marijuana treatment centers within 6 months after the registration of each additional 100,000 active qualified patients in the medical marijuana use registry that meet the requirements of this section.

5. Dispensing facilities are subject to the following requirements:

a. A medical marijuana treatment center may not establish or operate more than a statewide maximum of 25 dispensing facilities, unless the medical marijuana use registry reaches a total of 100,000 active registered qualified patients. When the medical marijuana use registry reaches 100,000 active registered qualified patients, and then upon each further instance of the total active registered qualified patients increasing by 100,000, the statewide maximum number of dispensing facilities that each licensed medical marijuana treatment center may establish and operate increases by five.

b. A medical marijuana treatment center may not establish more than the maximum number of dispensing facilities allowed in each of the Northwest, Northeast, Central, Southwest, and Southeast Regions. The department shall determine a medical marijuana treatment center's maximum number of dispensing facilities allowed in each region by calculating the percentage of the total statewide population contained within that region

and multiplying that percentage by the medical marijuana treatment center's statewide maximum number of dispensing facilities established under sub-subparagraph a., rounded to the nearest whole number. The department shall ensure that such rounding does not cause a medical marijuana treatment center's total number of statewide dispensing facilities to exceed its statewide maximum. The department shall initially calculate the maximum number of dispensing facilities allowed in each region for each medical marijuana treatment center using county population estimates from the Florida Estimates of Population 2016, as published by the Office of Economic and Demographic Research, and shall perform recalculations following the official release of county population data resulting from each United States Decennial Census. For the purposes of this subparagraph:

(I) The Northwest Region consists of Bay, Calhoun, Escambia, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Okaloosa, Santa Rosa, Taylor, Wakulla, Walton, and Washington Counties.

(II) The Northeast Region consists of Alachua, Baker, Bradford, Clay, Columbia, Dixie, Duval, Flagler, Gilchrist, Hamilton, Lafayette, Levy, Marion, Nassau, Putnam, St. Johns, Suwannee, and Union Counties.

(III) The Central Region consists of Brevard, Citrus, Hardee, Hernando, Indian River, Lake, Orange, Osceola, Pasco,

Pinellas, Polk, Seminole, St. Lucie, Sumter, and Volusia Counties.

(IV) The Southwest Region consists of Charlotte, Collier, DeSoto, Glades, Hendry, Highlands, Hillsborough, Lee, Manatee, Okeechobee, and Sarasota Counties.

(V) The Southeast Region consists of Broward, Miami-Dade, Martin, Monroe, and Palm Beach Counties.

c. If a medical marijuana treatment center establishes a number of dispensing facilities within a region that is less than the number allowed for that region under sub-subparagraph b., the medical marijuana treatment center may sell one or more of its unused dispensing facility slots to other licensed medical marijuana treatment centers. For each dispensing facility slot that a medical marijuana treatment center sells, that medical marijuana treatment center's statewide maximum number of dispensing facilities, as determined under sub-subparagraph a., is reduced by one. The statewide maximum number of dispensing facilities for a medical marijuana treatment center that purchases an unused dispensing facility slot is increased by one per slot purchased. Additionally, the sale of a dispensing facility slot shall reduce the seller's regional maximum and increase the purchaser's regional maximum number of dispensing facilities, as determined in sub-subparagraph b., by one for that region. For any slot purchased under this sub-subparagraph, the regional restriction applied to that slot's

location under sub-subparagraph b. before the purchase shall remain in effect following the purchase. A medical marijuana treatment center that sells or purchases a dispensing facility slot must notify the department within 3 days of sale.

d. This subparagraph shall expire on April 1, 2020.

If this subparagraph or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end, the provisions of this subparagraph are severable.

Section 2. This act shall take effect July 1, 2018.