

Tab 6	CS/SB 434 by HP, Harrell; (Compare to CS/1ST ENG/H 00843) Ambulatory Surgical Centers					
246860	A	S		AHS, Harrell	Delete L.41:	04/03 02:59 PM
Tab 1	SB 716 by Hooper (CO-INTRODUCERS) Stewart, Perry, Rodriguez, Berman, Harrell, Montford, Mayfield, Broxson, Taddeo; (Similar to H 00465) Dental Services					
740542	A	S	RCS	AHS, Hooper	Delete L.42 - 150:	04/09 08:31 PM
Tab 8	CS/SB 732 by HP, Flores; (Compare to CS/CS/CS/H 00933) Clinics and Office Surgery					
359744	A	S	RS	AHS, Flores	Delete L.414 - 624:	04/10 01:11 PM
978476	SD	S	RCS	AHS, Flores	Delete everything after	04/10 01:11 PM
868332	AA	S	RCS	AHS, Flores	Delete L.166:	04/10 01:11 PM
Tab 5	CS/SB 900 by CF, Harrell (CO-INTRODUCERS) Rader; (Similar to CS/CS/H 00369) Substance Abuse Services					
312576	A	S	WD	AHS, Harrell	Delete L.323 - 326.	04/10 12:59 PM
839894	SA	S	WD	AHS, Book	Delete L.326:	04/10 12:59 PM
122872	A	S	RCS	AHS, Harrell	Delete L.408 - 446.	04/10 12:59 PM
Tab 2	CS/SB 1218 by CF, Book (CO-INTRODUCERS) Rouson; (Similar to CS/H 01353) Homelessness					
235940	A	S	RCS	AHS, Book	Delete L.158 - 159:	04/09 08:32 PM
Tab 9	CS/SB 1460 by HP, Book (CO-INTRODUCERS) Powell; (Compare to CS/CS/H 00993) Stroke Centers					
538518	A	S	RCS	AHS, Book	Delete L.43 - 49:	04/09 08:44 PM
835638	A	S	RCS	AHS, Book	Delete L.119:	04/09 08:44 PM
Tab 4	CS/SB 1518 by HP, Wright (CO-INTRODUCERS) Book, Cruz; (Similar to CS/CS/H 00501) Alternative Treatment Options for Veterans					
132100	D	S	RCS	AHS, Wright	Delete everything after	04/10 08:52 AM
Tab 7	CS/SB 1528 by HP, Bean (CO-INTRODUCERS) Gruters; (Compare to CS/H 00019) Canadian Prescription Drug Importation Program					
872890	A	S	RCS	AHS, Bean	Delete L.116 - 281:	04/09 08:43 PM
104102	A	S	RCS	AHS, Bean	Delete L.321 - 339:	04/09 08:43 PM
Tab 3	CS/SB 1712 by HP, Harrell; (Compare to CS/H 00021) Hospital Licensure					
834398	A	S	RCS	AHS, Harrell	Delete L.240 - 242:	04/09 08:33 PM

The Florida Senate
COMMITTEE MEETING EXPANDED AGENDA
APPROPRIATIONS SUBCOMMITTEE ON HEALTH AND
HUMAN SERVICES
Senator Bean, Chair
Senator Harrell, Vice Chair

MEETING DATE: Tuesday, April 9, 2019
TIME: 4:00—6:00 p.m.
PLACE: Pat Thomas Committee Room, 412 Knott Building

MEMBERS: Senator Bean, Chair; Senator Harrell, Vice Chair; Senators Book, Diaz, Farmer, Flores, Hooper, Passidomo, Rader, and Rouson

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	SB 716 Hooper (Similar H 465)	Dental Services; Citing this act as the "Donated Dental Services Act"; establishing the Dental Student Loan Repayment Program to support dentists who practice in public health programs located in certain underserved areas; requiring the Department of Health to establish the Donated Dental Services Program to provide comprehensive dental care to certain eligible individuals, etc. HP 03/04/2019 Favorable AHS 04/09/2019 Fav/CS AP	Fav/CS Yeas 10 Nays 0
2	CS/SB 1218 Children, Families, and Elder Affairs / Book (Similar CS/H 1353)	Homelessness; Requiring that certain taxes of a specified amount be transferred annually to the Grants and Donations Trust Fund within the Department of Children and Families for the purpose of funding challenge grants; increasing the number of members on the Council on Homelessness to include a representative of the Florida Housing Coalition and the Secretary of the Department of Elder Affairs or his or her designee; revising the duties of the State Office on Homelessness, etc. CF 03/18/2019 Not Considered CF 03/25/2019 Fav/CS AHS 04/09/2019 Fav/CS AP	Fav/CS Yeas 10 Nays 0
3	CS/SB 1712 Health Policy / Harrell (Compare CS/H 21)	Hospital Licensure; Requiring certain hospitals licensed after a specified date to submit a notice to the Agency for Health Care Administration which contains specified information before filing for approval of plans and specifications to establish a new general hospital; authoring the agency to issue a license to a general hospital that has not been issued a certificate of need under certain circumstances; deleting provisions relating to certificates of need for osteopathic acute care hospitals, etc. HP 03/18/2019 Temporarily Postponed HP 04/01/2019 Fav/CS AHS 04/09/2019 Fav/CS AP	Fav/CS Yeas 10 Nays 0

COMMITTEE MEETING EXPANDED AGENDA

Appropriations Subcommittee on Health and Human Services
 Tuesday, April 9, 2019, 4:00—6:00 p.m.

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	CS/SB 1518 Health Policy / Wright (Similar CS/H 501)	Alternative Treatment Options for Veterans; Specifying eligibility to receive alternative treatment; authorizing the Department of Veterans' Affairs, subject to appropriation, to contract with a state university or Florida College System institution to enter into and manage contracts for the provision of alternative treatment options for certain veterans; providing requirements as to the provision of alternative treatment options and related assessment data, etc. HP 04/01/2019 Fav/CS AHS 04/09/2019 Fav/CS AP	Fav/CS Yeas 10 Nays 0
5	CS/SB 900 Children, Families, and Elder Affairs / Harrell (Similar CS/CS/H 369, Compare CS/CS/H 1187, CS/S 528)	Substance Abuse Services; Authorizing the Department of Children and Families and the Agency for Health Care Administration to grant exemptions from disqualification for certain service provider personnel; requiring individuals screened on or after a specified date to undergo specified background screening; increasing the criminal penalty for certain unlawful activities relating to personnel; prohibiting an individual who is not a certified peer specialist from advertising or providing recovery services unless the person is exempt; authorizing the department, a behavioral health managing entity, or the Medicaid program to reimburse peer specialist services as a recovery service, etc. CF 03/11/2019 Fav/CS AHS 04/09/2019 Fav/CS AP	Fav/CS Yeas 10 Nays 0
Continuation of April 4, 2019, Meeting:			
6	CS/SB 434 Health Policy / Harrell	Ambulatory Surgical Centers; Revising the definition of the term "ambulatory surgical center"; requiring the Agency for Health Care Administration, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules that establish requirements related to the delivery of surgical care to children in ambulatory surgical centers, in accordance with specified standards, etc. HP 02/19/2019 Fav/CS AHS 04/04/2019 Not Considered AHS 04/09/2019 Not Considered AP	Not Considered

COMMITTEE MEETING EXPANDED AGENDA

Appropriations Subcommittee on Health and Human Services
 Tuesday, April 9, 2019, 4:00—6:00 p.m.

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
7	CS/SB 1528 Health Policy / Bean (Compare CS/H 19, S 1452)	Canadian Prescription Drug Importation Program; Requiring the Agency for Health Care Administration to establish the Canadian Prescription Drug Importation Program; authorizing a Canadian supplier to export drugs into this state under the program under certain circumstances; providing eligibility criteria and requirements for drug importers; requiring the agency to contract with a vendor to facilitate wholesale prescription drug importation under the program, etc. HP 03/25/2019 Fav/CS AHS 04/04/2019 Not Considered AHS 04/09/2019 Fav/CS AP	Fav/CS Yeas 10 Nays 0
8	CS/SB 732 Health Policy / Flores (Similar CS/H 933)	Clinics and Office Surgery; Revising the definition of the term "clinic"; requiring a clinic to provide proof of its financial responsibility to pay certain claims and costs along with its application for licensure to the Agency for Health Care Administration; requiring the Department of Health to deny or revoke the registration of or impose certain penalties against a facility where certain office surgeries are performed under certain circumstances; requiring a physician who performs certain office surgery and the office in which the surgery is performed to maintain specified levels of financial responsibility, etc. HP 03/11/2019 Fav/CS AHS 04/04/2019 Not Considered AHS 04/09/2019 Fav/CS AP	Fav/CS Yeas 10 Nays 0
9	CS/SB 1460 Health Policy / Book (Compare CS/H 993)	Stroke Centers; Revising the criteria for hospitals to be included on the state list of stroke centers by the Agency for Health Care Administration; revising provisions relating to the statewide stroke registry to conform to changes made by the act; revising provisions prohibiting the advertisement of a hospital as a state-listed stroke center, unless certain conditions are met, to conform to changes made by the act, etc. HP 03/18/2019 Fav/CS AHS 04/04/2019 Not Considered AHS 04/09/2019 Fav/CS AP	Fav/CS Yeas 10 Nays 0

Other Related Meeting Documents

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL: CS/SB 434

INTRODUCER: Health Policy Committee and Senator Harrell

SUBJECT: Ambulatory Surgical Centers

DATE: April 3, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Looke</u>	<u>Brown</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>McKnight</u>	<u>Kidd</u>	<u>AHS</u>	<u>Pre-meeting</u>
3.	_____	_____	<u>AP</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 434 amends s. 395.002, F.S., to allow a patient to stay in an ambulatory surgical center (ASC) for 24 hours, thus allowing a patient to stay overnight, rather than requiring a patient be admitted and discharged on the same working day.

The bill also amends s. 395.1005, F.S., to require the Agency for Health Care Administration (AHCA), in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules to ensure the safe and effective delivery of surgical care to children in ambulatory surgical centers. The bill specifies that an ASC may provide surgical care that requires a length of stay past midnight to children younger than 18 years of age only after the AHCA authorizes such procedures in rule.

The bill has an indeterminate fiscal impact on the Florida Medicaid Program. See Section V. Fiscal Impact Statement.

The bill takes effect on July 1, 2019.

II. Present Situation:

Ambulatory Surgical Centers

An ambulatory surgical center (ASC) is a licensed facility not part of a hospital with the primary purpose of providing elective surgical care in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.¹

In Florida, ambulatory procedures are performed in two settings, hospital-based outpatient facilities and freestanding ASCs. As of January 2019, there are 458 ASCs and 308 licensed hospitals in Florida. Of the 308 licensed hospitals, 212 report providing hospital-based outpatient surgical services.²

Between April 2017 and March 2018, there were 3,049,558 visits to ASCs in Florida.³ Hospital outpatient facilities accounted for 1,419,020 visits (46.5 percent) and freestanding ASCs accounted for 1,622,013 visits (53.5 percent). Freestanding ASC average charges range from \$3,516 to \$9,347 and hospital-based ASC average charges range from \$10,522 to \$34,291 for the same time period.⁴ According to 2017 utilization data submitted to the Agency for Health Care Administration (AHCA), less than five percent of all outpatient surgical visits at hospitals and ASCs were for pediatric patients (age 0 to 17 years).⁵

Age Group	Visits	% of Visits
Age 0 (Less than 1 year old)	10,348	0.34%
1 – 4 years	48,802	1.60%
5 – 9 years	37,398	1.22%
10 – 14 years	25,958	0.85%
15 – 17 years	24,992	0.82%
Total Pediatrics	147,498	4.83%
Total All Ages	3,056,789	100%

Licensure

ASCs are licensed and regulated by the AHCA under the same regulatory framework as hospitals.⁶ Applicants for ASC licensure are required to submit certain information to the AHCA prior to accepting patients for care or treatment, including:

- An affidavit of compliance with fictitious name;
- Registration of articles of incorporation; and
- The applicant's zoning certificate or proof of compliance with zoning requirements.⁷

¹ Section 395.002(3), F.S.

² Agency for Health Care Administration, *Senate Bill 434 Analysis* (January 24, 2019) (on file with the Senate Committee on Health Policy).

³ Agency for Health Care Administration, *Florida Health Finder*, <http://www.floridahealthfinder.gov/CompareCare/CompareFacilities.aspx> (last viewed March 4, 2019).

⁴ *Id.*

⁵ *Id.* note 4.

⁶ Sections 395.001-395.1065, F.S., and part II, ch. 408, F.S.

⁷ Rule 59A-5.003(4), F.A.C.

Upon receipt of an initial ASC application, the AHCA is required to conduct a survey to determine compliance with all laws and rules. Applicants are required to provide certain information during the initial inspection, including:

- Governing body bylaws, rules, and regulations;
- A roster of registered nurses and licensed practical nurses with current license numbers;
- A fire plan; and
- A comprehensive emergency management plan.⁸

Florida Administrative Rules

Pursuant to s. 395.1055, F.S., the AHCA is authorized to adopt rules for hospitals and ASCs. Separate standards may be provided for general and specialty hospitals, ASCs, mobile surgical facilities, and statutory rural hospitals, but the rules for all hospitals and ASCs are required to include minimum standards for ensuring that:

- 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.

Rule 59A-5 of the Florida Administrative Code (F.A.C.) implements the minimum standards for ASCs. Those rules require policies and procedures to ensure the protection of patient rights.

Staff and Personnel Rules

ASCs are required to have written policies and procedures for surgical services, anesthesia services, nursing services, pharmaceutical services, laboratory services, and radiologic services. In providing these services, ACSs are required to have certain professional staff available, including:

- A qualified person responsible for the daily functioning and maintenance of the surgical suite;
- An anesthesiologist or other physician, or a certified registered nurse anesthetist under the on-site medical direction of a licensed physician, or an anesthesiologist assistant under the direct supervision of an anesthesiologist, who must be in the center during the anesthesia and post-anesthesia recovery period until all patients are cleared for discharge;
- A registered professional nurse who is responsible for coordinating and supervising all nursing services;
- A registered professional circulating nurse for a patient during that patient's surgical procedure; and
- A registered professional nurse who must be in the recovery area at all times when a patient is present.⁹

⁸ Rule 59A-5.003(5), F.A.C.

⁹ Rule 59A-5.0085, F.A.C.

Infection Control Program

ASCs are required to establish an infection control program involving members of the medical, nursing, and administrative staff. The program must include written policies and procedures reflecting the scope of the infection control program. The written policies and procedures must be reviewed at least every two years by the infection control program members. The infection control program must include:

- Surveillance, prevention, and control of infection among patients and personnel;
- A system for identifying, reporting, evaluating, and maintaining records of infections;
- Ongoing review and evaluation of aseptic, isolation, and sanitation techniques employed by the ASC; and
- Development and coordination of training programs in infection control for all personnel.¹⁰

Emergency Management Plan

ASCs are required to develop and adopt a written comprehensive emergency management plan for emergency care during an internal or external disaster or emergency. The ASC must review the plan and update it annually.¹¹

Accreditation

ASCs may seek voluntary accreditation by an accrediting organization whose standards are determined by the AHCA to be comparable to state licensure requirements. The AHCA is required to conduct a licensure inspection survey for non-accredited ASCs. The AHCA is authorized to accept survey reports of accredited ASCs from accrediting organizations if the standards included in the survey report are determined to document that the ASC is in substantial compliance with state licensure requirements. The AHCA is required to conduct annual validation inspections on a minimum of five percent of the ASCs which were inspected by an accreditation organization.¹²

The AHCA is required to conduct annual life safety inspections of all ASCs to ensure compliance with life safety codes and disaster preparedness requirements. However, the life-safety inspection may be waived if an accreditation inspection was conducted on an ASC by a certified life safety inspector and the ASC was found to be in compliance with the life safety requirements.¹³

Medicare Requirements

ASCs are required to have an agreement with the federal Centers for Medicare and Medicaid Services (CMS) to participate in Medicare. ASCs are also required to comply with specific conditions for coverage. The CMS defines “ASC” as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and for whom the expected duration of services would not exceed 24 hours following an admission.¹⁴

¹⁰ Rule 59A-5.011, F.A.C.

¹¹ Rule 59A-5.018, F.A.C.

¹² Rule 59A-5.004, F.A.C.

¹³ *Id.*

¹⁴ 42 C.F.R. s. 416.2

The CMS may deem an ASC to be in compliance with all of the conditions for coverage if the ASC is accredited by a national accrediting body or licensed by a state agency and if the CMS determines that such accreditation or licensure provides reasonable assurance that the conditions for coverage are met.¹⁵ All of the CMS conditions for coverage requirements are specifically required in Rule 59A-5, F.A.C., and apply to all ASCs in Florida. The conditions for coverage require ASCs to have a:

- Governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation;
- Quality assessment and performance improvement program;
- Transfer agreement with one or more acute care general hospitals, which will admit any patient referred who requires continuing care;
- Disaster preparedness plan;
- Organized medical staff;
- Fire control plan;
- Sanitary environment;
- Infection control program; and
- Procedure for patient admission, assessment and discharge.

American College of Surgeons: Optimal Resources for Children's Surgical Care v. 1

In 1913, the American College of Surgeons (ACS) was founded on the basic principles of improving the care of surgical patients and strengthening the education of surgeons. With these principles in mind, the ACS Children's Surgery Verification Committee was created in 2015 to continue, on a permanent basis within the ACS, the work of the ad hoc Task Force for Children's Surgical Care. This group was first convened in 2012. The recommendations of this task force are contained in the ACS' Standards Manual entitled, "Optimal Resources for Children's Surgical Care v. 1."¹⁶

Specific to ASCs, the report found that:

Children's ambulatory surgical centers must have treatment protocols for resuscitation, transfer protocols, and data reporting and must participate in systems for performance improvement. Children's ambulatory centers must have good working relationships and be fully integrated with a Level I, II, or III inpatient children's surgical center¹⁷ to be verified in this program... It is essential for the children's ambulatory surgical center to

¹⁵ 42 C.F.R. s. 416.26(a)(1)

¹⁶ American College of Surgeons, *Optimal Resources for Children's Surgical Care v.1*, (released in 2015) available at https://www.facs.org/~media/files/quality%20programs/csv/acs%20csv_standardsmanual.ashx (last visited on March 27, 2019).

¹⁷ The report details such relationship on page 19. "*Ideally, one hospital, typically a Level I center, would be looked upon as the resource leader within a given region. This hospital would serve as a resource to all other hospitals within the system. Outside major population centers, a Level II center may serve as the lead hospital for extended geographic areas. In some rural areas, where population densities are low and distances great, a Level III center may be the only resource for miles. Ambulatory surgical centers are considered separately but in any system will have clearly identified relationships and demonstrable integration with one or more verified Level I, II, or III children's inpatient facilities.*" *Id.*

have the involvement of one or more committed and appropriately trained pediatric health care providers to provide leadership and sustain the integration with other relevant components of an integrated children's health care system.¹⁸

III. Effect of Proposed Changes:

The bill amends s. 395.002, F.S., to allow a patient to stay in an ASC for 24 hours, rather than requiring that a patient be admitted and discharged on the same working day. This change complies with the CMS requirements for an ASC.¹⁹

The bill also amends s. 395.1005, F.S., to require the AHCA, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules to ensure the safe and effective delivery of surgical care to children in ambulatory surgical centers. The rules must be consistent with the American College of Surgeons' 2015 Standards Manual entitled "Optimal Resources for Children's Surgical Care."

The bill specifies that an ASC may provide surgical care that requires a length of stay past midnight to children younger than 18 years of age only after the AHCA authorizes such procedures in rule.

The bill takes effect on July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

¹⁸ *Id.*

¹⁹ 42 C.F.R. s. 416.2.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

CS/SB 434 may have an indeterminate positive fiscal impact on patients seeking surgical services if such patients are able to obtain the surgical services at an ASC for lower costs than the costs of receiving comparable services at a hospital.

The bill may have an indeterminate negative fiscal impact on hospitals if more patients choose to have their surgical procedures performed in an ASC.

C. Government Sector Impact:

The bill has an indeterminate fiscal impact on the Florida Medicaid program.

ASCs are reimbursed by Medicaid through an outpatient prospective payment reimbursement methodology called Enhanced Ambulatory Patient Groups (EAPGs). EAPGs categorize outpatient services and procedures into groups for payment based on clinical information present on an outpatient claim. ASCs are not currently reimbursed for an overnight stay. If ASCs are authorized to bill for an overnight stay through the EAPG system, there could potentially be an increase in the volume of ASC claims and therefore, a potential increase in ASC expenditures. However, a potential increase in claim volumes and expenditures may be offset due to a decrease in claims and expenditures for services provided in the outpatient or inpatient hospital setting.²⁰

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.002 and 395.1055.

²⁰ *Supra* note 2.

IX. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on February 19, 2019:

The CS revises the bill's requirement for the AHCA to adopt rules related to pediatric care in ASCs and eliminates the requirement that the AHCA adopt rules regulating practitioners providing such care. Additionally the CS eliminates specified items that the rules must address.

- B. **Amendments:**

None.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR GAYLE HARRELL
25th District

COMMITTEES:
Health Policy, *Chair*
Appropriations Subcommittee on Health
and Human Services, *Vice Chair*
Appropriations Subcommittee on Criminal
and Civil Justice
Children, Families, and Elder Affairs
Military and Veterans Affairs and Space

JOINT COMMITTEE:
Joint Committee on Public Counsel Oversight

March 9, 2019

Senator Aaron Bean
405 Senate Building
404 South Monroe Street
Tallahassee, FL 32399

Chair Bean,

I respectfully request that **SB 434 – Ambulatory Surgical Centers** be placed on the next available agenda for the Appropriations Subcommittee on Health and Human Services Committee Meeting.

Should you have any questions or concerns, please feel free to contact my office. Thank you in advance for your consideration.

Thank you,

A handwritten signature in blue ink that reads "Gayle".

Senator Gayle Harrell
Senate District 25

Cc: Tonya Kidd, Staff Director
Robin Jackson, Committee Administrative Assistant

REPLY TO:

- 215 SW Federal Highway, Suite 203, Stuart, Florida 34994 (772) 221-4019
- 310 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5025

Senate's Website: www.flsenate.gov

BILL GALVANO
President of the Senate

DAVID SIMMONS
President Pro Tempore

By the Committee on Health Policy; and Senator Harrell

588-02473-19

2019434c1

1 A bill to be entitled
 2 An act relating to ambulatory surgical centers;
 3 amending s. 395.002, F.S.; revising the definition of
 4 the term "ambulatory surgical center"; amending s.
 5 395.1055, F.S.; requiring the Agency for Health Care
 6 Administration, in consultation with the Board of
 7 Medicine and the Board of Osteopathic Medicine, to
 8 adopt rules that establish requirements related to the
 9 delivery of surgical care to children in ambulatory
 10 surgical centers, in accordance with specified
 11 standards; specifying that ambulatory surgical centers
 12 may provide certain procedures only if authorized by
 13 agency rule; providing an effective date.
 14
 15 Be It Enacted by the Legislature of the State of Florida:
 16
 17 Section 1. Subsection (3) of section 395.002, Florida
 18 Statutes, is amended to read:
 19 395.002 Definitions.—As used in this chapter:
 20 (3) "Ambulatory surgical center" means a facility the
 21 primary purpose of which is to provide elective surgical care,
 22 in which the patient is admitted to and discharged from such
 23 facility within 24 hours ~~the same working day and is not~~
 24 ~~permitted to stay overnight~~, and which is not part of a
 25 hospital. However, a facility existing for the primary purpose
 26 of performing terminations of pregnancy, an office maintained by
 27 a physician for the practice of medicine, or an office
 28 maintained for the practice of dentistry may not be construed to
 29 be an ambulatory surgical center, provided that any facility or

Page 1 of 2

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

588-02473-19

2019434c1

30 office which is certified or seeks certification as a Medicare
 31 ambulatory surgical center shall be licensed as an ambulatory
 32 surgical center pursuant to s. 395.003.
 33 Section 2. Present subsections (3) through (12) of section
 34 395.1055, Florida Statutes, are redesignated as subsections (4)
 35 through (13), respectively, and a new subsection (3) is added to
 36 that section, to read:
 37 395.1055 Rules and enforcement.—
 38 (3) (a) The agency, in consultation with the Board of
 39 Medicine and the Board of Osteopathic Medicine, shall adopt
 40 rules that establish requirements to ensure the safe and
 41 effective delivery of surgical care to children in ambulatory
 42 surgical centers. The rules must be consistent with the American
 43 College of Surgeons' 2015 standards document entitled "Optimal
 44 Resources for Children's Surgical Care" and must establish
 45 minimum standards for pediatric patient care in ambulatory
 46 surgical centers.
 47 (b) Ambulatory surgical centers may provide operative
 48 procedures that require a length of stay past midnight on the
 49 day of surgery for children younger than 18 years of age only if
 50 the agency authorizes the performance of such procedures by
 51 rule.
 52 Section 3. This act shall take effect July 1, 2019.

Page 2 of 2

CODING: Words ~~stricken~~ are deletions; words underlined are additions.



246860

LEGISLATIVE ACTION

Senate

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. .
. .
. .
. .

House

Appropriations Subcommittee on Health and Human Services
(Harrell) recommended the following:

Senate Amendment

Delete line 41
and insert:
effective delivery of surgical care to children kept past
midnight in ambulatory

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL: PCS/SB 716 (259042)

INTRODUCER: Appropriations Subcommittee on Health and Human Services; Senator Hooper and others

SUBJECT: Dental Services

DATE: April 11, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Lloyd</u>	<u>Brown</u>	<u>HP</u>	<u>Favorable</u>
2.	<u>Loe</u>	<u>Kidd</u>	<u>AHS</u>	<u>Recommend: Fav/CS</u>
3.	<u> </u>	<u> </u>	<u>AP</u>	<u> </u>

I. Summary:

PCS/SB 716 creates the Dental Student Loan Repayment Program for Florida-licensed dentists who practice in specific public health programs located in federally-designated dental health professional shortage areas (HPSAs) or medically underserved areas.

The bill creates the Donated Dental Services Program, which establishes a network of voluntary dentists and other dental providers for the purpose of providing comprehensive dental services at no cost to eligible individuals.

The bill has no impact on state revenues or state expenditures.

The bill is effective upon becoming a law.

II. Present Situation:

The Health Resources and Services Administration (HRSA) within the United States Department of Health and Human Services (HHS), is charged with, among other responsibilities, improving health care for individuals who are geographically isolated, or economically or medically vulnerable.¹ Four of the five HRSA goals focus on access to care through either building a healthy workforce or improvements in accessing quality care and services.²

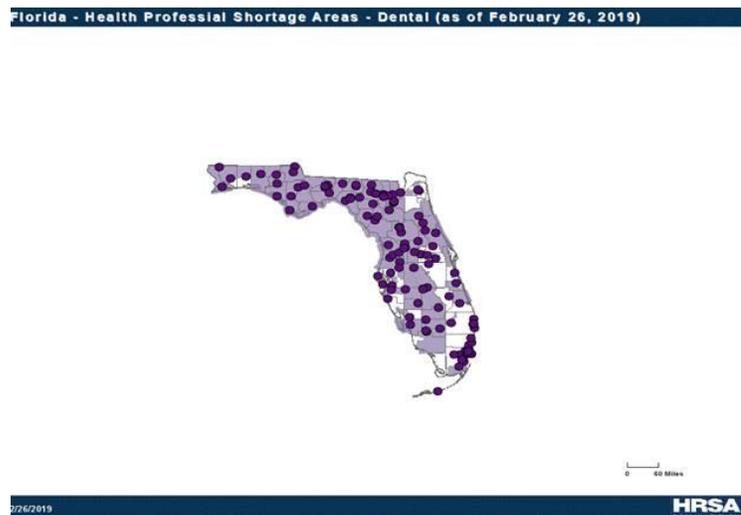
¹ U.S. Dep't of Health and Human Services, HRSA, *About HRSA*, <https://www.hrsa.gov/about/index.html> (last visited Feb. 26, 2019).

² *Id.*

Health Professional Shortage Areas (HPSAs)

Health Professional Shortage Areas (HPSAs) are designated by the HRSA according to criteria developed in accordance with section 332 of the Public Health Services Act. HPSA designations are used to identify areas within the United States that are experiencing a shortage of health care professionals or have population groups who face specific barriers to health care. An HPSA can be a geographic area, a population group, or a health care facility. These areas have a shortage of health care professionals or have population groups who face specific barriers to health care.

There are three categories for a HPSA designation: (1) primary medical care; (2) dental; and (3) mental health. The map below shows the locations of the current dental HPSAs in Florida.³



The primary factor used to determine a HPSA designation is the number of health professionals relative to the population, with consideration of high need. State Primary Care Offices, usually located within a state's main health agency, apply to HRSA for most designations of HPSAs in their states. HRSA will review provider-level data, whether providers are actively engaged in clinical practice, if a provider has any additional practice locations, the number of hours served at each location, the populations served, and the amount of time that a provider spends with specific populations.⁴ Primary care and mental health HPSAs can receive a score up to 25 points and dental health can receive a score up to 26 points.⁵

Three scoring criteria are common across all disciplines HPSA (primary care medical, dental, and mental health):

- The population to provider ratio;

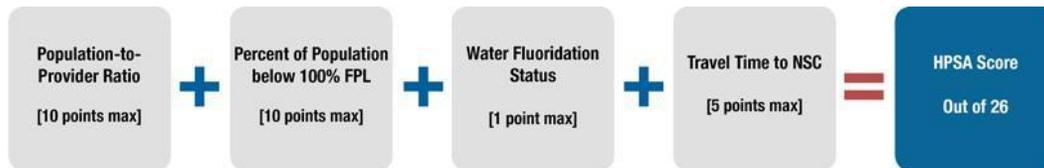
³ Map generated based on information held in the U.S. Dep't of Health and Human Services, HRSA Data Warehouse, *Dental Health Professional Shortage Areas (HPSAs) Primary Dataset*, <https://datawarehouse.hrsa.gov/Tools/DataPortalResults.aspx> (results last generated on Feb. 26, 2019).

⁴ U.S. Dep't of Health and Human Services, HRSA Health Workforce, *Health Professional Shortage Area (HPSA) Shortage Application and Scoring Process*, Shortage Designation Management System, <https://bhw.hrsa.gov/shortage-designation/application-scoring-process> (last visited Feb. 26, 2019).

⁵ U.S. Dep't of Health and Human Services, HRSA Health Workforce, *Health Professional Shortage Area (HPSA) Shortage Application and Scoring Process*, <https://bhw.hrsa.gov/shortage-designation/hpsa-process> (last visited Feb. 26, 2019)

- The percentage of the population below 100 percent of the federal poverty level;⁶ and
- The travel time to the nearest source of care outside of the HPSA designation.⁷

The dental scoring system also reviews the water fluoridation status of the areas. The components of the dental scoring system are then calculated using the points system shown below to arrive at a total score of up to 26 points.⁸



Automatic Designations as HPSAs

Certain facilities are automatically designated as HPSAs based either on statute or regulations which govern shortages or the type of facility. For example, federally qualified health centers (FQHCs) have a different scoring structure. These facilities may often have multiple sites under one organization. In those instances, the scores of all the related organizations are averaged together to attain a single score for the overall organization.⁹ Rural Health Clinics (RHCs) submit a Certificate of Eligibility form.¹⁰ The form requires the RHC to include its RHC Certification letter from the federal Centers for Medicare and Medicaid Services, a copy of its sliding fee scale, agreement to accept Medicare beneficiaries, Medicaid, and CHIP patients, and to make every effort to collect patient fees.¹¹

HRSA Workforce Programs

The HRSA's workforce programs are designed to strengthen and improve the health care workforce and to connect skilled professionals to communities in need. The HRSA's Bureau of Health Workforce (BHW) supports workforce training and seeks to expand the availability of clinicians in high-need areas, including in urban, rural, and frontier locations.¹² To determine the state's need, the chart below illustrates Florida's dental practitioner status, including the percentage of current need that is being met for Florida's dental HPSA compared to data nationwide.

⁶ For a family of 4, the maximum income at 100 percent of the federal poverty level is approximately \$25,750 annually. The 2019 federal Health and Human Services income guidelines can be found at <https://aspe.hhs.gov/poverty-guidelines>.

⁷ U.S. Dep't of Health and Human Services, *supra*, note 5.

⁸ *Id.*

⁹ *Id.*

¹⁰ U.S. Dep't of Health and Human Services, HRSA Health Workforce, *Certificate of Eligibility as an Automatic HPSA*, <https://bhw.hrsa.gov/sites/default/files/bhw/shortagedesignation/BHW%20Certificate%20of%20Eligibility%20Form%20%2810.20.16%29%20v%200.1.3.pdf> (last visited Feb. 26, 2019).

¹¹ *Id.*

¹² U.S. Dep't of Health and Human Services, HRSA, *HRSA Fact Sheet – FY 2018 – Florida*, <https://data.hrsa.gov/data/fact-sheets> (last visited Feb. 26, 2019).

Florida’s Dental HPSA Snapshot Compared to National Data ^{13,14}							
Number of Sites in Designations <i>(geographic area, population group, or facility)</i>		Population Covered by Designation <i>Low income population 200 percent FPL</i>		Number of Practitioners Needed Projected - 2025 ¹⁵		Percent of Projected Need Met – 2025	
<i>Nat'l</i>	<i>FL</i>	<i>Nat'l</i> ¹⁶	<i>FL</i>	<i>Nat'l</i>	<i>FL</i>	<i>Nat'l</i>	<i>FL</i>
5,732	235	20,501,816	1,420,551	28,100	1,152	35.28%	13.28%

According to a February 2015 HRSA study of the dental workforce, all 50 states and the District of Columbia will face a shortage of dentists by 2025. At the national level, the demand for dentists shows a ten percent increase over the need from 2012, from 197,800 to 218,200.¹⁷ Florida has the second highest level of projected demand, behind only California, with 1,152 dentists needed by 2025.¹⁸

Multiple national surveys of dentists since the 1950s through today have found significant shifts in the demographics of dentists. For example:¹⁹

- In the 1980s, less than 3 percent of the dental workforce were women. Today, women represent 27 percent of the dental workforce.
- In 1975, less than 10 percent of all working dentists worked part-time. Today, an estimated 14 percent of all working dentists in private practice and 12 percent of all dentists work part-time.
- In 1950, only 0.5 percent of all dentists were employed by another dentist; however, from 2007-2009 almost 17 percent of all active dentists were employees. Among private practitioners, 44 percent of dentists were employees.
- In 1970, less than 10 percent of all active dentists were specialists. Today, approximately 22 percent of dentists are specialists.
- In 1975, the profile of a dentist indicated someone who was generally younger than age 45 and male (98 percent). Today, 42 percent of dentists are at least 55 years of age with only 31 percent younger than 45 years of age.

¹³ *Id.*

¹⁴ U.S. Dep’t of Health and Human Services, HRSA, *HRSA Fact Sheet – FY 2018 – Nation*, <https://data.hrsa.gov/data/fact-sheets> (last visited Feb. 26, 2019).

¹⁵ U.S. Dep’t of Health and Human Services, HRSA, *National and State-Level Projections of Dentists and Dental Hygienists in the U.S., 2012-2025 (February 2015)*, <https://bhwa.hrsa.gov/sites/default/files/bhw/nchwa/projections/nationalstatelevelprojectionsdentists.pdf> (last visited Feb. 27, 2019).

¹⁶ U.S. Dep’t of Health and Human Services, HRSA, *Shortage Areas*, <https://data.hrsa.gov/data/fact-sheets> (last visited Feb. 26, 2019).

¹⁷ U.S. Dep’t of Health and Human Services, *supra* note 15.

¹⁸ *Id.*

¹⁹ Eric Soloman, DDS, MA, *Dental workforce trends and the future of dental practices*, DENTAL ECONOMICS <https://www.dentaleconomics.com/articles/print/volume-105/issue-2/macroeconomics/dental-workforce-trends-and-the-future-of-dental-practices.html> (last visited Feb. 27, 2018).

Medically Underserved Area

Medically Underserved Areas (MUAs) are also designated by the HRSA. These areas are designated using one of three methods and can consist of a whole county, a group of contiguous counties, or census tracts having too few health care providers, high infant mortality or poverty rates, or a high elderly population.²⁰ Nationally, there are 3,581 such designated areas, with 128 designated in Florida.²¹

The first method, the Index of Medical Underservice (IMU), calculates a score based on the ratio of primary medical care physicians per 1,000 in population, percentage of the population with incomes below the federal poverty level, infant mortality rate, and percentage of population aged 65 or older.²²

The second method, Medically Underserved Populations (MUP), is based on data collected under the MUA process and reviews the ratio of primary care physicians serving the population seeking the designation. A MUP is a group of people who encounter economic or cultural barriers to primary health care services.²³

The third process, Exceptional MUP Designations, includes those population groups that do not meet the criteria of an IMU but may be considered for designation because of unusual conditions with a request by the governor or another senior executive level official and a local state health official.²⁴

The Dental Workforce

The Health Policy Institute (HPI) for the American Dental Association (ADA) recently updated its estimates on the future supply of dentists and concluded Florida's per capita supply of dentists is projected to increase through 2035.²⁵ The unadjusted number of dentists per 100,000 in population increases from 52.0 in 2015 to 56.9 in 2035.²⁶ The per capita calculation performed in this report is a headcount of total dentists in comparison to the state's total population. The study was based on a headcount of 10,781 dentists and a state population of 20.6 million.

One drawback to a per capita count of dentists is that the study does not consider the location of the providers and any access to care issues in particular regions or the needs of special populations. For example, a shortage could be only for participation by dental health providers in

²⁰ U.S. Dep't of Health and Human Services, HRSA Health Workforce, *Medically Underserved Areas and Populations (MUA/Ps)*, <https://bhw.hrsa.gov/shortage-designation/muap> (last visited Feb. 28, 2019).

²¹ U.S. Dep't of Health and Human Services, HRSA, *Shortage Areas*, <https://data.hrsa.gov/topics/health-workforce/shortage-areas> (last visited Feb. 27, 2019).

²² U.S. Dep't of Health and Human Services, HRSA, *Shortage Designation*, <https://bhw.hrsa.gov/shortage-designation/muap-process> (last visited Feb. 27, 2019).

²³ *Supra* note 24.

²⁴ *Id.*

²⁵ American Dental Association, Health Policy Institute, *Projected Supply of Dentists: Florida*, <https://www.ada.org/~media/ADA/Science%20and%20Research/HPI/ProjectedSupplyofDentists/Florida-Projected-Supply-of-Dentists.pdf?la=en> (last visited Feb. 27, 2019).

²⁶ *Id.*

public programs such as Medicaid and the Children’s Health Insurance Program (CHIP), two programs that serve high numbers of children and families from low and moderate income families. Florida’s dental provider participation rate in these public programs is 30 percent while the national average is 39 percent.²⁷ The HPI’s data indicates that 96 percent of publicly insured children live within 15 minutes of a Medicaid dentist.²⁸

The chart below shows the current national participation rate by dental providers by type of provider.

Type of Provider	2015	2016	2017
<i>National %</i>	<i>% Public Assistance</i>	<i>% Public Assistance</i>	<i>% Public Assistance</i>
General Practitioner	36.4%	37.3%	32.9%
Specialists	35.5%	41.4%	33.5%
All Dentists	36.2%	38.2%	33.1%

Most dentists practice in general dentistry (157,676 dentists) followed by orthodontics as a distant second (10,779).³⁰ In many rural communities, the county health department may be the primary provider of health care services, including dental care. According to the Department of Health (DOH), Florida’s current designated dental HPSAs have only enough dentists to serve 13.22 percent of the population living within them.³¹ According to the DOH, there are seven currently vacant dentist positions in the DOH itself.³² As of December 31, 2018, HRSA estimated that 1,266 additional dentists were required to meet the state’s total need and eliminate the state’s shortage.³³

The ADA has also studied this issue and found that while there may be a sufficient number of dentists overall for the state’s population or the national population, there may be an inadequate number available for certain populations or geographic areas.³⁴ Children are acutely affected by

²⁷ American Dental Association, *Dentist Participation in Medicaid or CHIP*, https://www.ada.org/~media/ADA/Science%20and%20Research/HPI/Files/HPIGraphic_0318_1.pdf?la=en (last visited Feb. 27, 2019).

²⁸ Health Policy Institute, American Dental Association, *Geographic Access to Dental Care: Florida*, <https://www.ada.org/~media/ADA/Science%20and%20Research/HPI/AccessToDentalCare-StateFacts/Florida-Access-To-Dental-Care.pdf> (last visited Feb. 27, 2019).

²⁹ Health Policy Institute, American Dental Association, *Dental Practice – 2017 Characteristics of Private Dental Practice – Table 4 – Percentage of Dentists’ Practices That Had Any Patients Covered by Public Assistance, 1990-2017* (January 2016), <http://www.ada.org/en/science-research/health-policy-institute/data-center/dental-practice> (last visited Feb. 28, 2019).

³⁰ American Dental Association, *Supra*, note 29.

³¹ U.S. Dep’t of Health and Human Services, Bureau of Health Workforce – HRSA, *Designated Health Professional Shortage Areas Statistics* (as of December 31, 2017), https://ersrs.hrsa.gov/ReportServer?/HGDW_Reports/BCD_HPSA/BCD_HPSA_SCR50_Qtr_Smry_HTML&rc:Toolbar=false (last visited Feb. 28, 2019).

³² E-Mail from Bryan Wendell, Office of Legislative Planning, Florida Dep’t. of Health, (Feb. 27, 2019) (on file with the Senate Committee on Health Policy).

³³ U.S. Dep’t of Health and Human Services, HRSA, *Shortage Areas – Explore MUSAs Dashboard-Florida*, <https://data.hrsa.gov/topics/health-workforce/shortage-areas> (report last generated Feb. 28, 2019).

³⁴ Bradley Munson, B.A., and Marko Vujcic, Ph.D.: Health Policy Institute Research Brief, American Dental Association, *Supply of Dentists in the United States Likely to Grow*, p.2. (October 2014)

the shortage of dentists to serve low-income patients. For example in Florida for federal fiscal year 2016, 37.6 percent of Medicaid-enrolled children and 42.8 percent of CHIP-enrolled children received preventive dental services.³⁵ For Medicaid, this was an increase from 2012, when only 26 percent of Medicaid-enrolled children received at least one dental care service.³⁶

Medicaid

In 2011, the Legislature passed HB 7107³⁷ creating the Statewide Medicaid Managed Care (SMMC) program as part IV of ch. 409, F.S. The program has two primary components: Managed Medical Assistance (MMA) and Long-Term Care Managed Care (LTCMC). To implement MMA, the law required the AHCA to create an integrated managed care program for the delivery of Medicaid primary and acute care services, including dental. Medicaid recipients who are enrolled in MMA initially received their dental services and other medical services through the same managed care plan. With the recent re-procurement of the SMMC contracts, the dental benefits were carved out of the MMA contracts and separately procured. Three statewide SMMC dental plans were selected as a result of that procurement: Managed Care of North America (MCNA), DentaQuest of Florida, and Liberty Dental Plan.

Medicaid dental benefits are currently being delivered to recipients in MMA, fee-for-service reimbursement systems, iBudget waiver participants, and Medically Needy enrollees under the separately procured dental contracts.³⁸ Preexisting enrollees were required to select a dental plan as their regions were implemented, starting in December 2018. Most dental services are designated as a required benefit only for Medicaid recipients under age the age of 21; however, the dental plans are also providing adult benefits at no extra cost to the state.³⁹

Future Outlook for Dentists

According to the United States Department of Labor, Bureau of Labor Statistics, the occupational outlook for dental students is growing much faster than the average for other occupations for the time period between 2016 through 2026, and an estimated 29,300 additional jobs are anticipated during this same time period.⁴⁰ Florida has one metropolitan area in the top 10 list of highest paying areas for dentists: Sebring, which pays an annual median wage of

http://www.ada.org/~media/ADA/Science%20and%20Research/HPI/Files/HPIBrief_1014_1.ashx (last visited Feb. 27, 2019).

³⁵ Brishke, J., Gaskins, J., and Shenkman, B., *Florida KidCare: The Florida KidCare Program Evaluation Calendar Year 2016* (Dec. 1 2017), p. 141,

http://ahca.myflorida.com/medicaid/Policy_and_Quality/Quality/performance_evaluation/MER/contracts/med147/FL_KidCare_MED147_Deliverable_66_12-2017_Final.pdf (last visited Feb. 27, 2019).

³⁶ Agency for Health Care Administration, *Statewide Medicaid Managed Care Dental Program Overview Presentation* (October 2018), Slide 8, https://ahca.myflorida.com/Medicaid/statewide_mc/pdf/SMMC_Dental_Overview.pdf (visited Feb. 27, 2019).

³⁷ See chapter 2011-134, Laws of Fla.

³⁸ Agency for Health Care Administration, *Statewide Medicaid Managed Care Dental Program Overview Presentation* (October 2018), Slides 21-30, https://ahca.myflorida.com/Medicaid/statewide_mc/pdf/SMMC_Dental_Overview.pdf (visited Feb. 27, 2019).

³⁹ AHCA, Invitation to Negotiate 012-17/18 (Oct. 16, 2017). A copy of the ITN can be downloaded from http://www.myflorida.com/apps/vbs/vbs_www.ad_r2.view_ad?advertisement_key_num=137442 (last visited Feb. 27, 2019). See also Chapter 2016-109, Laws of Fla.

⁴⁰ U.S. Dep't of Labor, Bureau of Labor Statistics, *Occupational Outlook Handbook – Dentists*, <https://www.bls.gov/ooh/healthcare/dentists.htm#tab-1> (last visited Feb. 27, 2019).

\$269,300.⁴¹ Below is a chart comparing the mean annual wages of different types of dentists nationally and for Florida.

Comparison of Dental Professions by Mean Annual Wages – May 2017		
Dental Profession Type	Mean National Annual Wage	Mean State Annual Wage
Dentist, generally ⁴²	\$176,630	\$166,610
Oral & Maxillofacial Surgeons ⁴³	\$242,740	\$288,450
Orthodontists ⁴⁴	\$229,380	\$221,990
Dentists, all other specialists ⁴⁵	\$199,980	\$166,610

Wages can vary dramatically depending on the setting in which the provider is located. Generally, a provider located in a private office setting has higher wages, for example, an annual wage of \$176,630, while a dentist located in a hospital setting or in the office of another health care practitioner who is not a dentist, might have a significantly lower average annual wage, from \$138,480 to \$132,990.⁴⁶

The Cost of Dental Education

According to a survey of dental school students, the average debt for graduates in 2017 was \$287,337,⁴⁷ a 72 percent increase in the last decade.⁴⁸ Over 30 percent of the Class of 2016 reported student loan debt in excess of \$300,000.⁴⁹ For the Class of 2018, 40 percent of the graduates reported a student loan debt greater than \$300,000.⁵⁰

For in-state tuition at a state university, such as the University of Florida, one year's tuition is currently \$41,720 and non-residents pay \$68,202. When housing, books, and other costs are included, three or four years of dental school tuition can result in a total dental school bill ranging from \$226,042 to \$291,836.⁵¹ In comparison, a northern private school's tuition is listed at \$73,364 per year and with other supplies, housing and fees, the total estimated costs over four years for 2018-2019 would be \$463,490.⁵²

⁴¹ U.S. Dep't of Labor, Bureau of Labor Statistics, *Occupational Employment Statistics, May 2017 (Florida)*, <https://www.bls.gov/oes/current/oes291021.htm#st> (last visited Feb. 27, 2019).

⁴² U.S. Dep't of Labor, Bureau of Labor Statistics, *Occupational Employment and Wages, May 2017, Dentists, General*, <https://www.bls.gov/oes/current/oes291021.htm#st> (last visited Feb. 27, 2019).

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ U.S. Dep't of Labor, Bureau of Labor Statistics, *Occupational Employment and Wages, May 2017, Dentists, All Other Specialists*, <https://www.bls.gov/oes/current/oes291029.htm#st> (last visited Feb. 27, 2019).

⁴⁶ *Supra* note 46.

⁴⁷ American Student Dental Education Association, *Dental Student Debt*, <https://www.asdanet.org/index/get-involved/advocate/issues-and-legislative-priorities/Dental-Student-Debt> (last visited Feb. 27, 2019).

⁴⁸ American Student Dental Education Association, *Paying for Dental School*, <https://www.asdanet.org/index/get-into-dental-school/before-you-apply/paying-for-dental-school>, (last visited Feb. 27, 2019).

⁴⁹ American Dental Education Association, *Education Debt*, http://www.adea.org/GoDental/Money_Matters/Educational_Debt.aspx#sthash.rYlqVawm.dpbs (last visited Feb. 27, 2019).

⁵⁰ *Id.*

⁵¹ University of Florida, Office of Admissions – College of Dentistry, *Budgets & Costs of Attendance: DMD*, <http://admissions.dental.ufl.edu/financial-aid-2/d-m-d/budgets-cost-of-attendance-d-m-d/> (last visited Feb. 27, 2019).

⁵² Tufts School of Dental Medicine, *Financial Aid Application Forms and Costs of Attendance for D.M.D. and D.I.S. Programs*, <https://dental.tufts.edu/academics/financial-aid/forms-and-costs-dmd-and-dis-programs> (last visited Feb. 27, 2019).

In 2013, Congress enacted the Bipartisan Student Loan Certainty Act of 2013 (Public Law 113-28) that tied certain student loan interest rates to the 10-year Treasury Note plus 2.05 percent for undergraduates. For graduate and professional student loans, the interest rate is tied to the 10-year Treasury note plus 3.6 percent but may not exceed 9.5 percent in any given year.⁵³

In June 2014, through a Presidential Memorandum, President Barack Obama directed the Secretary of Education to propose final regulations to allow additional students with student loan debt to cap their payments at 10 percent of their income, by December 31, 2015.⁵⁴ The Presidential Memorandum called the plan the “*Pay as You Earn Plan*.”⁵⁵ President Obama’s memorandum also called for the Secretary to improve communication with vulnerable borrowers to help with loan rehabilitation, to encourage support and awareness of repayment options during tax filing season, and to promote collaboration between students and their families to ensure better borrowing decisions.⁵⁶ Two years after President Obama announced his debt relief plan, Florida had over 826,000 federal student loan borrowers with 188,613 borrowers enrolled in the *Pay as You Earn* or other income driven payment plans. The state had a total student federal loan debt outstanding of \$23.9 billion.⁵⁷

Loan forgiveness is also one of the top priorities of the American Student Dental Association (ASDA). Listed among the organization’s priorities is for Congress and state legislatures to pass measures that include loan forgiveness, scholarship opportunities, and tax deductions or rebates for students that agree to practice in underserved areas after graduation.⁵⁸

Florida does not have a current state program to address the dental health professional shortage areas or medically underserved areas.

Florida Health Services Corps

In 1992, the Legislature created the Florida Health Services Corps (FHSC), administered by the DOH, to encourage medical professionals to practice in locations that are underserved because of a shortage of qualified professionals.⁵⁹ The FHSC was defined⁶⁰ as a program that offered scholarships to allopathic, osteopathic, chiropractic, podiatric, dental, physician assistant, and nursing students, and loan repayment assistance and travel and relocation expenses to allopathic and osteopathic residents and physicians, chiropractic physicians, podiatric physicians, nurse practitioners, dentists, and physician assistants, in return for service in a public health care

⁵³ Bipartisan Student Loan Certainty Act of 2013, Pub. L. No. 113-28, §2, 127 Stat. 506, 506 (2013).

⁵⁴ *Id.*

⁵⁵ The White House, Office of the Press Secretary, *Presidential Memorandum - Federal Student Loan Repayments* (June 9, 2014) <https://www.whitehouse.gov/the-press-office/2014/06/09/presidential-memorandum-federal-student-loan-repayments> (last visited Feb. 27, 2019).

⁵⁶ The White House, Office of the Press Secretary, *Presidential Memorandum – Federal Student Loan Repayments* (June 9, 2014) <https://obamawhitehouse.archives.gov/the-press-office/2014/06/09/presidential-memorandum-federal-student-loan-repayments> (last visited Feb. 27, 2019).

⁵⁷ Jason Furman, Sandra Black, The White House, Office of Press Secretary, *Six Recent Trends in Student Debt* (April 28, 2016), <https://obamawhitehouse.archives.gov/blog/2016/04/28/six-recent-trends-student-debt> (last visited Feb. 27, 2018).

⁵⁸ American Student Dental Education Association, *supra* note 37.

⁵⁹ Chapter 92-33, s. 111, Laws of Fla. (creating s. 381.0302, F.S., effective July 1, 1992).

⁶⁰ Section 381.0302(2)(b)1., F.S. (2011).

program⁶¹ or in a medically underserved area.⁶² Membership in the FHSC could be extended to any health care practitioner who provided uncompensated care to medically indigent patients.⁶³ All FHSC members were required to enroll in Medicaid and to accept all patients referred by the DOH pursuant to the program agreement.⁶⁴ In exchange for this service, an FHSC member was made an agent of the state and granted sovereign immunity under s. 768.28(9), F.S., when providing uncompensated care to medically indigent patients referred for treatment by the DOH.⁶⁵

The statute authorized the DOH to provide loan repayment assistance and travel and relocation reimbursement to allopathic and osteopathic medical residents with primary care specialties during their last two years of residency training or upon completion of residency training, and to physician assistants and nurse practitioners with primary care specialties, in return for an agreement to serve a minimum of two years in the FHSC. During the period of service, the maximum amount of annual financial payments was limited to no more than the annual total of loan repayment assistance and tax subsidies authorized by the National Health Services Corps (NHSC) loan repayment program.⁶⁶

During the 20 years the program was authorized by law, it was funded only three times. A total of \$3,684,000 was appropriated in three consecutive state fiscal years beginning with the 1994-1995 fiscal year for loan assistance payments to all categories of eligible health care practitioners. Of that amount, \$971,664 was directed to 18 dentists for an average award of \$25,570 per year of service in the program.⁶⁷ The 2007 Legislature attempted to reinvigorate the program by appropriating \$700,000 to fund loan repayment assistance for dentists only.⁶⁸ However, the appropriation and a related substantive bill were vetoed.⁶⁹ The Legislature repealed the program in 2012.⁷⁰

⁶¹ “Public health program” was defined to include a county health department, a children’s medical services program, a federally funded community health center, a federally funded migrant health center, or other publicly funded or nonprofit health care program designated by the department. Section 381.0302(2)(e), F.S. (2011).

⁶² “Medically underserved area” was defined to include: a geographic area, a special population, or a facility that has a shortage of health professionals as defined by federal regulations; a county health department, community health center, or migrant health center; or a geographic area or facility designated by rule of the department that has a shortage of health care practitioners who serve Medicaid and other low-income patients. Section 381.0302(2)(c), F.S. (2011).

⁶³ “Medically indigent person” was defined as a person who lacks public or private health insurance, is unable to pay for care, and is a member of a family with income at or below 185 percent of the federal poverty level. Section 381.0302(2)(d), F.S. (2011).

⁶⁴ Section 381.0302(10), F.S. (2011).

⁶⁵ Section 381.0302(11), F.S. (2011).

⁶⁶ Section 381.0302(6), F.S. (2011).

⁶⁷ E-mail from Karen Lundberg, Florida Dept. of Health, to Joe Anne Hart, Florida Dental Association (Sept. 16, 2005) (on file with the Senate Committee on Health Policy).

⁶⁸ Chapter 2007-72, Laws of Fla. The funding was contained in Specific Appropriations 677A of the General Appropriation Act, but later vetoed pursuant to the Governor’s line item veto authority.

⁶⁹ *Journal of the Florida Senate*, at 3 (June 12, 2007).

⁷⁰ Chapter 2012-184, s. 45, Laws of Fla.

National Health Service Corps (NHSC)

The NHSC programs provide scholarships and educational loan repayment to primary care providers⁷¹ who agree to practice in areas that are medically underserved and are located in selected HPSAs. The chart below shows the different loan programs that dental students may be eligible for based on where the participant is placed (HPSA score) and whether the participant provides full (40 hours per week) or part-time (20 hours per week) service.

Federal Loan Programs Applicable for Dental Students – National Health Services Corps (NHSC)				
Program Name	Time Commitment	Maximum Amount	Service Commitment Locations	Additional Time
Loan Repayment Program (LRP) ^{72,73}	2 years	Vary based on where placed Range: \$30,000 - \$50,000 (Full-time) \$15,000- \$25,000 – (Part-time)	NHSC approved sites in HPSAs	Option to annually renew after 2 years
Student to Service LRP ⁷⁴	Students in last year of school must commit to serve 3 years	Up to \$120,000	At an HPSA of greatest need	Option to annually renew after 3 year commitment to pay off loan remainder
Public Service Loan Forgiveness ⁷⁵	120 qualifying on-time loan payments ⁷⁶	Forgiveness of remainder of qualified federal loan	Qualified public service employment while making 120 loan payments	Remainder of qualified federal loan amounts forgiven at end of 120 payments

All of the NHSC programs require an application process. Some require a background check depending on the setting, and all require that the applicant be:

- A U.S. Citizen or U.S. National;

⁷¹ Primary care physicians, nurse practitioners, certified nurse midwives, physician assistants, dentists, dental hygienists, and behavioral and mental health providers, including health service psychologists, licensed clinical social workers, marriage and family therapists, psychiatrist nurse specialists, and licensed professional counselors.

⁷² The definition of part-time and full-time vary by discipline. The guidelines for both can be found in the *Fiscal Year 2018 Application and Program Guidance (March 2018)* beginning on pg. 24, <https://nhsc.hrsa.gov/downloads/loan-repayment/nhsc-LRP-application-program-guidance.pdf> (last viewed Feb. 28, 2019).

⁷³ U.S. Dep’t. of Health and Human Services, *Loan Repayment Program - Fiscal Year 2019 Application and Program Guidance* (December 2018) <https://nhsc.hrsa.gov/sites/default/files/NHSC/loan-repayment/lrp-application-guidance.pdf> (last viewed Feb. 27, 2019).

⁷⁴ U.S. Dep’t of Health and Human Services, HRSA, *Loan Repayment – NHSC Loan Repayment Program*, <https://www.nhsc.hrsa.gov/loanrepayment/index.html> (last visited Feb. 27, 2019).

⁷⁵ 34 CFR § 685.219. A qualifying public employer is a government organization at any level (federal, state, local, or tribal), not-for-profit organizations that are tax exempt under Section 501(c)(3) of the Internal Revenue Code, or other types of not-for-profit organizations that provide certain types of qualifying public services.

⁷⁶ 34 CFR § 685.219(c)(1)(iii). To qualify for public service loan forgiveness, a borrower must make 120 separate on-time monthly payments after October, 1, 2007, on eligible Direct Subsidized, Unsubsidized, PLUS, or Consolidation student loans that are part of either an income-based repayment plan or income contingent repayment plan; a standard repayment plan; or, except for the alternative repayment plan, any other repayment plan if the monthly payment amount is not less than what would have been paid under the Direct Loan standard repayment plan. Except for borrowers in an AmeriCorps or Peace Corps position, or any other student loan administered by the Department of Defense, a payment is considered on-time if it is made within 15 days of the scheduled due date for the full scheduled installment amount.

- Eligible to participate in the Medicare, Medicaid, and the State Children’s Health Insurance Program, as appropriate; and
- Fully trained and licensed to practice in the NHSC-eligible primary care medical, dental, or mental/behavioral health discipline for which the applicant seeks approval.

Additionally, the applicant must:

- Have unpaid student loans, taken before application to the NHSC’s Loan Repayment Program to support undergraduate or graduate education and
- Be working at or have accepted an offer of employment at an NHSC-approved site by the designated date (date determined each year).⁷⁷

The NHSC-approved sites are community-based health care facilities that provide comprehensive outpatient, ambulatory, and primary health care services. Eligible dental facilities must be located in a dental HPSA and offer comprehensive primary dental health services. NHSC-approved sites (with the exception of correctional facilities and free clinics) are required to provide services free or on a sliding fee scale (SFS) or discounted fee schedule for low-income individuals.

Participants may be eligible to continue loan repayment beyond the initial term. If a participant breaches his or her loan repayment agreement, he or she will be subject to monetary damages, which are the sum of the amount of assistance received by the participant representing any period of obligated service not completed, a penalty, and interest. As of February 28, 2019, there were 42 full-time-equivalent NHSC dentists in Florida in the loan repayment program, all of which are located at federally qualified health centers.⁷⁸

The State Loan Repayment Program (SLRP) offers cost-sharing grants to states to operate their own state educational loan repayment programs for primary care providers, including dental professionals, working in HPSAs within the state. The SLRP varies from state to state and may differ in eligible categories of providers, practice sites, length of required service commitment, and the amount of loan repayment assistance offered. However, there are certain statutory requirements SLRP grantees must meet. There is a minimum two-year service commitment with an additional one-year commitment for each year of additional support requested. Any SLRP program participant must practice at an eligible site located in a federally-designated HPSA.

In addition, the SLRP requires a \$1 state match for every \$1 provided under the federal grant. While the SLRP does not limit award amounts, the maximum award amount per provider that the federal government will support through its grant is \$50,000 per year, with a minimum service commitment of two years. Florida does not currently participate in the SLRP.

Several other federal loan repayment programs are open to most borrowers, including dental, that have certain post-graduate working conditions such as a requirement to work as a faculty member at an approved health institution, as a biomedical researcher, as a provider at an Indian

⁷⁷ National Health Services Corps, Loan Repayment Program, *Eligibility*, <https://nhsc.hrsa.gov/loan-repayment/nhsc-loan-repayment-program.html#eligibility> (last visited Feb. 27, 2019).

⁷⁸ E-Mail from John Rich, Office of Legislative Planning, Florida Dep’t. of Health, (Feb. 28, 2019) (on file with the Senate Committee on Health Policy).

health program site, as a commissioned dental officer in the U.S. Public Health Service Commissioned Corps, or with the United States Army or Navy.⁷⁹

III. Effect of Proposed Changes:

Section 1 provides that the legislative intent for the Dental Student Loan Repayment Program is to promote programs and initiatives that make preventive and educational dental services available to Floridians. It recognizes that better oral health leads to a more productive workplace and improves the cognitive abilities of schoolchildren, resulting in a reduction in the number of missed school days.

Section 2 creates the Dental Student Loan Repayment Program at the Department of Health (DOH) under s. 381.4019, F.S. The initiative is intended to promote access to dental care by encouraging dentists to practice in dental health professional shortage areas or medically underserved areas, or serve a medically underserved population.

The DOH is required to establish a Dental Student Loan Repayment Program, subject to a legislative appropriation, to benefit state-licensed dentists who demonstrate active employment in a public health program that serves Medicaid recipients and other low-income patients. The employment must be located in a dental health professional shortage area (HPSA) or a medically underserved area (MUA).

The DOH is directed to award funds from the loan program to repay student dental loans of a Florida-licensed dentist who meets these requirements; however, no award may exceed \$50,000 per year, per dentist. The DOH must limit the number of new dentists participating in the loan program to no more than 10 per fiscal year. A dentist may receive funds for at least one year and up to a maximum of five years. The dentist's period of obligated service begins when the dentist who receives the funds begins his or her employment.

Only loans taken out to pay the costs of tuition, books, dental equipment and supplies, uniforms, and living expenses may be covered under the loan program. Loan repayments are contingent upon continued proof of eligibility and must be made directly to the holder of the loan.

A dentist is not eligible to benefit from program funding if the dentist:

- Is no longer employed by a public health program that meets the requirements;
- Ceases to participate in the Florida Medicaid program; or
- Has disciplinary action taken against his or her license by the Board of Dentistry for a violation of s. 466.028, F.S.⁸⁰

The DOH is required to adopt rules to administer the loan program.

⁷⁹ American Dental Education Association, *State and Federal Loan Forgiveness Programs* (November 1, 2017), www.adea.org/advocacy/state/loan-forgiveness-programs.aspx (last visited Feb. 27, 2019).

⁸⁰ A violation of s. 466.028, F.S., constitutes grounds for denial of dental licensure or disciplinary action by the Board of Dentistry, as specified in s. 456.072(2), F.S.

Section 3 creates the Donated Dental Services Program under s. 381.40195, F.S., in the DOH. The Donated Dental Services Program is intended to provide comprehensive dental care through a network of volunteer dentists and other dental providers to needy, disabled, elderly, and medically comprised individuals who are ineligible for public assistance programs such as Medicaid or CHIP. Services under the program may be provided in a private office location or at any other suitable location. The eligible individual is not required to pay any fees or costs associated with the services for any treatments received.

The DOH is responsible for the implementation and operation of the program if an appropriation is provided by the Legislature for such purpose. The DOH is required to contract with a nonprofit organization that has experience providing and administering similar services and any such contract must delineate all of the vendor's responsibilities as provided in the statute. These responsibilities include, but are not limited to:

- Maintaining a network of volunteer providers who can provide a comprehensive range of dental services;
- Maintaining a referral system to an appropriate volunteer dentist or other participating provider;
- Developing a public awareness and marketing campaign to promote the program and to educate eligible individuals about the program;
- Providing the necessary administrative and technical support to administer the program;
- Submitting an annual report to the DOH with the required statutory components; and
- Performing any other program-related duties and responsibilities as required by the DOH.

The DOH is required to adopt rules to administer the program.

Section 4 provides that the bill is effective upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

Floridians living in those areas identified as medically underserved with little or no access to dental care could benefit from the Dental Student Loan Repayment Program. The program could bring additional dental professionals to underserved communities, populations, and facilities. The program could also be a reason that a dental graduate elects to stay in Florida instead of practicing in another state after graduation.

Dentists who qualify for the loan program will benefit from another option to reduce their student loan debt.

As a dentist practices in his or her public service employment program, the DOH will make payments on the dentist's previously incurred student loans. The DOH notes that during the period that the state funded repayment assistance is in place, underwriters for the student loans will receive guaranteed repayments. The DOH will need to have financial arrangements in place to ensure timely payments to the loan guarantors and arrangements with the dentists who participate in the program to ensure continued eligibility while payments are being made.

C. Government Sector Impact:

The implementation of the Dental Student Loan Repayment Program and the Donated Dental Services Program is subject to legislative appropriation; therefore, the bill has no impact on state revenues or state expenditures. If an appropriation is provided for such purpose, the DOH indicates that one additional other personal services employee at a cost of \$65,670, inclusive of compensation and applicable expenses, will be required if the Dental Student Loan Repayment Program is implemented by the department.⁸¹ The DOH estimates the implementation of the Donated Dental Services Program will require an appropriation of \$200,000 in recurring general revenue funds.⁸²

VI. Technical Deficiencies:

None.

VII. Related Issues:

On lines 61 and 71, the term "other low income patients" is used to identify other clients that could be the focus of dental graduates who are the beneficiaries of the Dental Student Loan

⁸¹ Department of Health, *Senate Bill 716 Analysis* (January 22, 2019) (on file with Senate Appropriations Subcommittee on Health and Human Services).

⁸² *Id.*

Repayment program. However, the term is not defined in the bill and it is unclear what the threshold is for “other low income patients.”

On line 88 of the bill, the number of new dentists participating in the Dental Student Loan Repayment program cannot exceed 10 in a fiscal year. Lines 97 and 98 authorize the DOH to adopt rules to administer the program; however, rather than rely on the DOH to develop its own process, it may be beneficial to include specific standards in the bill that prioritize the selection of dentists to participate in the program in the event that the DOH receives more than 10 new applications in a fiscal year.

On lines 111 and 112, a series of terms to describe the target population for the Donated Dental Services Program are introduced without being defined: needy, disabled, elderly, and medically compromised. These terms may need further clarification to ensure that the DOH is accurately focusing its efforts on the populations desired under the legislation.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 381.4019, 381.40195

IX. Additional Information:

- A. **Committee Substitute – Statement of Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

Recommended CS by Appropriations Subcommittee on Health and Human Services on April 9, 2019:

The committee substitute conditions the implementation of the Dental Student Loan Repayment Program and the Donated Dental Services Program by the Department of Health on the receipt of a legislative appropriation.

- B. **Amendments:**

None.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Governmental Oversight and Accountability, Chair
Appropriations Subcommittee on Agriculture,
Environment, and General Government
Appropriations Subcommittee on Health and
Human Services
Health Policy
Infrastructure and Security
Joint Select Committee on Collective Bargaining,
Alternating Chair
Joint Administrative Procedures Committee

SENATOR ED HOOPER
16th District

March 4th, 2019

The Honorable Aaron Bean, Chair
Appropriations Subcommittee on Health and Human Services Committee
201 The Capitol
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Chair Bean:

I am writing to request that SB 716, Dental Services, be placed on the agenda of the next Appropriations Subcommittee on Health and Human Services Committee meeting.

Should you have any questions regarding this bill, please do not hesitate to reach out to me. Thank you for your time and consideration.

Warm regards,

Ed Hooper

SENATE APPROPRIATIONS
RECEIVED
19 MAR -5 AM 8:18
SENT TO CHAIRMAN
STAFF DIR. _____
STAFF _____

CC: Tonya Kidd, Staff Director
Robin Jackson, Administrative Assistant

REPLY TO:
 3450 East Lake Road, Suite 305, Palm Harbor, Florida 34685-2411 (727) 771-2102
 326 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5016

Senate's Website: www.flisenate.gov

BILL GALVANO
President of the Senate

DAVID SIMMONS
President Pro Tempore

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19

Meeting Date

SB 716

Bill Number (if applicable)

Topic Dental Services

Amendment Barcode (if applicable)

Name Joe Anne Hart

Job Title Chief Legislative Officer

Address 118 E. Jefferson Street

Phone 850.224.1089

Street Tallahassee FL 32301

Email jahart@floridadental.org

City State Zip

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Florida Dental Association

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19
Meeting Date

SB 716
Bill Number (if applicable)

740542
Amendment Barcode (if applicable)

Topic Dental Services

Name Joe Anne Hart

Job Title Chief Legislative Officer

Address 118 E. Jefferson Street Phone 888.224.1089

Tallahassee FL 32301
City State Zip

Email jaharta@floridadental.org

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Florida Dental Association

Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

By Senator Hooper

16-00819A-19

2019716__

1 A bill to be entitled
 2 An act relating to dental services; providing
 3 legislative intent; creating s. 381.4019, F.S.;
 4 establishing the Dental Student Loan Repayment Program
 5 to support dentists who practice in public health
 6 programs located in certain underserved areas;
 7 providing definitions; requiring the Department of
 8 Health to establish a dental student loan repayment
 9 program for specified purposes; providing for the
 10 award of funds; providing the maximum number of years
 11 funds may be awarded; providing eligibility
 12 requirements; requiring the department to adopt rules;
 13 creating s. 381.40195, F.S.; providing a short title;
 14 providing definitions; requiring the Department of
 15 Health to establish the Donated Dental Services
 16 Program to provide comprehensive dental care to
 17 certain eligible individuals; requiring the department
 18 to contract with a nonprofit organization to implement
 19 and administer the program; specifying minimum
 20 contractual responsibilities; requiring the department
 21 to adopt rules; providing an effective date.
 22
 23 Be It Enacted by the Legislature of the State of Florida:
 24
 25 Section 1. It is the intent of the Legislature to promote
 26 programs and initiatives that help make available preventive and
 27 educational dental services for the citizens of the state, as
 28 well as provide quality dental treatment services. The
 29 geographic characteristics among the citizens of the state are

Page 1 of 6

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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30 distinctive and vary from region to region, with such citizens
 31 having unique needs regarding access to dental care. The
 32 Legislature recognizes that maintaining good oral health is
 33 integral to the overall health status of individuals and that
 34 the good health of the residents of this state is an important
 35 contributing factor in economic development. Better health,
 36 including better oral health, increases workplace productivity,
 37 reduces the burden of health care costs, and improves the
 38 cognitive development of children, resulting in a reduction of
 39 missed school days.
 40 Section 2. Section 381.4019, Florida Statutes, is created
 41 to read:
 42 381.4019 Dental Student Loan Repayment Program.—Subject to
 43 the availability of funds, the Legislature shall establish the
 44 Dental Student Loan Repayment Program to promote access to
 45 dental care by supporting qualified dentists who treat medically
 46 underserved populations in dental health professional shortage
 47 areas or medically underserved areas.
 48 (1) As used in this section, the term:
 49 (a) “Dental health professional shortage area” means a
 50 geographic area designated as such by the Health Resources and
 51 Services Administration of the United States Department of
 52 Health and Human Services.
 53 (b) “Department” means the Department of Health.
 54 (c) “Loan program” means the Dental Student Loan Repayment
 55 Program.
 56 (d) “Medically underserved area” means a geographic area,
 57 an area having a special population, or a facility which is
 58 designated by department rule as a health professional shortage

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59 area as defined by federal regulation and which has a shortage
 60 of dental health professionals who serve Medicaid recipients and
 61 other low-income patients.

62 (e) "Public health program" means a county health
 63 department, the Children's Medical Services program, a federally
 64 funded community health center, a federally funded migrant
 65 health center, or other publicly funded or nonprofit health care
 66 program designated by the department.

67 (2) The department shall establish a dental student loan
 68 repayment program to benefit Florida-licensed dentists who
 69 demonstrate, as required by department rule, active employment
 70 in a public health program that serves Medicaid recipients and
 71 other low-income patients and is located in a dental health
 72 professional shortage area or a medically underserved area.

73 (3) The department shall award funds from the loan program
 74 to repay the student loans of a dentist who meets the
 75 requirements of subsection (2).

76 (a) An award may not exceed \$50,000 per year per eligible
 77 dentist.

78 (b) Only loans to pay the costs of tuition, books, dental
 79 equipment and supplies, uniforms, and living expenses shall be
 80 covered.

81 (c) All repayments shall be contingent upon continued proof
 82 of eligibility and shall be made directly to the holder of the
 83 loan. The state shall bear no responsibility for the collection
 84 of any interest charges or other remaining balances.

85 (d) A dentist is eligible to receive funds under the loan
 86 program for at least 1 year, up to a maximum of 5 years.

87 (e) The department shall limit the number of new dentists

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88 participating in the loan program to no more than 10 per fiscal
 89 year.

90 (4) A dentist is no longer eligible to receive funds under
 91 the loan program if the dentist:

92 (a) Is no longer employed by a public health program that
 93 meets the requirements of subsection (2).

94 (b) Ceases to participate in the Florida Medicaid program.

95 (c) Has disciplinary action taken against his or her
 96 license by the Board of Dentistry for a violation of s. 466.028.

97 (5) The department shall adopt rules to administer the loan
 98 program.

99 Section 3. Section 381.40195, Florida Statutes, is created
 100 to read:
 101 381.40195 Donated Dental Services Program.—

102 (1) This act may be cited as the "Donated Dental Services
 103 Act."

104 (2) As used in this section, the term:

105 (a) "Department" means the Department of Health.

106 (b) "Program" means the Donated Dental Services Program as
 107 established pursuant to subsection (3).

108 (3) The department shall establish the Donated Dental
 109 Services Program for the purpose of providing comprehensive
 110 dental care through a network of volunteer dentists and other
 111 dental providers to needy, disabled, elderly, and medically
 112 compromised individuals who cannot afford necessary treatment
 113 but are ineligible for public assistance. An eligible individual
 114 may receive treatment in a volunteer dentist's or participating
 115 dental provider's private office or at any other suitable
 116 location. An eligible individual is not required to pay any fee

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117 or cost associated with the treatment he or she receives.
 118 (4) The department shall implement and administer the
 119 program. The department shall contract with a nonprofit
 120 organization that has experience in providing similar services
 121 or administering similar programs. The contract must specify the
 122 responsibilities of the nonprofit organization, which may
 123 include, but are not limited to:
 124 (a) Maintaining a network of volunteer dentists and other
 125 dental providers, including, but not limited to, dental
 126 specialists and dental laboratories, to provide comprehensive
 127 dental services to eligible individuals.
 128 (b) Maintaining a system to refer eligible individuals to
 129 the appropriate volunteer dentist or participating dental
 130 provider.
 131 (c) Developing a public awareness and marketing campaign to
 132 promote the program and educate eligible individuals about its
 133 availability and services.
 134 (d) Providing the necessary administrative and technical
 135 support to administer the program.
 136 (e) Submitting an annual report to the department which
 137 must include, at a minimum:
 138 1. Financial data relating to administering the program.
 139 2. Demographic data and other information relating to the
 140 eligible individuals who are referred to and receive treatment
 141 through the program.
 142 3. Demographic data and other information relating to the
 143 volunteer dentists and participating dental providers who
 144 provide dental services through the program.
 145 4. Any other data or information that the department may

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146 require.
 147 (f) Performing any other program-related duties and
 148 responsibilities as required by the department.
 149 (5) The department shall adopt rules to administer the
 150 program.
 151 Section 4. This act shall take effect upon becoming a law.

Page 6 of 6

CODING: Words ~~stricken~~ are deletions; words underlined are additions.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/09/2019	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services
(Hooper) recommended the following:

Senate Amendment (with title amendment)

Delete lines 42 - 150

and insert:

381.4019 Dental Student Loan Repayment Program.—The
Legislature shall establish the Dental Student Loan Repayment
Program to promote access to dental care by supporting qualified
dentists who treat medically underserved populations in dental
health professional shortage areas or medically underserved
areas.



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- 11 (1) As used in this section, the term:
- 12 (a) "Dental health professional shortage area" means a
13 geographic area designated as such by the Health Resources and
14 Services Administration of the United States Department of
15 Health and Human Services.
- 16 (b) "Department" means the Department of Health.
- 17 (c) "Loan program" means the Dental Student Loan Repayment
18 Program.
- 19 (d) "Medically underserved area" means a geographic area,
20 an area having a special population, or a facility which is
21 designated by department rule as a health professional shortage
22 area as defined by federal regulation and which has a shortage
23 of dental health professionals who serve Medicaid recipients and
24 other low-income patients.
- 25 (e) "Public health program" means a county health
26 department, the Children's Medical Services program, a federally
27 funded community health center, a federally funded migrant
28 health center, or other publicly funded or nonprofit health care
29 program designated by the department.
- 30 (2) The department shall establish a dental student loan
31 repayment program to benefit Florida-licensed dentists who
32 demonstrate, as required by department rule, active employment
33 in a public health program that serves Medicaid recipients and
34 other low-income patients and is located in a dental health
35 professional shortage area or a medically underserved area.
- 36 (3) The department shall award funds from the loan program
37 to repay the student loans of a dentist who meets the
38 requirements of subsection (2).
- 39 (a) An award may not exceed \$50,000 per year per eligible



740542

40 dentist.

41 (b) Only loans to pay the costs of tuition, books, dental
42 equipment and supplies, uniforms, and living expenses may be
43 covered.

44 (c) All repayments shall be contingent upon continued proof
45 of eligibility and shall be made directly to the holder of the
46 loan. The state shall bear no responsibility for the collection
47 of any interest charges or other remaining balances.

48 (d) A dentist is eligible to receive funds under the loan
49 program for at least 1 year, up to a maximum of 5 years.

50 (e) The department shall limit the number of new dentists
51 participating in the loan program to not more than 10 per fiscal
52 year.

53 (4) A dentist is no longer eligible to receive funds under
54 the loan program if the dentist:

55 (a) Is no longer employed by a public health program that
56 meets the requirements of subsection (2).

57 (b) Ceases to participate in the Florida Medicaid program.

58 (c) Has disciplinary action taken against his or her
59 license by the Board of Dentistry for a violation of s. 466.028.

60 (5) The department shall adopt rules to administer the loan
61 program.

62 (6) Implementation of the loan program is subject to
63 legislative appropriation.

64 Section 3. Section 381.40195, Florida Statutes, is created
65 to read:

66 381.40195 Donated Dental Services Program.—

67 (1) This act may be cited as the "Donated Dental Services
68 Act."



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- 69 (2) As used in this section, the term:
70 (a) "Department" means the Department of Health.
71 (b) "Program" means the Donated Dental Services Program as
72 established pursuant to subsection (3).
73 (3) The department shall establish the Donated Dental
74 Services Program for the purpose of providing comprehensive
75 dental care through a network of volunteer dentists and other
76 dental providers to needy, disabled, elderly, and medically
77 compromised individuals who cannot afford necessary treatment
78 but are ineligible for public assistance. An eligible individual
79 may receive treatment in a volunteer dentist's or participating
80 dental provider's private office or at any other suitable
81 location. An eligible individual is not required to pay any fee
82 or cost associated with the treatment he or she receives.
83 (4) The department shall implement and administer the
84 program. The department shall contract with a nonprofit
85 organization that has experience in providing similar services
86 or administering similar programs. The contract must specify the
87 responsibilities of the nonprofit organization, which may
88 include, but are not limited to:
89 (a) Maintaining a network of volunteer dentists and other
90 dental providers, including, but not limited to, dental
91 specialists and dental laboratories, to provide comprehensive
92 dental services to eligible individuals.
93 (b) Maintaining a system to refer eligible individuals to
94 the appropriate volunteer dentist or participating dental
95 provider.
96 (c) Developing a public awareness and marketing campaign to
97 promote the program and educate eligible individuals about its



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98 availability and services.

99 (d) Providing the necessary administrative and technical
100 support to administer the program.

101 (e) Submitting an annual report to the department which
102 must include, at a minimum:

103 1. Financial data relating to administering the program.

104 2. Demographic data and other information relating to the
105 eligible individuals who are referred to and receive treatment
106 through the program.

107 3. Demographic data and other information relating to the
108 volunteer dentists and participating dental providers who
109 provide dental services through the program.

110 4. Any other data or information that the department may
111 require.

112 (f) Performing any other program-related duties and
113 responsibilities as required by the department.

114 (5) The department shall adopt rules to administer the
115 program.

116 (6) Implementation of the program is subject to legislative
117 appropriation.

118
119 ===== T I T L E A M E N D M E N T =====

120 And the title is amended as follows:

121 Delete lines 13 - 21

122 and insert:

123 specifying that implementation of the program is
124 subject to legislative appropriation; creating s.
125 381.40195, F.S.; providing a short title; providing
126 definitions; requiring the Department of Health to



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127 establish the Donated Dental Services Program to
128 provide comprehensive dental care to certain eligible
129 individuals; requiring the department to contract with
130 a nonprofit organization to implement and administer
131 the program; specifying minimum contractual
132 responsibilities; requiring the department to adopt
133 rules; specifying that implementation of the program
134 is subject to legislative appropriation; providing an
135 effective date.

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL: PCS/CS/SB 732 (432502)

INTRODUCER: Appropriations Subcommittee on Health and Human Services; Health Policy Committee;
and Senator Flores

SUBJECT: Clinics and Office Surgery

DATE: April 11, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	Fav/CS
2.	Gerbrandt	Kidd	AHS	Recommend: Fav/CS
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 732 authorizes the Department of Health (DOH) to register and regulate office surgery centers. The bill requires the DOH to deny or revoke the registration of or impose certain penalties against any facility where certain office surgeries are performed under certain circumstances.

The bill authorizes the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) to adopt rules to administer the registration, inspection, and safety of office surgery centers and the standards of practice for physicians who perform office surgery.

The bill will have an indeterminate fiscal impact upon the DOH.

The bill is effective upon becoming a law.

II. Present Situation:

Regulation of Office Surgery

The practice of medicine in Florida is regulated under ch. 458, F.S., and the practice of osteopathic medicine is regulated under ch. 459, F.S. Both professions have broad authority to

adopt rules to implement the provisions of their respective practice acts.¹ The Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) were created within the Department of Health (DOH) to ensure that every physician practicing in the state meets minimum requirements for safe practice.²

In Florida, surgeries performed in a doctor's office, outside a facility licensed under ch. 390 or ch. 395, F.S., are regulated by ss. 458.309(3) and 459.005(2), F.S. Both sections are identical except for the references to the BOM or the BOOM. Both require that a physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, Level II procedures lasting more than five minutes, and all Level III surgical procedures in an office setting, to register the doctor's office with the DOH, unless that office is licensed as a facility under ch. 395, F.S. Level II procedures and Level III procedures are not defined in the Florida statute, but the respective boards have defined three levels of office surgery by administrative rule,³ which are subject to change by the boards through the administrative rule propagation process.

The DOH is required to inspect a registered doctor's office annually unless the office is accredited by a nationally-recognized accrediting agency or an accrediting organization approved by the BOM or the BOOM. The actual costs of registration, inspection and/or accreditation are to be paid by the person seeking to register and operate the office in which office surgeries are performed.⁴

All other aspects of office surgeries are regulated by administrative rules promulgated by the BOM and the BOOM.

Specifically, the BOM and the BOOM have established the standards of practice and the standards of care for particular practice settings, including but not limited to:

- Education and training;
- Equipment and supplies;
- Medications, including anesthetics;
- Assistance of and delegation to other personnel;
- Transfer agreements;
- Sterilization;
- Records;
- Performance of complex or multiple procedures;
- Informed consent; and
- Policy and procedure manuals.⁵

The current BOM and BOOM rules are very similar, with only three substantive differences. The BOOM's rule requires the following, and the BOM's rule does not require, that:

¹ Sections 458.309(1) and 459.005(1), F.S.

² Sections 458.307(1), 458.301, 459.004 and 459.001, F.S.

³ See rules 64B8-9.009 and 64B15-14.007, F.A.C.

⁴ See ss. 358.309(3) and 459.005(2), F.S.

⁵ *Id.*

- If a surgeon is unavailable to provide post-operative care, the surgeon must notify the patient, prior to the procedure, of his or her unavailability after the procedure;⁶
- When Level II, IIA, or III procedures are performed, the surgeon is responsible for providing the patient, in writing, prior to the procedure, the name and location of the hospital where the surgeon has privileges to perform the same procedure as that being performed in the outpatient setting, or the name and location of the hospital where the surgeon or facility has a transfer agreement;⁷ and
- The surgeon performing Level I procedures in an office setting must hold a current certification in an Advanced Cardiac Life Support course with didactic and skills components, approved by Pacific Medical Training, the American Heart Association, or the American Safety and Health Institute.⁸

The BOM and BOOM rules regarding levels of office surgeries (I, II, IIA and III) differentiate each level primarily by the level of sedation and anesthesia required for the procedure and patient risk.

The BOM and the BOOM general requirements for all office surgery,⁹ as well as specific standards for the levels of office surgery, are virtually identical, other than the three substantive differences noted above, further reference to the rules in this analysis will pertain to BOM Rule 64B8-9.009, F.A.C.

General Office Surgery Practice Standards

Current rule requires a surgeon¹⁰ to examine the patient immediately before the surgery to evaluate the patient's risk of anesthesia and the surgical procedure to be performed. The surgeon may delegate the preoperative heart and lung evaluation to a qualified anesthesia provider within the scope of the provider's practice and, if applicable, protocol. The surgeon must maintain complete records¹¹ of each surgical procedure, including:

- Anesthesia records;
- A written informed consent from the patient reflecting the patient's knowledge of:
 - Identified risks;
 - Consent to the procedure;¹²
 - Type of anesthesia;
 - Anesthesia provider; and

⁶ Rule 64B15-14.007(2)(h), F.A.C.

⁷ Rule 64B15-14.007, F.A.C.

⁸ Rule 64B15-14.003(3)(b)1., F.A.C. The BOM recommends the surgeon have Basic Life Support Certification, but it is not required. See 64B8-9.009(3)(b)1., F.A.C.

⁹ "Office surgery" is defined by the BOM and the BOOM, as surgery which is performed outside of any facility licensed under ch. 390, F.S., (an abortion clinic) or ch. 395, F.S., (a hospital or ambulatory surgical center). See Rules 64B8-9.009(1)(d) and 64B15-14.007(1)(d), F.A.C.

¹⁰ Rules 64B8-9.009(1)(b) and 64B15-14.007(1)(b), F.A.C., define a "surgeon" as a licensed physician performing any procedure included within the definition of surgery.

¹¹ See Rules 64B8-9.003(2)(a) and 64B15-14.007(2)(a), F.A.C.

¹² A written informed consent is not necessary for minor Level I procedures limited to the skin and mucosa. See Rule 64B8-9.009(2)(b), F.A.C.

- The availability of a choice of anesthesia provider, including an anesthesiologist, anesthesiologist assistant, another appropriately trained physician, certified registered nurse anesthetist, or physician assistant.¹³

The rule further requires the surgeon to maintain a log of all Level II and Level III surgical procedures performed, which must include:

- A confidential patient identifier;
- The time the patient arrives in the operating suite;
- The name of the physician who provided medical clearance;
- The surgeon's name;
- The diagnosis;
- The CPT Codes for the procedures performed;
- The patient's ASA classification;
- The type of procedure performed;
- The level of surgery;
- The anesthesia provider;
- The type of anesthesia used;
- The duration of the procedure;
- The type of post-operative care;
- The duration of recovery;
- The disposition of the patient upon discharge;
- A list of medications used during surgery and recovery; and
- Any adverse incidents.

The log and all surgical records must be provided to the DOH investigators upon request.¹⁴

Current rules define the three levels of office surgery as follows:¹⁵

Level I Office Surgery¹⁶ includes:

- Minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas and repair of lacerations, or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient;
- Liposuction involving the removal of less than 4000cc supernatant fat;
- Incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cystoscopic procedures, and closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints);
- The patient's level of sedation is that of minimal sedation and anxiolysis¹⁷ and the chances of complications requiring hospitalization are remote. Minimal sedation and anxiolysis is a

¹³ Rule 64B8-9.009(2)(a), F.A.C.

¹⁴ Rule 64B8-9.009(2)(c), F.A.C.

¹⁵ See rules 64B8-9.009 and 64B15-14.007, F.A.C.

¹⁶ Rule 64B8-9.009(3), F.A.C.

¹⁷ "Anxiolysis" is defined as a state of mild sedation obtained with minor tranquilizers or antianxiety medication. See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1993866/>

defined as a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilation and cardiovascular functions are unaffected. Controlled substances, as defined in ss. 893.02 and 893.03, F.S., are limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety or pain; and

- Chances of complication requiring hospitalization are remote.

Level II Office Surgery¹⁸ includes, but is not limited to:

- Hemorrhoidectomy, hernia repair, large joint dislocations, colonoscopy, and liposuction involving the removal of up to 4,000cc supernatant fat;
- Any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation. Moderate sedation and analgesia or conscious sedation is defined as a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response;
- The physician, or the facility where the procedure is being performed, must have a transfer agreement with a licensed hospital within reasonable proximity if the physician performing the procedure does not have staff privileges to perform the same procedure as that being performed in the out-patient setting at a licensed hospital within reasonable proximity; and "Reasonable proximity" is defined as not to exceed 30 minutes transport time to the hospital.

Level III Office Surgery¹⁹ includes:

- Surgery in which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. Deep sedation and analgesia is defined as a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response. General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. The use of spinal or epidural anesthesia shall be considered Level III;
- Only patients classified under the American Society of Anesthesiologist's (ASA) risk classification criteria as Class I or II are appropriate candidates for Level III office surgery, and require:
 - All Level III surgeries on patients classified as ASA III and higher are to be performed only in a hospital or ambulatory surgery center; and

¹⁸ Rule 64B8-9.009(4) and (5), F.A.C.

¹⁹ Rule 64B8-9.009(6), F.A.C.

- For all ASA II patients above the age of 50, the surgeon must obtain a complete workup performed prior to the performance of Level III surgery in a physician office setting. If the patient has a cardiac history or is deemed to be a complicated medical patient, the patient must have a preoperative EKG and be referred to an appropriate consultant for medical optimization. The referral to a consultant may be waived after evaluation by the patient's anesthesiologist.
- In addition to the standards for Level II Office Surgery, the surgeon must:
 - Have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board qualification by a Board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine or must be able to demonstrate to the accrediting organization or to the Department comparable background, training and experience. Such Board certification or comparable background, training and experience must also be directly related to and include the procedure(s) being performed by the physician in the office surgery facility. In addition, the surgeon must have knowledge of the principles of general anesthesia;
 - Have one assistant who is currently certified by an American Heart Association, American Safety and Health Institute, American Red Cross, Pacific Medical Training approved Basic Life Support course with didactic and skills components, or ACLS Certification Institute Basic Life Support course with didactic and skills components, and the surgeon must be currently certified by an American Heart Association, American Safety and Health Institute, Pacific Medical Training approved Advanced Cardiac Life Support course with didactic and skills components, or ACLS Certification Institute Advanced Cardiac Life Support course with didactic and skills components;
- Have emergency policies and procedures related to serious anesthesia complications must be formulated, periodically reviewed, practiced, updated, and posted in a conspicuous location. Topics to be covered shall include the following:
 - Airway Blockage (foreign body obstruction),
 - Allergic Reactions,
 - Bradycardia,
 - Bronchospasm,
 - Cardiac Arrest,
 - Chest Pain,
 - Hypoglycemia,
 - Hypotension,
 - Hypoventilation,
 - Laryngospasm,
 - Local Anesthetic Toxicity Reaction; and,
 - Malignant Hyperthermia.

Liposuction Procedures in an Office Setting

Liposuction is the surgical removal of subcutaneous fat by means of an aspiration cannula introduced through small skin incisions, assisted by suction. Synonyms used in literature include

liposuction surgery, suction-assisted lipectomy, suction lipoplasty, fat suction, blunt suction lipectomy, and liposculpture.²⁰

The BOM sets the general practice requirements for all liposuction procedures in an office setting as follows:²¹

- The surgeon must maintain a log of all liposuction procedures where more than 1,000 cubic centimeters of supernatant fat is removed, and Level II and Level III surgical procedures performed, which must include a confidential patient identifier, time of arrival in the operating suite, documentation of completion of the medical clearance as performed by the anesthesiologist or the operating physician, the surgeon's name, diagnosis, CPT Codes, patient ASA classification, the type of procedure, the level of surgery, the anesthesia provider, the type of anesthesia used, the duration of the procedure, and any adverse incidents, as identified in s. 458.351, F.S.
- In any liposuction procedure, the surgeon is responsible for determining the appropriate amount of supernatant fat to be removed from a particular patient. A maximum of 4000cc supernatant fat may be removed by liposuction in the office setting. A maximum of 50mg/kg of Lidocaine can be injected for tumescent liposuction in the office setting.
- Liposuction may be performed in combination with another separate surgical procedure during a single Level II or Level III operation, only in the following circumstances:
 - When combined with abdominoplasty, liposuction may not exceed 1000cc of supernatant fat;
 - When liposuction is associated and directly related to another procedure, the liposuction may not exceed 1000 cc of supernatant fat; and
 - Major liposuction in excess of 1000cc supernatant fat may not be performed in a remote location from any other procedure.

III. Effect of Proposed Changes:

The bill regulates office surgery procedures performed by physicians in an office setting, and amends ss. 458.305 and 459.003, F.S., to define the following terms:

- “Surgeon” means a licensed physician performing any procedure included within the definition of surgery;
- “Surgery” means any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, relieving suffering or any elective procedure for aesthetic, reconstructive or cosmetic purposes, to include, but not be limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic;
- “Office surgery” means surgery which is performed outside of any facility licensed under chapter 390 or 395, F.S., and includes:

²⁰ Venkataram, Jayashree, *Journal of Cutaneous and Aesthetic Surgery, Tumescent Liposuction: A Review July – December, 2008*, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2840906/> (last visited March 29, 2019).

²¹ See rules 64B8-9.009(2)(b)-(e), F.A.C. and 64B15-14.007(2), F.A.C.

- “Level I Office Surgery” means surgery limited to minor procedures where anesthesia is limited to minimal sedation;
- “Level II Office Surgery means any surgery in which the patient’s level of sedation is that of moderate sedation and analgesia or conscious sedation; and
- Level III Office Surgery means surgery in which the patient’s level of sedation is that of deep sedation and analgesia or general anesthesia. The use of spinal or epidural anesthesia shall be considered Level III. **(See Sections 3 and 6)**

The bill further amends ss. 458.305 and 459.003, F.S., to define six levels of anesthesia that are used to describe the three levels of office surgery as the following:

- “Minimal sedation” means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and respiratory and cardiovascular functions are unaffected;
- “Moderate sedation and analgesia”, or “conscious sedation”, means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response;
- “Deep sedation and analgesia” means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain respiratory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response.
- “General anesthesia” means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain respiratory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.
- “Epidural anesthesia” means the injection of an anesthetic agent into the epidural space of the spinal cord to produce regional anesthesia resulting in loss of sensation in the lower abdominal, genital and/or pelvic areas.
- “Spinal Anesthesia” means the injection of an anesthetic agent beneath the arachnoid membrane that surrounds the spinal cord to produce a loss of sensation to the lower half of the body. **(See Sections 3 and 6)**

The bill amends ss. 458.309 and 459.005, F.S., to authorize the BOM and the BOOM to develop rules to administer the registration, inspection, and safety of an office performing office surgery; and directs the BOM and the BOOM to adopt rules governing the standards of practice of physicians practicing in an office registered to perform office surgery. The BOM and BOOM must impose a fine of \$5,000 per day on a physician who performs certain office surgical procedures in an office that has not registered with the DOH. **(See Sections 4 and 7)**

As a condition of registration, a physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, and Level II and level III office

surgeries in an office setting, and the office itself is a separate legal entity from the physician, must maintain the same levels of financial responsibility required in ss. 458.320 and 459.0085, F.S. The office seeking registration with the DOH must designate a physician who is responsible for compliance with the laws and rules for office surgery. The designated physician must be licensed under chapters 458 (Medicine) or 459 (Osteopathic Medicine), and practice at the office for which he or she has assumed responsibility for compliance. The DOH may suspend the registration of an office without a designated physician who practices at the office. If a designated physician's employment is terminated by the office, the office must notify the DOH within 10 days of termination of the identity of a new designated physician.

(See Sections 4 and 7)

The bill authorizes the DOH to perform annual inspections, including a review of patient records, of all offices except those that are accredited by a nationally recognized accrediting agency approved by the BOM or BOOM. The bill also permits the DOH to perform unannounced inspections. However, the bill requires the DOH to perform announced inspections of certain pain management clinics.²² **(See Sections 4 and 7)**

The bill amends ss. 458.331 and 459.015(1), F.S., to establish specific grounds for discipline against a physician's license for performing office surgical procedures in an office not registered with the DOH. **(See Sections 5 and 8)**

The bill amends s. 456.004, F.S., to direct the DOH to deny or revoke the registration of, or impose penalties against, an office or facility where a physician performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, for failure of its physicians, owners, or operators to comply with the BOM or the BOOM rules; and authorizes the DOH to deny future office surgery registrations for five years to any person named in office surgery registration documents, including owners and operators of an office surgery facility, that has had a registration revoked by the DOH. **(See Section 1)**

The bill amends s. 456.074, F.S., to authorize the DOH to issue an emergency suspension, or restriction, of an office surgery registration that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, upon a finding of:

- Probable cause that the facility or its surgeons are not in compliance with the standards of practice for office surgery adopted by the BOM and the BOOM;
- Probable cause that the facility or its surgeons are in violation practicing or offering to practice beyond the scope permitted by law; and
- That such noncompliance constitutes an immediate danger to the public. **(See Section 2)**

The bill is effective upon becoming a law.

²² See s. 458.3265(1)(a)3.g. and h., F.S., and s. 459.0137(1)(a)3.g. and h., F.S.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

As a condition of registration under ss. 458.308 and 459.003, F.S., a physician who performs office surgical procedures in an office setting, and the office itself if it is a separate legal entity from the physician, must now maintain the same levels of financial responsibility required in ss. 458.320 and 459.0085, F.S. This may produce an additional cost to the physician and the office if they are a separate legal entities.

C. Government Sector Impact:

The revised registration requirements created by the bill will have an indeterminate fiscal impact on the DOH.²³ However, current law allows the DOH to recover the cost of registration and inspection from the person seeking to register with the department.²⁴ The cost of rulemaking can be absorbed within existing resources.²⁵

²³ The Agency for Health Care Administration, *SB 732 (Strike All Amendment 859422) Bill Analysis* (March 3, 2019) (on file with the Senate Appropriations Subcommittee on Health and Human Services).

²⁴ See ss. 458.309(3), 459.005(2), F.S.

²⁵ Email from Ty Gentle, Budget Director, The Florida Department of Health (April 2, 2019) (on file with the Senate Appropriations Subcommittee on Health and Human Services).

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

The bill substantially amends the following sections of the Florida Statutes: 456.004, 456.074, 458.305, 458.309, 458.331, 459.003, 459.005, 459.015, 464.012, and 766.101.

IX. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

Recommended CS/CS by Appropriations Subcommittee on Health and Human Services on April 9, 2019:

The committee substitute:

- Deletes Sections 1-4 of the bill related to the Health Care Clinic Act.
- Requires the BOM and the BOOM, instead of the DOH, to adopt rules to administer the registration, inspection and safety of offices in which a physician performs office surgery.
- Requires offices seeking registration with the DOH to designate a physician who is responsible for compliance with the laws and rules for office surgery. The designated physician must be licensed under chapters 458 (Medicine) or 459 (Osteopathic Medicine), and practice at the office for which he or she has assumed responsibility for compliance. The DOH may suspend the registration of an office without a designated physician who practices at the office. If a designated physician's employment is terminated by the office, the office must notify the DOH within 10 days of termination of the identity of a new designated physician.
- Authorizes the DOH to inspect all offices, including a review of patient records, except those offices that are accredited by a nationally recognized accrediting agency approved by the BOM or BOOM. Permits the DOH to perform unannounced inspections unless the office meets certain criteria as a pain management clinic.
- Deletes Section 13 of the bill that required certified nurse anesthetists to provide certain services within the framework of an established protocol with a licensed anesthesiologist.

CS by Health Policy on March 11, 2019:

The committee substitute:

- Defines a "clinic" in ch. 400 F.S., to include an entity that provides health care services "that receives compensation," expanding the definition to include more than just those that bill third parties, such as Medicare, Medicaid, and insurance companies;

- Creates additional responsibilities for clinics to ensure that clinics complies with the standards of practice defined by the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) for office surgery;
- Directs the Agency for Health Care Administration (AHCA) to impose an administrative fine of \$5,000 per day on any licensed clinic whose owner, medical director, or clinic director, operates an unlicensed clinic that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgery procedures, and is not registered with the Department of Health (DOH) as an office surgery facility;
- Directs that the clinic maintain financial responsibility requirements to pay claims and costs arising out of the rendering, or failure to render, medical care and services in the manner prescribed for liposuction procedures in which more than 1,000 cc of supernatant fat is removed, Level II and Level III office surgery procedures performed in the clinic;
- Regulates office surgery procedures performed by physicians; and defines surgeon, surgery, and office surgery, and six levels of anesthesia used to describe the three levels of office surgery as: Minimal sedation; Moderate sedation with analgesia or conscious sedation; Deep sedation with analgesia; General anesthesia; Epidural anesthesia; and Spinal anesthesia.
- Directs the DOH to deny or revoke the registration of, or impose penalties against, an office or facility where a physician performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, for failure of its physicians, owners, or operators to comply with the BOM or the BOOM rules;
- Authorized the DOH to deny future office surgery registrations for five years to any person named in office surgery registration documents, including owners and operators, of an office surgery facility that has had a registration revoked by the DOH;
- Authorizes the DOH to issue an emergency suspension, or restriction, of an office surgery registration that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, upon a specific findings;
- Authorizes the DOH to develop rules to administer the registration, inspection, and safety of an office performing office surgery;
- Directs the BOM and the BOOM to adopt rules governing the standards of practice of physicians practicing in an office registered to perform office surgery;
- Directs the BOM and the BOOM to impose a fine of \$5,000 per day on a physician who performs office surgical procedures in an office that has not registered;
- Establishes specific grounds for discipline against a physician's license for performing office surgical procedures in an office not registered with the DOH; and
- Directs that any certified registered nurse anesthetist who provide services in a registered office surgery facility work within the framework of an established protocol with an anesthesiologist;

B. Amendments:

None.

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



The Florida Senate

Committee Agenda Request

To: Senator Aaron Bean, Chair
Appropriations Subcommittee on Health and Human Services

Subject: Committee Agenda Request

Date: March 12, 2019

I respectfully request that **Senate Bill #732**, relating to Office Surgery, be placed on the:

- committee agenda at your earliest possible convenience.
- next committee agenda.

A handwritten signature in cursive script that reads "Anitere Flores".

Senator Anitere Flores
Florida Senate, District 39

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19

Meeting Date

732

Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Nland

Job Title _____

Address 1000 Riverside Ave

Phone 904-233-3051

Street

Jacksonville, FL 32204

Email nlandlaw@aol.com

City

State

Zip

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Florida Society of Plastic Surgeons

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

By the Committee on Health Policy; and Senator Flores

588-02904-19

2019732c1

1 A bill to be entitled
 2 An act relating to clinics and office surgery;
 3 amending s. 400.9905, F.S.; revising the definition of
 4 the term "clinic"; amending s. 400.991, F.S.;
 5 requiring a clinic to provide proof of its financial
 6 responsibility to pay certain claims and costs along
 7 with its application for licensure to the Agency for
 8 Health Care Administration; amending s. 400.9935,
 9 F.S.; requiring a medical director or a clinic
 10 director to ensure that the clinic complies with
 11 specified rules; amending s. 400.995, F.S.; requiring
 12 the agency to impose a specified administrative fine
 13 on an unregistered clinic that performs certain office
 14 surgeries; amending s. 456.004, F.S.; requiring the
 15 Department of Health to deny or revoke the
 16 registration of or impose certain penalties against a
 17 facility where certain office surgeries are performed
 18 under certain circumstances; specifying provisions
 19 that apply enforcement actions against such
 20 facilities; authorizing the department to deny certain
 21 persons associated with an office of which the
 22 registration was revoked from registering a new office
 23 to perform certain office surgery; amending s.
 24 456.074, F.S.; authorizing the department to issue an
 25 emergency order suspending or restricting the
 26 registration of a certain office if it makes certain
 27 findings; amending s. 458.305, F.S.; defining terms;
 28 amending s. 458.309, F.S.; requiring a physician who
 29 performs certain office surgery and the office in

Page 1 of 24

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

588-02904-19

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30 which the surgery is performed to maintain specified
 31 levels of financial responsibility; authorizing the
 32 department to adopt rules to administer the
 33 registration, inspection, and safety of offices that
 34 perform certain office surgery; requiring the Board of
 35 Medicine to adopt rules governing the standard of care
 36 for physicians practicing in such offices; requiring
 37 the board to impose a specified fine on physicians who
 38 perform certain office surgeries in an unregistered
 39 office; amending s. 458.331, F.S.; providing that a
 40 physician performing certain office surgeries in an
 41 unregistered office constitutes grounds for denial of
 42 a license or disciplinary action; amending s. 459.003,
 43 F.S.; defining terms; amending s. 459.005, F.S.;
 44 requiring a physician who performs certain office
 45 surgery and the office in which the surgery is
 46 performed to maintain specified levels of financial
 47 responsibility; authorizing the department to adopt
 48 rules to administer the registration, inspection, and
 49 safety of offices that perform certain office surgery;
 50 requiring the Board of Osteopathic Medicine to adopt
 51 rules governing the standard of care for physicians
 52 practicing in such offices; requiring the board to
 53 impose a specified fine on physicians who perform
 54 certain office surgeries in an unregistered office;
 55 amending s. 459.015, F.S.; providing that a physician
 56 performing certain office surgeries in an unregistered
 57 office constitutes grounds for denial of a license or
 58 disciplinary action; amending s. 464.012, F.S.;

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59 authorizing a certified registered nurse anesthetist
 60 to provide specified services in a an office
 61 registered to perform office surgery within the
 62 framework of an established protocol with a licensed
 63 anesthesiologist; amending s. 766.101, F.S.;

64 conforming a cross-reference; providing an effective
 65 date.

66
 67 Be It Enacted by the Legislature of the State of Florida:

68
 69 Section 1. Subsection (4) of section 400.9905, Florida
 70 Statutes, is amended to read:

71 400.9905 Definitions.—

72 (4) "Clinic" means an entity that provides where health
 73 care services ~~are provided~~ to individuals and that receives
 74 compensation and which tenders charges for reimbursement for
 75 those such services, including a mobile clinic and a portable
 76 equipment provider. As used in this part, the term does not
 77 include and the licensure requirements of this part do not apply
 78 to:

79 (a) Entities licensed or registered by the state under
 80 chapter 395; entities licensed or registered by the state and
 81 providing only health care services within the scope of services
 82 authorized under their respective licenses under ss. 383.30-
 83 383.332, chapter 390, chapter 394, chapter 397, this chapter
 84 except part X, chapter 429, chapter 463, chapter 465, chapter
 85 466, chapter 478, chapter 484, or chapter 651; end-stage renal
 86 disease providers authorized under 42 C.F.R. part 405, subpart
 87 U; providers certified under 42 C.F.R. part 485, subpart B or

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88 subpart H; or any entity that provides neonatal or pediatric
 89 hospital-based health care services or other health care
 90 services by licensed practitioners solely within a hospital
 91 licensed under chapter 395.

92 (b) Entities that own, directly or indirectly, entities
 93 licensed or registered by the state pursuant to chapter 395;
 94 entities that own, directly or indirectly, entities licensed or
 95 registered by the state and providing only health care services
 96 within the scope of services authorized pursuant to their
 97 respective licenses under ss. 383.30-383.332, chapter 390,
 98 chapter 394, chapter 397, this chapter except part X, chapter
 99 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter
 100 484, or chapter 651; end-stage renal disease providers
 101 authorized under 42 C.F.R. part 405, subpart U; providers
 102 certified under 42 C.F.R. part 485, subpart B or subpart H; or
 103 any entity that provides neonatal or pediatric hospital-based
 104 health care services by licensed practitioners solely within a
 105 hospital licensed under chapter 395.

106 (c) Entities that are owned, directly or indirectly, by an
 107 entity licensed or registered by the state pursuant to chapter
 108 395; entities that are owned, directly or indirectly, by an
 109 entity licensed or registered by the state and providing only
 110 health care services within the scope of services authorized
 111 pursuant to their respective licenses under ss. 383.30-383.332,
 112 chapter 390, chapter 394, chapter 397, this chapter except part
 113 X, chapter 429, chapter 463, chapter 465, chapter 466, chapter
 114 478, chapter 484, or chapter 651; end-stage renal disease
 115 providers authorized under 42 C.F.R. part 405, subpart U;
 116 providers certified under 42 C.F.R. part 485, subpart B or

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117 subpart H; or any entity that provides neonatal or pediatric
 118 hospital-based health care services by licensed practitioners
 119 solely within a hospital under chapter 395.

120 (d) Entities that are under common ownership, directly or
 121 indirectly, with an entity licensed or registered by the state
 122 pursuant to chapter 395; entities that are under common
 123 ownership, directly or indirectly, with an entity licensed or
 124 registered by the state and providing only health care services
 125 within the scope of services authorized pursuant to their
 126 respective licenses under ss. 383.30-383.332, chapter 390,
 127 chapter 394, chapter 397, this chapter except part X, chapter
 128 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter
 129 484, or chapter 651; end-stage renal disease providers
 130 authorized under 42 C.F.R. part 405, subpart U; providers
 131 certified under 42 C.F.R. part 485, subpart B or subpart H; or
 132 any entity that provides neonatal or pediatric hospital-based
 133 health care services by licensed practitioners solely within a
 134 hospital licensed under chapter 395.

135 (e) An entity that is exempt from federal taxation under 26
 136 U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan
 137 under 26 U.S.C. s. 409 that has a board of trustees at least
 138 two-thirds of which are Florida-licensed health care
 139 practitioners and provides only physical therapy services under
 140 physician orders, any community college or university clinic,
 141 and any entity owned or operated by the federal or state
 142 government, including agencies, subdivisions, or municipalities
 143 thereof.

144 (f) A sole proprietorship, group practice, partnership, or
 145 corporation that provides health care services by physicians

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146 covered by s. 627.419, that is directly supervised by one or
 147 more of such physicians, and that is wholly owned by one or more
 148 of those physicians or by a physician and the spouse, parent,
 149 child, or sibling of that physician.

150 (g) A sole proprietorship, group practice, partnership, or
 151 corporation that provides health care services by licensed
 152 health care practitioners under chapter 457, chapter 458,
 153 chapter 459, chapter 460, chapter 461, chapter 462, chapter 463,
 154 chapter 466, chapter 467, chapter 480, chapter 484, chapter 486,
 155 chapter 490, chapter 491, or part I, part III, part X, part
 156 XIII, or part XIV of chapter 468, or s. 464.012, and that is
 157 wholly owned by one or more licensed health care practitioners,
 158 or the licensed health care practitioners set forth in this
 159 paragraph and the spouse, parent, child, or sibling of a
 160 licensed health care practitioner if one of the owners who is a
 161 licensed health care practitioner is supervising the business
 162 activities and is legally responsible for the entity's
 163 compliance with all federal and state laws. However, a health
 164 care practitioner may not supervise services beyond the scope of
 165 the practitioner's license, except that, for the purposes of
 166 this part, a clinic owned by a licensee in s. 456.053(3)(b)
 167 which provides only services authorized pursuant to s.
 168 456.053(3)(b) may be supervised by a licensee specified in s.
 169 456.053(3)(b).

170 (h) Clinical facilities affiliated with an accredited
 171 medical school at which training is provided for medical
 172 students, residents, or fellows.

173 (i) Entities that provide only oncology or radiation
 174 therapy services by physicians licensed under chapter 458 or

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175 chapter 459 or entities that provide oncology or radiation
 176 therapy services by physicians licensed under chapter 458 or
 177 chapter 459 which are owned by a corporation whose shares are
 178 publicly traded on a recognized stock exchange.

179 (j) Clinical facilities affiliated with a college of
 180 chiropractic accredited by the Council on Chiropractic Education
 181 at which training is provided for chiropractic students.

182 (k) Entities that provide licensed practitioners to staff
 183 emergency departments or to deliver anesthesia services in
 184 facilities licensed under chapter 395 and that derive at least
 185 90 percent of their gross annual revenues from the provision of
 186 such services. Entities claiming an exemption from licensure
 187 under this paragraph must provide documentation demonstrating
 188 compliance.

189 (l) Orthotic, prosthetic, pediatric cardiology, or
 190 perinatology clinical facilities or anesthesia clinical
 191 facilities that are not otherwise exempt under paragraph (a) or
 192 paragraph (k) and that are a publicly traded corporation or are
 193 wholly owned, directly or indirectly, by a publicly traded
 194 corporation. As used in this paragraph, a publicly traded
 195 corporation is a corporation that issues securities traded on an
 196 exchange registered with the United States Securities and
 197 Exchange Commission as a national securities exchange.

198 (m) Entities that are owned by a corporation that has \$250
 199 million or more in total annual sales of health care services
 200 provided by licensed health care practitioners where one or more
 201 of the persons responsible for the operations of the entity is a
 202 health care practitioner who is licensed in this state and who
 203 is responsible for supervising the business activities of the

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204 entity and is responsible for the entity's compliance with state
 205 law for purposes of this part.

206 (n) Entities that employ 50 or more licensed health care
 207 practitioners licensed under chapter 458 or chapter 459 where
 208 the billing for medical services is under a single tax
 209 identification number. The application for exemption under this
 210 subsection shall contain information that includes: the name,
 211 residence, and business address and phone number of the entity
 212 that owns the practice; a complete list of the names and contact
 213 information of all the officers and directors of the
 214 corporation; the name, residence address, business address, and
 215 medical license number of each licensed Florida health care
 216 practitioner employed by the entity; the corporate tax
 217 identification number of the entity seeking an exemption; a
 218 listing of health care services to be provided by the entity at
 219 the health care clinics owned or operated by the entity and a
 220 certified statement prepared by an independent certified public
 221 accountant which states that the entity and the health care
 222 clinics owned or operated by the entity have not received
 223 payment for health care services under personal injury
 224 protection insurance coverage for the preceding year. If the
 225 agency determines that an entity which is exempt under this
 226 subsection has received payments for medical services under
 227 personal injury protection insurance coverage, the agency may
 228 deny or revoke the exemption from licensure under this
 229 subsection.

230
 231 Notwithstanding this subsection, an entity shall be deemed a
 232 clinic and must be licensed under this part in order to receive

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233 reimbursement under the Florida Motor Vehicle No-Fault Law, ss.
 234 627.730-627.7405, unless exempted under s. 627.736(5)(h).
 235 Section 2. Subsection (4) of section 400.991, Florida
 236 Statutes, is amended to read:
 237 400.991 License requirements; background screenings;
 238 prohibitions.—
 239 (4) In addition to the requirements of part II of chapter
 240 408, the applicant must file with the application satisfactory
 241 proof that the clinic is in compliance with this part and
 242 applicable rules, including:
 243 (a) A listing of services to be provided either directly by
 244 the applicant or through contractual arrangements with existing
 245 providers;
 246 (b) The number and discipline of each professional staff
 247 member to be employed; ~~and~~
 248 (c) Proof of financial ability to operate as required under
 249 s. 408.810(8). As an alternative to submitting proof of
 250 financial ability to operate as required under s. 408.810(8),
 251 the applicant may file a surety bond of at least \$500,000 which
 252 guarantees that the clinic will act in full conformity with all
 253 legal requirements for operating a clinic, payable to the
 254 agency. The agency may adopt rules to specify related
 255 requirements for such surety bond; and
 256 (d) Proof that the clinic maintains the financial
 257 responsibility in the manner set forth in s. 458.320(2) or s.
 258 459.0085(2), as applicable, to pay claims and costs ancillary
 259 thereto arising out of the rendering of or the failure to render
 260 medical care and services, for physicians and osteopathic
 261 physicians who perform liposuction procedures in which more than

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262 1,000 cubic centimeters of supernatant fat is removed, Level II
 263 office surgery, or Level III office surgery as those terms are
 264 defined in ss. 458.305(8) and 459.003(9), in an office setting.
 265 Section 3. Paragraph (j) is added to subsection (1) of
 266 section 400.9935, Florida Statutes, to read:
 267 400.9935 Clinic responsibilities.—
 268 (1) Each clinic shall appoint a medical director or clinic
 269 director who shall agree in writing to accept legal
 270 responsibility for the following activities on behalf of the
 271 clinic. The medical director or the clinic director shall:
 272 (j) If the clinic is registered with the department to
 273 perform office surgery, ensure that the clinic complies with the
 274 standards of practice for office surgery adopted by rule under
 275 ss. 458.309(4) and 459.005(3).
 276 Section 4. Subsection (4) of section 400.995, Florida
 277 Statutes, is amended to read:
 278 400.995 Agency administrative penalties.—
 279 (4) Any licensed clinic whose owner, medical director, or
 280 clinic director concurrently operates an unlicensed clinic or a
 281 clinic that is not registered with the department where any
 282 liposuction procedure in which more than 1,000 cubic centimeters
 283 of supernatant fat is removed or where any Level II office
 284 surgery or Level III office surgery, as those terms are defined
 285 in ss. 458.305(8) and 459.003(9), is performed, is ~~shall be~~
 286 subject to an administrative fine of \$5,000 per day.
 287 Section 5. Subsection (12) is added to section 456.004,
 288 Florida Statutes, to read:
 289 456.004 Department; powers and duties.—The department, for
 290 the professions under its jurisdiction, shall:

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291 (12) Deny or revoke the registration of, or impose any
 292 penalty set forth in s. 456.072(2) against, any facility where
 293 office surgery, as defined in ss. 458.305(8) and 459.003(9), is
 294 performed for failure of any of its physicians, owners, or
 295 operators to comply with rules adopted under ss. 458.309(3) and
 296 459.005(2). Section 456.073 applies to enforcement actions
 297 brought against such facilities. If a facility's registration is
 298 revoked, the department may deny any person named in the
 299 registration documents of the facility, including the persons
 300 who own or operate the facility, individually or as part of a
 301 group, from registering a facility to perform surgical
 302 procedures pursuant to s. 458.309(3) or s. 459.005(2) for 5
 303 years after the revocation date.

304 Section 6. Subsection (6) is added to section 456.074,
 305 Florida Statutes, to read:

306 456.074 Certain health care practitioners; immediate
 307 suspension of license.—

308 (6) The department may issue an emergency order suspending
 309 or restricting the registration of a facility in which
 310 liposuction procedures in which more than 1,000 cubic
 311 centimeters of supernatant fat is removed, Level II office
 312 surgery, or Level III office surgery as those terms are defined
 313 in ss. 458.305(8) and 459.003(9), are performed upon a finding
 314 of probable cause that the facility or its surgeons are not in
 315 compliance with the standards of practice for office surgery
 316 adopted by the boards pursuant to s. 458.309(4) or s.
 317 459.005(3), as applicable, or are in violation of s.
 318 458.331(1)(v) or s. 459.015(1)(z) and that such noncompliance
 319 constitutes an immediate danger to the public.

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320 Section 7. Section 458.305, Florida Statutes, is amended to
 321 read:

322 458.305 Definitions.—As used in this chapter, the term:

323 (1) "Board" means the Board of Medicine.

324 (2) "Deep sedation and analgesia" means a drug-induced
 325 depression of consciousness during which all of the following
 326 apply:

327 (a) The patient cannot be easily aroused but responds by
 328 purposefully following repeated or painful stimulation.

329 (b) The patient's ability to independently maintain
 330 ventilatory function may be impaired.

331 (c) The patient may require assistance in maintaining a
 332 patent airway, and spontaneous ventilation may be inadequate.

333 (d) The patient's cardiovascular function is usually
 334 maintained.

335 (e) The patient's reflex withdrawal from painful stimulus
 336 is not considered a purposeful response.

337 (3)(2) "Department" means the Department of Health.

338 (4) "Epidural anesthesia" means anesthesia produced by the
 339 injection of an anesthetic agent into the space on or around the
 340 dura mater of the spinal cord.

341 (5) "General anesthesia" means a drug-induced loss of
 342 consciousness administered by a qualified general anesthesia
 343 provider during which all of the following apply:

344 (a) The patient is not able to be aroused, even by painful
 345 stimulation.

346 (b) The patient's ability to independently maintain
 347 ventilatory function is often impaired.

348 (c) The patient has a level of depressed neuromuscular

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349 function.

350 (d) The patient may require assistance in maintaining a
 351 patent airway, and positive pressure ventilation may be
 352 required.

353 (e) The patient's cardiovascular function may be impaired.

354 (6) "Minimal sedation" means a drug-induced state during
 355 which patients respond normally to verbal commands. Although
 356 cognitive function and physical coordination may be impaired,
 357 airway reflexes and respiratory and cardiovascular functions are
 358 unaffected.

359 (7) "Moderate sedation and analgesia" or "conscious
 360 sedation" means drug-induced depression of consciousness and a
 361 state of consciousness during which all of the following apply:

362 (a) The patient responds purposefully to verbal commands,
 363 either alone or accompanied by light tactile stimulation.

364 (b) Interventions are not required to maintain a patent
 365 airway, and spontaneous ventilation is adequate.

366 (c) Cardiovascular function is maintained.

367 (d) Reflex withdrawal from a painful stimulus is not
 368 considered a purposeful response.

369 (8) "Office surgery" means a surgery that is performed in a
 370 physician's office or any facility that is not licensed under
 371 chapter 390 or chapter 395.

372 (a) "Level I office surgery" includes any surgery that
 373 consists of only minor procedures and in which anesthesia is
 374 limited to minimal sedation.

375 (b) "Level II office surgery" includes any surgery in which
 376 the patient's level of sedation is that of moderate sedation and
 377 analgesia or conscious sedation.

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378 (c) "Level III office surgery" includes any surgery in
 379 which the patient's level of sedation is that of deep sedation
 380 and analgesia or general anesthesia. The term includes any
 381 surgery that includes the use of spinal anesthesia or epidural
 382 anesthesia.

383 (10)-(3) "Practice of medicine" means the diagnosis,
 384 treatment, operation, or prescription for any human disease,
 385 pain, injury, deformity, or other physical or mental condition.

386 (11) "Spinal anesthesia" means anesthesia produced by the
 387 injection of an anesthetic agent into the subarachnoid space of
 388 the spinal cord.

389 (12) "Surgeon" means a physician who performs surgery.

390 (13) "Surgery" means any manual or operative procedure,
 391 including the use of lasers, performed upon the body of a living
 392 human being for the purposes of preserving health, diagnosing or
 393 curing disease, repairing injury, correcting deformity or
 394 defects, prolonging life, or relieving suffering or any elective
 395 procedure for aesthetic, reconstructive, or cosmetic purposes,
 396 including, but not limited to: incision or curettage of tissue
 397 or an organ; suture or other repair of tissue or organ,
 398 including a closed as well as an open reduction of a fracture;
 399 extraction of tissue including premature extraction of the
 400 products of conception from the uterus; insertion of natural or
 401 artificial implants; or an endoscopic procedure with use of
 402 local or general anesthetic.

403 (9)-(4) "Physician" means a person who is licensed to
 404 practice medicine in this state.

405 Section 8. Subsection (3) of section 458.309, Florida
 406 Statutes, is amended and subsection (4) is added to that

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407 section, to read:

408 458.309 Rulemaking authority.—

409 (3) A physician who performs any liposuction procedure
 410 ~~procedures~~ in which more than 1,000 cubic centimeters of
 411 supernatant fat is removed, any Level II office surgery level 2
 412 ~~procedures lasting more than 5 minutes, or any Level III office~~
 413 ~~surgery and all level 3 surgical procedures~~ in an office setting
 414 must register the office with the department unless that office
 415 is licensed as a facility under chapter 395. The department
 416 shall inspect the physician's office annually unless the office
 417 is accredited by a nationally recognized accrediting agency or
 418 an accrediting organization ~~subsequently~~ approved by the Board
 419 of Medicine. The actual costs for registration and inspection or
 420 accreditation shall be paid by the person seeking to register
 421 and operate the office setting in which office surgery is
 422 performed. As a condition of registration, a physician who
 423 performs such surgical procedures in an office setting, and the
 424 office itself if it is a separate legal entity from the
 425 physician, must maintain the same levels of financial
 426 responsibility required in s. 458.320.

427 (4) The department may adopt rules to administer the
 428 registration, inspection, and safety of offices in which a
 429 physician performs office surgery. The board shall adopt by rule
 430 standards of practice for physicians who perform office surgery.
 431 The board shall impose a fine of \$5,000 per day on a physician
 432 who performs a surgical procedure identified in subsection (3)
 433 in an office that is not registered with the department.

434 Section 9. Paragraph (vv) is added to subsection (1) of
 435 section 458.331, Florida Statutes, to read:

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436 458.331 Grounds for disciplinary action; action by the
 437 board and department.—

438 (1) The following acts constitute grounds for denial of a
 439 license or disciplinary action, as specified in s. 456.072(2):
 440 (vv) Performing a liposuction procedure in which more than
 441 1,000 cubic centimeters of supernatant fat is removed, a Level
 442 II office surgery, or a Level III office surgery in an office
 443 that is not registered with the department pursuant to s.
 444 458.309(3).

445 Section 10. Section 459.003, Florida Statutes, is amended
 446 to read:

447 459.003 Definitions.—As used in this chapter, the term:

448 (1) "Board" means the Board of Osteopathic Medicine.

449 (2) "Deep sedation and analgesia" means a drug-induced
 450 depression of consciousness during which all of the following
 451 apply:

452 (a) The patient cannot be easily aroused but responds by
 453 purposefully following repeated or painful stimulation.

454 (b) The patient's ability to independently maintain
 455 ventilatory function may be impaired.

456 (c) The patient may require assistance in maintaining a
 457 patent airway, and spontaneous ventilation may be inadequate.

458 (d) The patient's cardiovascular function is usually
 459 maintained.

460 (e) The patient's reflex withdrawal from painful stimulus
 461 is not considered a purposeful response.

462 (3)-(2) "Department" means the Department of Health.

463 (5) "Epidural anesthesia" means anesthesia produced by the
 464 injection of an anesthetic agent into the space on or around the

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465 dura mater of the spinal cord.

466 (6) "General anesthesia" means a drug-induced loss of
 467 consciousness administered by a qualified general anesthesia
 468 provider during which all of the following apply:

469 (a) The patient is not able to be aroused, even by painful
 470 stimulation.

471 (b) The patient's ability to independently maintain
 472 ventilatory function is often impaired.

473 (c) The patient has a level of depressed neuromuscular
 474 function.

475 (d) The patient may require assistance in maintaining a
 476 patent airway, and positive pressure ventilation may be
 477 required.

478 (e) The patient's cardiovascular function may be impaired.

479 (7) "Minimal sedation" means a drug-induced state during
 480 which patients respond normally to verbal commands. Although
 481 cognitive function and physical coordination may be impaired,
 482 airway reflexes, and respiratory and cardiovascular functions
 483 are unaffected.

484 (8) "Moderate sedation and analgesia" or "conscious
 485 sedation" means drug-induced depression of consciousness and a
 486 state of consciousness during which all of the following apply:

487 (a) The patient responds purposefully to verbal commands,
 488 either alone or accompanied by light tactile stimulation.

489 (b) Interventions are not required to maintain a patent
 490 airway, and spontaneous ventilation is adequate.

491 (c) Cardiovascular function is maintained.

492 (d) Reflex withdrawal from a painful stimulus is not
 493 considered a purposeful response.

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494 (9) "Office surgery" means a surgery that is performed in a
 495 physician's office or any facility that is not licensed under
 496 chapter 390 or chapter 395.

497 (a) "Level I office surgery" includes any surgery that
 498 consists of only minor procedures and in which anesthesia is
 499 limited to minimal sedation.

500 (b) "Level II office surgery" includes any surgery in which
 501 the patient's level of sedation is that of moderate sedation and
 502 analgesia or conscious sedation.

503 (c) "Level III office surgery" includes any surgery in
 504 which the patient's level of sedation is that of deep sedation
 505 and analgesia or general anesthesia. The term includes any
 506 surgery that includes the use of spinal anesthesia or epidural
 507 anesthesia.

508 (11)~~(3)~~ "Practice of osteopathic medicine" means the
 509 diagnosis, treatment, operation, or prescription for any human
 510 disease, pain, injury, deformity, or other physical or mental
 511 condition, which practice is based in part upon educational
 512 standards and requirements which emphasize the importance of the
 513 musculoskeletal structure and manipulative therapy in the
 514 maintenance and restoration of health.

515 (12) "Spinal anesthesia" means anesthesia produced by the
 516 injection of an anesthetic agent into the subarachnoid space of
 517 the spinal cord.

518 (13) "Surgeon" means a physician who performs surgery.

519 (14) "Surgery" means any manual or operative procedure,
 520 including the use of lasers, performed upon the body of a living
 521 human being for the purposes of preserving health, diagnosing or
 522 curing disease, repairing injury, correcting deformity or

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523 defects, prolonging life, or relieving suffering or any elective
 524 procedure for aesthetic, reconstructive, or cosmetic purposes,
 525 including, but not limited to: incision or curettage of tissue
 526 or an organ; suture or other repair of tissue or organ,
 527 including a closed as well as an open reduction of a fracture;
 528 extraction of tissue including premature extraction of the
 529 products of conception from the uterus; insertion of natural or
 530 artificial implants; or an endoscopic procedure with use of
 531 local or general anesthetic.

532 (10)(4) "Osteopathic physician" means a person who is
 533 licensed to practice osteopathic medicine in this state.

534 (4)(5) "Doctor of Osteopathy" and "Doctor of Osteopathic
 535 Medicine," when referring to degrees, shall be construed to be
 536 equivalent and equal degrees.

537 Section 11. Subsection (2) of section 459.005, Florida
 538 Statutes, is amended and subsection (3) is added to that
 539 section, to read:

540 459.005 Rulemaking authority.—

541 (2) A physician who performs any liposuction procedure
 542 ~~procedures~~ in which more than 1,000 cubic centimeters of
 543 supernatant fat is removed, any Level II office surgery level 2
 544 ~~procedures lasting more than 5 minutes, or any Level III office~~
 545 surgery and all level 3 surgical procedures in an office setting
 546 must register the office with the department unless that office
 547 is licensed as a facility under chapter 395. The department
 548 shall inspect the physician's office annually unless the office
 549 is accredited by a nationally recognized accrediting agency or
 550 an accrediting organization ~~subsequently~~ approved by the Board
 551 of Osteopathic Medicine. The actual costs for registration and

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552 inspection or accreditation shall be paid by the person seeking
 553 to register and operate the office setting in which office
 554 surgery is performed. As a condition of registration, a
 555 physician who performs such surgical procedures in an office
 556 setting, and the office itself if it is a separate legal entity
 557 from the physician, must maintain the same levels of financial
 558 responsibility required in s. 459.0085.

559 (3) The department may adopt rules to administer the
 560 registration, inspection, and safety of offices in which a
 561 physician performs office surgery. The board shall adopt by rule
 562 standards of practice for physicians who perform office surgery.
 563 The board shall impose a fine of \$5,000 per day on a physician
 564 who performs a surgical procedure identified in subsection (2)
 565 in an office that is not registered with the department.

566 Section 12. Paragraph (xx) is added to subsection (1) of
 567 section 459.015, Florida Statutes, to read:

568 459.015 Grounds for disciplinary action; action by the
 569 board and department.—

570 (1) The following acts constitute grounds for denial of a
 571 license or disciplinary action, as specified in s. 456.072(2):

572 (xx) Performing a liposuction procedure in which more than
 573 1,000 cubic centimeters of supernatant fat is removed, a Level
 574 II office surgery, or a Level III office surgery in an office
 575 that is not registered with the department pursuant to s.
 576 459.005(2).

577 Section 13. Paragraph (b) of subsection (4) of section
 578 464.012, Florida Statutes, is amended to read:

579 464.012 Licensure of advanced practice registered nurses;
 580 fees; controlled substance prescribing.—

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581 (4) In addition to the general functions specified in
582 subsection (3), an advanced practice registered nurse may
583 perform the following acts within his or her specialty:

584 (b) The certified registered nurse anesthetist may, to the
585 extent authorized by established protocol approved by the
586 medical staff of the facility in which the anesthetic service is
587 performed, perform any or all of the following:

588 1. Determine the health status of the patient as it relates
589 to the risk factors and to the anesthetic management of the
590 patient through the performance of the general functions.

591 2. Based on history, physical assessment, and supplemental
592 laboratory results, determine, with the consent of the
593 responsible physician, the appropriate type of anesthesia within
594 the framework of the protocol.

595 3. Order under the protocol preanesthetic medication.

596 4. Perform under the protocol procedures commonly used to
597 render the patient insensible to pain during the performance of
598 surgical, obstetrical, therapeutic, or diagnostic clinical
599 procedures. These procedures include ordering and administering
600 regional, spinal, and general anesthesia; inhalation agents and
601 techniques; intravenous agents and techniques; and techniques of
602 hypnosis.

603 5. Order or perform monitoring procedures indicated as
604 pertinent to the anesthetic health care management of the
605 patient.

606 6. Support life functions during anesthesia health care,
607 including induction and intubation procedures, the use of
608 appropriate mechanical supportive devices, and the management of
609 fluid, electrolyte, and blood component balances.

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610 7. Recognize and take appropriate corrective action for
611 abnormal patient responses to anesthesia, adjunctive medication,
612 or other forms of therapy.

613 8. Recognize and treat a cardiac arrhythmia while the
614 patient is under anesthetic care.

615 9. Participate in management of the patient while in the
616 postanesthesia recovery area, including ordering the
617 administration of fluids and drugs.

618 10. Place special peripheral and central venous and
619 arterial lines for blood sampling and monitoring as appropriate.

620 11. Provide the services identified in subsections 1.-10.
621 in an office registered to perform office surgery pursuant to s.
622 458.309(3) or s. 459.005(2) within the framework of an
623 established protocol with an anesthesiologist licensed under
624 chapter 458 or chapter 459.

625 Section 14. Paragraph (a) of subsection (1) of section
626 766.101, Florida Statutes, is amended to read:

627 766.101 Medical review committee, immunity from liability.-

628 (1) As used in this section:

629 (a) The term "medical review committee" or "committee"
630 means:

631 1.a. A committee of a hospital or ambulatory surgical
632 center licensed under chapter 395 or a health maintenance
633 organization certificated under part I of chapter 641;

634 b. A committee of a physician-hospital organization, a
635 provider-sponsored organization, or an integrated delivery
636 system;

637 c. A committee of a state or local professional society of
638 health care providers;

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639 d. A committee of a medical staff of a licensed hospital or
 640 nursing home, provided the medical staff operates pursuant to
 641 written bylaws that have been approved by the governing board of
 642 the hospital or nursing home;

643 e. A committee of the Department of Corrections or the
 644 Correctional Medical Authority as created under s. 945.602, or
 645 employees, agents, or consultants of either the department or
 646 the authority or both;

647 f. A committee of a professional service corporation formed
 648 under chapter 621 or a corporation organized under part I of
 649 chapter 607 or chapter 617, which is formed and operated for the
 650 practice of medicine as defined in s. 458.305 ~~s. 458.305(3)~~, and
 651 which has at least 25 health care providers who routinely
 652 provide health care services directly to patients;

653 g. A committee of the Department of Children and Families
 654 which includes employees, agents, or consultants to the
 655 department as deemed necessary to provide peer review,
 656 utilization review, and mortality review of treatment services
 657 provided pursuant to chapters 394, 397, and 916;

658 h. A committee of a mental health treatment facility
 659 licensed under chapter 394 or a community mental health center
 660 as defined in s. 394.907, provided the quality assurance program
 661 operates pursuant to the guidelines that have been approved by
 662 the governing board of the agency;

663 i. A committee of a substance abuse treatment and education
 664 prevention program licensed under chapter 397 provided the
 665 quality assurance program operates pursuant to the guidelines
 666 that have been approved by the governing board of the agency;

667 j. A peer review or utilization review committee organized

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CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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668 under chapter 440;

669 k. A committee of the Department of Health, a county health
 670 department, healthy start coalition, or certified rural health
 671 network, when reviewing quality of care, or employees of these
 672 entities when reviewing mortality records; or

673 l. A continuous quality improvement committee of a pharmacy
 674 licensed pursuant to chapter 465,

675

676 which committee is formed to evaluate and improve the quality of
 677 health care rendered by providers of health service, to
 678 determine that health services rendered were professionally
 679 indicated or were performed in compliance with the applicable
 680 standard of care, or that the cost of health care rendered was
 681 considered reasonable by the providers of professional health
 682 services in the area; or

683 2. A committee of an insurer, self-insurer, or joint
 684 underwriting association of medical malpractice insurance, or
 685 other persons conducting review under s. 766.106.

686 Section 15. This act shall take effect upon becoming a law.

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CODING: Words ~~stricken~~ are deletions; words underlined are additions.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RS	.	
04/10/2019	.	
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Appropriations Subcommittee on Health and Human Services
(Flores) recommended the following:

Senate Amendment (with title amendment)

Delete lines 414 - 624

and insert:

must register the office with the department ~~unless that office~~
~~is licensed as a facility under chapter 395~~. The department
shall inspect the physician's office annually unless the office
is accredited by a nationally recognized accrediting agency or
an accrediting organization ~~subsequently~~ approved by the Board
of Medicine. The actual costs for registration and inspection or



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11 accreditation shall be paid by the person seeking to register
12 and operate the office setting in which office surgery is
13 performed. As a condition of registration, a physician who
14 performs such surgical procedures in an office setting, and the
15 office itself if it is a separate legal entity from the
16 physician, must maintain the same levels of financial
17 responsibility required in s. 458.320.

18 (4) (a) The board may adopt rules to administer the
19 registration, inspection, and safety of offices in which a
20 physician performs office surgery.

21 (b) As a part of registration, such an office must
22 designate a physician who is responsible for the office's
23 compliance with this section and the rules adopted hereunder.
24 Within 10 days after termination of the designated physician,
25 the office must notify the department of the identity of another
26 designated physician for that office. The designated physician
27 must have a full, active, and unencumbered license under this
28 chapter or chapter 459 and shall practice at the office for
29 which he or she has assumed responsibility. The department may
30 suspend a registration certificate for an office without a
31 designated physician who practices at the office.

32 (c) The department shall inspect the office at least
33 annually, including a review of patient records, to ensure that
34 it complies with this section and rules adopted hereunder unless
35 the office is accredited by a nationally recognized accrediting
36 agency approved by the board. The inspection must be
37 unannounced.

38 (d) The board shall adopt by rule standards of practice for
39 physicians who perform office surgery. The board shall impose a



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40 fine of \$5,000 per day on a physician who performs a surgical
41 procedure identified in subsection (3) in an office that is not
42 registered with the department.

43 Section 9. Paragraph (vv) is added to subsection (1) of
44 section 458.331, Florida Statutes, to read:

45 458.331 Grounds for disciplinary action; action by the
46 board and department.-

47 (1) The following acts constitute grounds for denial of a
48 license or disciplinary action, as specified in s. 456.072(2):

49 (vv) Performing a liposuction procedure in which more than
50 1,000 cubic centimeters of supernatant fat is removed, a Level
51 II office surgery, or a Level III office surgery in an office
52 that is not registered with the department pursuant to s.
53 458.309(3).

54 Section 10. Section 459.003, Florida Statutes, is amended
55 to read:

56 459.003 Definitions.-As used in this chapter, the term:

57 (1) "Board" means the Board of Osteopathic Medicine.

58 (2) "Deep sedation and analgesia" means a drug-induced
59 depression of consciousness during which all of the following
60 apply:

61 (a) The patient cannot be easily aroused but responds by
62 purposefully following repeated or painful stimulation.

63 (b) The patient's ability to independently maintain
64 ventilatory function may be impaired.

65 (c) The patient may require assistance in maintaining a
66 patent airway, and spontaneous ventilation may be inadequate.

67 (d) The patient's cardiovascular function is usually
68 maintained.



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69 (e) The patient's reflex withdrawal from painful stimulus
70 is not considered a purposeful response.

71 (3)~~(2)~~ "Department" means the Department of Health.

72 (5) "Epidural anesthesia" means anesthesia produced by the
73 injection of an anesthetic agent into the space on or around the
74 dura mater of the spinal cord.

75 (6) "General anesthesia" means a drug-induced loss of
76 consciousness administered by a qualified general anesthesia
77 provider during which all of the following apply:

78 (a) The patient is not able to be aroused, even by painful
79 stimulation.

80 (b) The patient's ability to independently maintain
81 ventilatory function is often impaired.

82 (c) The patient has a level of depressed neuromuscular
83 function.

84 (d) The patient may require assistance in maintaining a
85 patent airway, and positive pressure ventilation may be
86 required.

87 (e) The patient's cardiovascular function may be impaired.

88 (7) "Minimal sedation" means a drug-induced state during
89 which patients respond normally to verbal commands. Although
90 cognitive function and physical coordination may be impaired,
91 airway reflexes, and respiratory and cardiovascular functions
92 are unaffected.

93 (8) "Moderate sedation and analgesia" or "conscious
94 sedation" means drug-induced depression of consciousness and a
95 state of consciousness during which all of the following apply:

96 (a) The patient responds purposefully to verbal commands,
97 either alone or accompanied by light tactile stimulation.



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98 (b) Interventions are not required to maintain a patent
99 airway, and spontaneous ventilation is adequate.

100 (c) Cardiovascular function is maintained.

101 (d) Reflex withdrawal from a painful stimulus is not
102 considered a purposeful response.

103 (9) "Office surgery" means a surgery that is performed in a
104 physician's office or any facility that is not licensed under
105 chapter 390 or chapter 395.

106 (a) "Level I office surgery" includes any surgery that
107 consists of only minor procedures and in which anesthesia is
108 limited to minimal sedation.

109 (b) "Level II office surgery" includes any surgery in which
110 the patient's level of sedation is that of moderate sedation and
111 analgesia or conscious sedation.

112 (c) "Level III office surgery" includes any surgery in
113 which the patient's level of sedation is that of deep sedation
114 and analgesia or general anesthesia. The term includes any
115 surgery that includes the use of spinal anesthesia or epidural
116 anesthesia.

117 (11)~~(3)~~ "Practice of osteopathic medicine" means the
118 diagnosis, treatment, operation, or prescription for any human
119 disease, pain, injury, deformity, or other physical or mental
120 condition, which practice is based in part upon educational
121 standards and requirements which emphasize the importance of the
122 musculoskeletal structure and manipulative therapy in the
123 maintenance and restoration of health.

124 (12) "Spinal anesthesia" means anesthesia produced by the
125 injection of an anesthetic agent into the subarachnoid space of
126 the spinal cord.



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127 (13) "Surgeon" means a physician who performs surgery.

128 (14) "Surgery" means any manual or operative procedure,
129 including the use of lasers, performed upon the body of a living
130 human being for the purposes of preserving health, diagnosing or
131 curing disease, repairing injury, correcting deformity or
132 defects, prolonging life, or relieving suffering or any elective
133 procedure for aesthetic, reconstructive, or cosmetic purposes,
134 including, but not limited to: incision or curettage of tissue
135 or an organ; suture or other repair of tissue or organ,
136 including a closed as well as an open reduction of a fracture;
137 extraction of tissue including premature extraction of the
138 products of conception from the uterus; insertion of natural or
139 artificial implants; or an endoscopic procedure with use of
140 local or general anesthetic.

141 (10)(4) "Osteopathic physician" means a person who is
142 licensed to practice osteopathic medicine in this state.

143 (4)(5) "Doctor of Osteopathy" and "Doctor of Osteopathic
144 Medicine," when referring to degrees, shall be construed to be
145 equivalent and equal degrees.

146 Section 11. Subsection (2) of section 459.005, Florida
147 Statutes, is amended and subsection (3) is added to that
148 section, to read:

149 459.005 Rulemaking authority.—

150 (2) A physician who performs any liposuction procedure
151 ~~procedures~~ in which more than 1,000 cubic centimeters of
152 supernatant fat is removed, any Level II office surgery ~~level 2~~
153 ~~procedures lasting more than 5 minutes,~~ or any Level III office
154 surgery and all ~~level 3 surgical procedures~~ in an office setting
155 must register the office with the department ~~unless that office~~



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156 ~~is licensed as a facility under chapter 395.~~ The department
157 shall inspect the physician's office annually unless the office
158 is accredited by a nationally recognized accrediting agency or
159 an accrediting organization ~~subsequently~~ approved by the Board
160 of Osteopathic Medicine. The actual costs for registration and
161 inspection or accreditation shall be paid by the person seeking
162 to register and operate the office setting in which office
163 surgery is performed. As a condition of registration, a
164 physician who performs such surgical procedures in an office
165 setting, and the office itself if it is a separate legal entity
166 from the physician, must maintain the same levels of financial
167 responsibility required in s. 459.0085.

168 (3) (a) The board may adopt rules to administer the
169 registration, inspection, and safety of offices in which a
170 physician performs office surgery.

171 (b) As a part of registration, such an office must
172 designate a physician who is responsible for the office's
173 compliance with this section and the rules adopted hereunder.
174 Within 10 days after termination of the designated physician,
175 the office must notify the department of the identity of another
176 designated physician for that office. The designated physician
177 must have a full, active, and unencumbered license under this
178 chapter or chapter 458 and shall practice at the office for
179 which he or she has assumed responsibility. The department may
180 suspend a registration certificate for an office without a
181 designated physician who practices at the office.

182 (c) The department shall inspect the office at least
183 annually, including a review of patient records, to ensure that
184 it complies with this section and rules adopted hereunder unless



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185 the office is accredited by a nationally recognized accrediting
186 agency approved by the board. The inspection must be
187 unannounced.

188 (d) The board shall adopt by rule standards of practice for
189 physicians who perform office surgery. The board shall impose a
190 fine of \$5,000 per day on a physician who performs a surgical
191 procedure identified in subsection (2) in an office that is not
192 registered with the department.

193 Section 12. Paragraph (xx) is added to subsection (1) of
194 section 459.015, Florida Statutes, to read:

195 459.015 Grounds for disciplinary action; action by the
196 board and department.-

197 (1) The following acts constitute grounds for denial of a
198 license or disciplinary action, as specified in s. 456.072(2):

199 (xx) Performing a liposuction procedure in which more than
200 1,000 cubic centimeters of supernatant fat is removed, a Level
201 II office surgery, or a Level III office surgery in an office
202 that is not registered with the department pursuant to s.
203 459.005(2).

204
205 ===== T I T L E A M E N D M E N T =====

206 And the title is amended as follows:

207 Delete lines 32 - 63

208 and insert:

209 Board of Medicine to adopt rules to administer the
210 registration, inspection, and safety of offices that
211 perform certain office surgery; requiring such an
212 office to designate a certain physician responsible
213 for the office's compliance with specified provisions;



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214 authorizing the department to suspend an office's
215 registration certificate under certain circumstances;
216 requiring the department to conduct certain
217 inspections; providing an exception; requiring the
218 board to adopt rules governing the standard of care
219 for physicians practicing in such offices; requiring
220 the board to impose a specified fine on physicians who
221 perform certain office surgeries in an unregistered
222 office; amending s. 458.331, F.S.; providing that a
223 physician performing certain office surgeries in an
224 unregistered office constitutes grounds for denial of
225 a license or disciplinary action; amending s. 459.003,
226 F.S.; defining terms; amending s. 459.005, F.S.;
227 requiring a physician who performs certain office
228 surgery and the office in which the surgery is
229 performed to maintain specified levels of financial
230 responsibility; authorizing the Board of Osteopathic
231 Medicine to adopt rules to administer the
232 registration, inspection, and safety of offices that
233 perform certain office surgery; requiring such an
234 office to designate a certain physician responsible
235 for the office's compliance with specified provisions;
236 authorizing the department to suspend an office's
237 registration certificate under certain circumstances;
238 requiring the department to conduct certain
239 inspections; providing an exception; requiring the
240 board to adopt rules governing the standard of care
241 for physicians practicing in such offices; requiring
242 the board to impose a specified fine on physicians who



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243 perform certain office surgeries in an unregistered
244 office; amending s. 459.015, F.S.; providing that a
245 physician performing certain office surgeries in an
246 unregistered office constitutes grounds for denial of
247 a license or disciplinary action; amending s. 766.101,
248 F.S.;



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/10/2019	.	
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Appropriations Subcommittee on Health and Human Services
(Flores) recommended the following:

1 **Senate Substitute for Amendment (359744) (with title**
2 **amendment)**

3
4 Delete everything after the enacting clause
5 and insert:

6 Section 1. Subsection (12) is added to section 456.004,
7 Florida Statutes, to read:

8 456.004 Department; powers and duties.—The department, for
9 the professions under its jurisdiction, shall:

10 (12) Deny or revoke the registration of, or impose any



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11 penalty set forth in s. 456.072(2) against, any facility where
12 office surgery, as defined in ss. 458.305(8) and 459.003(9), is
13 performed for failure of any of its physicians, owners, or
14 operators to comply with rules adopted under ss. 458.309(3) and
15 459.005(2). Section 456.073 applies to enforcement actions
16 brought against such facilities. If a facility's registration is
17 revoked, the department may deny any person named in the
18 registration documents of the facility, including the persons
19 who own or operate the facility, individually or as part of a
20 group, from registering a facility to perform surgical
21 procedures pursuant to s. 458.309(3) or s. 459.005(2) for 5
22 years after the revocation date.

23 Section 2. Subsection (6) is added to section 456.074,
24 Florida Statutes, to read:

25 456.074 Certain health care practitioners; immediate
26 suspension of license.—

27 (6) The department may issue an emergency order suspending
28 or restricting the registration of a facility in which
29 liposuction procedures in which more than 1,000 cubic
30 centimeters of supernatant fat is removed, Level II office
31 surgery, or Level III office surgery as those terms are defined
32 in ss. 458.305(8) and 459.003(9), are performed upon a finding
33 of probable cause that the facility or its surgeons are not in
34 compliance with the standards of practice for office surgery
35 adopted by the boards pursuant to s. 458.309(4) or s.
36 459.005(3), as applicable, or are in violation of s.
37 458.331(1)(v) or s. 459.015(1)(z) and that such noncompliance
38 constitutes an immediate danger to the public.

39 Section 3. Section 458.305, Florida Statutes, is amended to



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40 read:

41 458.305 Definitions.—As used in this chapter, the term:

42 (1) "Board" means the Board of Medicine.

43 (2) "Deep sedation and analgesia" means a drug-induced
44 depression of consciousness during which all of the following
45 apply:

46 (a) The patient cannot be easily aroused but responds by
47 purposefully following repeated or painful stimulation.

48 (b) The patient's ability to independently maintain
49 ventilatory function may be impaired.

50 (c) The patient may require assistance in maintaining a
51 patent airway, and spontaneous ventilation may be inadequate.

52 (d) The patient's cardiovascular function is usually
53 maintained.

54 (e) The patient's reflex withdrawal from painful stimulus
55 is not considered a purposeful response.

56 ~~(3)~~ (2) "Department" means the Department of Health.

57 (4) "Epidural anesthesia" means anesthesia produced by the
58 injection of an anesthetic agent into the space on or around the
59 dura mater of the spinal cord.

60 (5) "General anesthesia" means a drug-induced loss of
61 consciousness administered by a qualified general anesthesia
62 provider during which all of the following apply:

63 (a) The patient is not able to be aroused, even by painful
64 stimulation.

65 (b) The patient's ability to independently maintain
66 ventilatory function is often impaired.

67 (c) The patient has a level of depressed neuromuscular
68 function.



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69 (d) The patient may require assistance in maintaining a
70 patent airway, and positive pressure ventilation may be
71 required.

72 (e) The patient's cardiovascular function may be impaired.

73 (6) "Minimal sedation" means a drug-induced state during
74 which patients respond normally to verbal commands. Although
75 cognitive function and physical coordination may be impaired,
76 airway reflexes and respiratory and cardiovascular functions are
77 unaffected.

78 (7) "Moderate sedation and analgesia" or "conscious
79 sedation" means drug-induced depression of consciousness and a
80 state of consciousness during which all of the following apply:

81 (a) The patient responds purposefully to verbal commands,
82 either alone or accompanied by light tactile stimulation.

83 (b) Interventions are not required to maintain a patent
84 airway, and spontaneous ventilation is adequate.

85 (c) Cardiovascular function is maintained.

86 (d) Reflex withdrawal from a painful stimulus is not
87 considered a purposeful response.

88 (8) "Office surgery" means a surgery that is performed in a
89 physician's office or any facility that is not licensed under
90 chapter 390 or chapter 395.

91 (a) "Level I office surgery" includes any surgery that
92 consists of only minor procedures and in which anesthesia is
93 limited to minimal sedation.

94 (b) "Level II office surgery" includes any surgery in which
95 the patient's level of sedation is that of moderate sedation and
96 analgesia or conscious sedation.

97 (c) "Level III office surgery" includes any surgery in



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98 which the patient's level of sedation is that of deep sedation
99 and analgesia or general anesthesia. The term includes any
100 surgery that includes the use of spinal anesthesia or epidural
101 anesthesia.

102 (10)-~~(3)~~ "Practice of medicine" means the diagnosis,
103 treatment, operation, or prescription for any human disease,
104 pain, injury, deformity, or other physical or mental condition.

105 (11) "Spinal anesthesia" means anesthesia produced by the
106 injection of an anesthetic agent into the subarachnoid space of
107 the spinal cord.

108 (12) "Surgeon" means a physician who performs surgery.

109 (13) "Surgery" means any manual or operative procedure,
110 including the use of lasers, performed upon the body of a living
111 human being for the purposes of preserving health, diagnosing or
112 curing disease, repairing injury, correcting deformity or
113 defects, prolonging life, or relieving suffering or any elective
114 procedure for aesthetic, reconstructive, or cosmetic purposes,
115 including, but not limited to: incision or curettage of tissue
116 or an organ; suture or other repair of tissue or organ,
117 including a closed as well as an open reduction of a fracture;
118 extraction of tissue including premature extraction of the
119 products of conception from the uterus; insertion of natural or
120 artificial implants; or an endoscopic procedure with use of
121 local or general anesthetic.

122 (9)-~~(4)~~ "Physician" means a person who is licensed to
123 practice medicine in this state.

124 Section 4. Subsection (3) of section 458.309, Florida
125 Statutes, is amended and subsection (4) is added to that
126 section, to read:



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127 458.309 Rulemaking authority.—

128 (3) A physician who performs any liposuction procedure
129 ~~procedures~~ in which more than 1,000 cubic centimeters of
130 supernatant fat is removed, any Level II office surgery level 2
131 ~~procedures lasting more than 5 minutes, or any Level III office~~
132 surgery and all level 3 surgical procedures in an office setting
133 must register the office with the department unless that office
134 is licensed as a facility under chapter 395. The department
135 shall inspect the physician's office annually unless the office
136 is accredited by a nationally recognized accrediting agency or
137 an accrediting organization ~~subsequently~~ approved by the Board
138 of Medicine. The actual costs for registration and inspection or
139 accreditation shall be paid by the person seeking to register
140 and operate the office setting in which office surgery is
141 performed. As a condition of registration, a physician who
142 performs such surgical procedures in an office setting, and the
143 office itself if it is a separate legal entity from the
144 physician, must maintain the same levels of financial
145 responsibility required in s. 458.320.

146 (4) (a) The board may adopt rules to administer the
147 registration, inspection, and safety of offices in which a
148 physician performs office surgery.

149 (b) As a part of registration, such an office must
150 designate a physician who is responsible for the office's
151 compliance with this section and the rules adopted hereunder.
152 Within 10 days after termination of the designated physician,
153 the office must notify the department of the identity of another
154 designated physician for that office. The designated physician
155 must have a full, active, and unencumbered license under this



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156 chapter or chapter 459 and shall practice at the office for
157 which he or she has assumed responsibility. The department may
158 suspend a registration certificate for an office without a
159 designated physician who practices at the office.

160 (c) The department shall inspect the office at least
161 annually, including a review of patient records, to ensure that
162 it complies with this section and rules adopted hereunder unless
163 the office is accredited by a nationally recognized accrediting
164 agency approved by the board. The inspection may be unannounced,
165 except for the inspection of a physician's office that meets the
166 description of a clinic specified in s. 458.3265(1)(a)1.h.,
167 which must be announced.

168 (d) The board shall adopt by rule standards of practice for
169 physicians who perform office surgery. The board shall impose a
170 fine of \$5,000 per day on a physician who performs a surgical
171 procedure identified in subsection (3) in an office that is not
172 registered with the department.

173 Section 5. Paragraph (vv) is added to subsection (1) of
174 section 458.331, Florida Statutes, to read:

175 458.331 Grounds for disciplinary action; action by the
176 board and department.—

177 (1) The following acts constitute grounds for denial of a
178 license or disciplinary action, as specified in s. 456.072(2):

179 (vv) Performing a liposuction procedure in which more than
180 1,000 cubic centimeters of supernatant fat is removed, a Level
181 II office surgery, or a Level III office surgery in an office
182 that is not registered with the department pursuant to s.
183 458.309(3).

184 Section 6. Section 459.003, Florida Statutes, is amended to



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185 read:

186 459.003 Definitions.—As used in this chapter, the term:

187 (1) "Board" means the Board of Osteopathic Medicine.

188 (2) "Deep sedation and analgesia" means a drug-induced
189 depression of consciousness during which all of the following
190 apply:

191 (a) The patient cannot be easily aroused but responds by
192 purposefully following repeated or painful stimulation.

193 (b) The patient's ability to independently maintain
194 ventilatory function may be impaired.

195 (c) The patient may require assistance in maintaining a
196 patent airway, and spontaneous ventilation may be inadequate.

197 (d) The patient's cardiovascular function is usually
198 maintained.

199 (e) The patient's reflex withdrawal from painful stimulus
200 is not considered a purposeful response.

201 ~~(3)~~ (2) "Department" means the Department of Health.

202 (5) "Epidural anesthesia" means anesthesia produced by the
203 injection of an anesthetic agent into the space on or around the
204 dura mater of the spinal cord.

205 (6) "General anesthesia" means a drug-induced loss of
206 consciousness administered by a qualified general anesthesia
207 provider during which all of the following apply:

208 (a) The patient is not able to be aroused, even by painful
209 stimulation.

210 (b) The patient's ability to independently maintain
211 ventilatory function is often impaired.

212 (c) The patient has a level of depressed neuromuscular
213 function.



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214 (d) The patient may require assistance in maintaining a
215 patent airway, and positive pressure ventilation may be
216 required.

217 (e) The patient's cardiovascular function may be impaired.

218 (7) "Minimal sedation" means a drug-induced state during
219 which patients respond normally to verbal commands. Although
220 cognitive function and physical coordination may be impaired,
221 airway reflexes, and respiratory and cardiovascular functions
222 are unaffected.

223 (8) "Moderate sedation and analgesia" or "conscious
224 sedation" means drug-induced depression of consciousness and a
225 state of consciousness during which all of the following apply:

226 (a) The patient responds purposefully to verbal commands,
227 either alone or accompanied by light tactile stimulation.

228 (b) Interventions are not required to maintain a patent
229 airway, and spontaneous ventilation is adequate.

230 (c) Cardiovascular function is maintained.

231 (d) Reflex withdrawal from a painful stimulus is not
232 considered a purposeful response.

233 (9) "Office surgery" means a surgery that is performed in a
234 physician's office or any facility that is not licensed under
235 chapter 390 or chapter 395.

236 (a) "Level I office surgery" includes any surgery that
237 consists of only minor procedures and in which anesthesia is
238 limited to minimal sedation.

239 (b) "Level II office surgery" includes any surgery in which
240 the patient's level of sedation is that of moderate sedation and
241 analgesia or conscious sedation.

242 (c) "Level III office surgery" includes any surgery in



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243 which the patient's level of sedation is that of deep sedation
244 and analgesia or general anesthesia. The term includes any
245 surgery that includes the use of spinal anesthesia or epidural
246 anesthesia.

247 (11)-(3) "Practice of osteopathic medicine" means the
248 diagnosis, treatment, operation, or prescription for any human
249 disease, pain, injury, deformity, or other physical or mental
250 condition, which practice is based in part upon educational
251 standards and requirements which emphasize the importance of the
252 musculoskeletal structure and manipulative therapy in the
253 maintenance and restoration of health.

254 (12) "Spinal anesthesia" means anesthesia produced by the
255 injection of an anesthetic agent into the subarachnoid space of
256 the spinal cord.

257 (13) "Surgeon" means a physician who performs surgery.

258 (14) "Surgery" means any manual or operative procedure,
259 including the use of lasers, performed upon the body of a living
260 human being for the purposes of preserving health, diagnosing or
261 curing disease, repairing injury, correcting deformity or
262 defects, prolonging life, or relieving suffering or any elective
263 procedure for aesthetic, reconstructive, or cosmetic purposes,
264 including, but not limited to: incision or curettage of tissue
265 or an organ; suture or other repair of tissue or organ,
266 including a closed as well as an open reduction of a fracture;
267 extraction of tissue including premature extraction of the
268 products of conception from the uterus; insertion of natural or
269 artificial implants; or an endoscopic procedure with use of
270 local or general anesthetic.

271 (10)-(4) "Osteopathic physician" means a person who is



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272 licensed to practice osteopathic medicine in this state.

273 ~~(4)-(5)~~ "Doctor of Osteopathy" and "Doctor of Osteopathic
274 Medicine," when referring to degrees, shall be construed to be
275 equivalent and equal degrees.

276 Section 7. Subsection (2) of section 459.005, Florida
277 Statutes, is amended and subsection (3) is added to that
278 section, to read:

279 459.005 Rulemaking authority.—

280 (2) A physician who performs any liposuction procedure
281 ~~procedures~~ in which more than 1,000 cubic centimeters of
282 supernatant fat is removed, any Level II office surgery level 2
283 ~~procedures lasting more than 5 minutes, or any Level III office~~
284 surgery and all level 3 surgical procedures in an office setting
285 must register the office with the department unless that office
286 is licensed as a facility under chapter 395. The department
287 shall inspect the physician's office annually unless the office
288 is accredited by a nationally recognized accrediting agency or
289 an accrediting organization ~~subsequently~~ approved by the Board
290 of Osteopathic Medicine. The actual costs for registration and
291 inspection or accreditation shall be paid by the person seeking
292 to register and operate the office setting in which office
293 surgery is performed. As a condition of registration, a
294 physician who performs such surgical procedures in an office
295 setting, and the office itself if it is a separate legal entity
296 from the physician, must maintain the same levels of financial
297 responsibility required in s. 459.0085.

298 (3) (a) The board may adopt rules to administer the
299 registration, inspection, and safety of offices in which a
300 physician performs office surgery.



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301 (b) As a part of registration, such an office must
302 designate a physician who is responsible for the office's
303 compliance with this section and the rules adopted hereunder.
304 Within 10 days after termination of the designated physician,
305 the office must notify the department of the identity of another
306 designated physician for that office. The designated physician
307 must have a full, active, and unencumbered license under this
308 chapter or chapter 458 and shall practice at the office for
309 which he or she has assumed responsibility. The department may
310 suspend a registration certificate for an office without a
311 designated physician who practices at the office.

312 (c) The department shall inspect the office at least
313 annually, including a review of patient records, to ensure that
314 it complies with this section and rules adopted hereunder unless
315 the office is accredited by a nationally recognized accrediting
316 agency approved by the board. The inspection may be unannounced,
317 except for the inspection of a physician's office that meets the
318 description of a clinic specified in s. 459.0137(1)(a)1.h.,
319 which must be announced.

320 (d) The board shall adopt by rule standards of practice for
321 physicians who perform office surgery. The board shall impose a
322 fine of \$5,000 per day on a physician who performs a surgical
323 procedure identified in subsection (2) in an office that is not
324 registered with the department.

325 Section 8. Paragraph (xx) is added to subsection (1) of
326 section 459.015, Florida Statutes, to read:

327 459.015 Grounds for disciplinary action; action by the
328 board and department.—

329 (1) The following acts constitute grounds for denial of a



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330 license or disciplinary action, as specified in s. 456.072(2):
331 (xx) Performing a liposuction procedure in which more than
332 1,000 cubic centimeters of supernatant fat is removed, a Level
333 II office surgery, or a Level III office surgery in an office
334 that is not registered with the department pursuant to s.
335 459.005(2).

336 Section 9. Paragraph (a) of subsection (1) of section
337 766.101, Florida Statutes, is amended to read:

338 766.101 Medical review committee, immunity from liability.—

339 (1) As used in this section:

340 (a) The term "medical review committee" or "committee"
341 means:

342 1.a. A committee of a hospital or ambulatory surgical
343 center licensed under chapter 395 or a health maintenance
344 organization certificated under part I of chapter 641;

345 b. A committee of a physician-hospital organization, a
346 provider-sponsored organization, or an integrated delivery
347 system;

348 c. A committee of a state or local professional society of
349 health care providers;

350 d. A committee of a medical staff of a licensed hospital or
351 nursing home, provided the medical staff operates pursuant to
352 written bylaws that have been approved by the governing board of
353 the hospital or nursing home;

354 e. A committee of the Department of Corrections or the
355 Correctional Medical Authority as created under s. 945.602, or
356 employees, agents, or consultants of either the department or
357 the authority or both;

358 f. A committee of a professional service corporation formed



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359 under chapter 621 or a corporation organized under part I of
360 chapter 607 or chapter 617, which is formed and operated for the
361 practice of medicine as defined in s. 458.305 ~~s. 458.305(3)~~, and
362 which has at least 25 health care providers who routinely
363 provide health care services directly to patients;

364 g. A committee of the Department of Children and Families
365 which includes employees, agents, or consultants to the
366 department as deemed necessary to provide peer review,
367 utilization review, and mortality review of treatment services
368 provided pursuant to chapters 394, 397, and 916;

369 h. A committee of a mental health treatment facility
370 licensed under chapter 394 or a community mental health center
371 as defined in s. 394.907, provided the quality assurance program
372 operates pursuant to the guidelines that have been approved by
373 the governing board of the agency;

374 i. A committee of a substance abuse treatment and education
375 prevention program licensed under chapter 397 provided the
376 quality assurance program operates pursuant to the guidelines
377 that have been approved by the governing board of the agency;

378 j. A peer review or utilization review committee organized
379 under chapter 440;

380 k. A committee of the Department of Health, a county health
381 department, healthy start coalition, or certified rural health
382 network, when reviewing quality of care, or employees of these
383 entities when reviewing mortality records; or

384 l. A continuous quality improvement committee of a pharmacy
385 licensed pursuant to chapter 465,

386
387 which committee is formed to evaluate and improve the quality of



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388 health care rendered by providers of health service, to
389 determine that health services rendered were professionally
390 indicated or were performed in compliance with the applicable
391 standard of care, or that the cost of health care rendered was
392 considered reasonable by the providers of professional health
393 services in the area; or

394 2. A committee of an insurer, self-insurer, or joint
395 underwriting association of medical malpractice insurance, or
396 other persons conducting review under s. 766.106.

397 Section 10. This act shall take effect upon becoming a law.
398

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

400 And the title is amended as follows:

401 Delete everything before the enacting clause
402 and insert:

403 A bill to be entitled

404 An act relating to clinics and office surgery;
405 amending s. 456.004, F.S.; requiring the Department of
406 Health to deny or revoke the registration of or impose
407 certain penalties against a facility where certain
408 office surgeries are performed under certain
409 circumstances; specifying provisions that apply
410 enforcement actions against such facilities;
411 authorizing the department to deny certain persons
412 associated with an office of which the registration
413 was revoked from registering a new office to perform
414 certain office surgery; amending s. 456.074, F.S.;
415 authorizing the department to issue an emergency order
416 suspending or restricting the registration of a



417 certain office if it makes certain findings; amending
418 s. 458.305, F.S.; defining terms; amending s. 458.309,
419 F.S.; requiring a physician who performs certain
420 office surgery and the office in which the surgery is
421 performed to maintain specified levels of financial
422 responsibility; authorizing the Board of Medicine to
423 adopt rules to administer the registration,
424 inspection, and safety of offices that perform certain
425 office surgery; requiring such an office to designate
426 a certain physician responsible for the office's
427 compliance with specified provisions; authorizing the
428 department to suspend an office's registration
429 certificate under certain circumstances; requiring the
430 department to conduct certain inspections; providing
431 an exception; requiring the board to adopt rules
432 governing the standard of care for physicians
433 practicing in such offices; requiring the board to
434 impose a specified fine on physicians who perform
435 certain office surgeries in an unregistered office;
436 amending s. 458.331, F.S.; providing that a physician
437 performing certain office surgeries in an unregistered
438 office constitutes grounds for denial of a license or
439 disciplinary action; amending s. 459.003, F.S.;
440 defining terms; amending s. 459.005, F.S.; requiring a
441 physician who performs certain office surgery and the
442 office in which the surgery is performed to maintain
443 specified levels of financial responsibility;
444 authorizing the Board of Osteopathic Medicine to adopt
445 rules to administer the registration, inspection, and



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446 safety of offices that perform certain office surgery;
447 requiring such an office to designate a certain
448 physician responsible for the office's compliance with
449 specified provisions; authorizing the department to
450 suspend an office's registration certificate under
451 certain circumstances; requiring the department to
452 conduct certain inspections; providing an exception;
453 requiring the board to adopt rules governing the
454 standard of care for physicians practicing in such
455 offices; requiring the board to impose a specified
456 fine on physicians who perform certain office
457 surgeries in an unregistered office; amending s.
458 459.015, F.S.; providing that a physician performing
459 certain office surgeries in an unregistered office
460 constitutes grounds for denial of a license or
461 disciplinary action; amending s. 766.101, F.S.;
462 conforming a cross-reference; providing an effective
463 date.



868332

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/10/2019	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services
(Flores) recommended the following:

Senate Amendment to Amendment (978476)

Delete line 166

and insert:

description of a clinic specified in s. 458.3265(1)(a)3.g. and

h.,

Delete line 318

and insert:

description of a clinic specified in s. 459.0137(1)(a)3.g. and

h.,

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL: PCS/CS/SB 900 (415318)

INTRODUCER: Appropriations Subcommittee on Health and Human Services; Children, Families, and Elder Affairs Committee; and Senator Harrell

SUBJECT: Substance Abuse Services

DATE: April 11, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Delia</u>	<u>Hendon</u>	<u>CF</u>	<u>Fav/CS</u>
2.	<u>Sneed</u>	<u>Kidd</u>	<u>AHS</u>	<u>Recommend: Fav/CS</u>
3.	<u> </u>	<u> </u>	<u>AP</u>	<u> </u>

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 900 promotes the use of peer specialists in behavioral health care and revises requirements for recovery residences (also known as “sober homes”). Peer specialists are persons who have recovered from a substance use disorder or mental illness who support a person with a current substance use disorder or mental illness. The bill revises background screening requirements and codifies existing training and certification requirements for peer specialists.

The bill also modifies requirements for licensed substance abuse service providers offering treatment to individuals living in recovery residences. The bill provides due process procedures for actions taken by an approved certifying entity on a recovery residence’s certification.

The bill exempts certified recovery residences from landlord/tenant laws in cases where a discharge is deemed necessary to protect the resident at issue, other residents, or staff, provided the recovery residence has an approved discharge policy. The bill also exempts Oxford houses from certification requirements, and treats single and two-family recovery residences like other residences for purposes of the Florida Building Code.

The bill addresses individuals who have been disqualified for employment with substance abuse service providers following a failed background screening and adds offenses for which individuals may seek an exemption from such disqualification.

The bill will result in the need for technology changes to the Care Provider Background Screening Clearinghouse system administered by the Agency for Health Care Administration. The bill is also expected to have an indeterminate, though insignificant fiscal impact on the Department of Children and Families. See Section V.

The bill takes effect July 1, 2019.

II. Present Situation:

Substance Abuse

Substance abuse refers to the harmful or hazardous use of psychoactive substances, including alcohol and illicit drugs.¹ Substance use disorder occurs when the chronic use of alcohol or drugs causes significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home.² Repeated drug use leads to changes in the brain's structure and function that can make a person more susceptible to developing a substance use disorder.³ Brain imaging studies of persons with substance use disorder show physical changes in areas of the brain that are critical to judgment, decision making, learning and memory, and behavior control.⁴

Substance Abuse Treatment in Florida

The 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. SAMH programs include a range of prevention, acute interventions (such as crisis stabilization or detoxification), residential, transitional housing, outpatient treatment, and recovery support services.

The DCF provides treatment for substance abuse through a community-based provider system that serves adolescents and adults affected by substance misuse, abuse or dependence.⁵ The DCF regulates substance abuse treatment by licensing individual treatment components pursuant to ch. 397, F.S., and Florida Administrative Code Rule 65D-30.

The 2017 Legislature passed and the Governor approved HB 807, which made several changes to the DCF's licensure program for substance abuse treatment providers in chapter 397, F.S.⁶ HB 807 revised the licensure application requirements and process and required applicants to provide detailed information about the clinical services they provide.

¹ World Health Organization, *Substance Abuse*, available at http://www.who.int/topics/substance_abuse/en/ (last visited Mar. 8, 2019).

² Substance Abuse and Mental Health Services Administration, *Substance Use Disorders*, available at <http://www.samhsa.gov/disorders/substance-use> (last visited Mar. 8, 2019).

³ National Institute on Drug Abuse, *Drugs, Brains, and Behavior: The Science of Addiction*, available at <https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/drug-abuse-addiction> (last visited Mar. 8, 2019).

⁴ Id.

⁵ Department of Children and Families, *Treatment for Substance Abuse*, <http://www.myflfamilies.com/service-programs/samh/substance-abuse.shtml> (last visited Mar. 8, 2019).

⁶ Ch. 2017-173, Laws of .O.F.

Recovery Residences

Recovery residences function under the premise that individuals benefit in their recovery by residing in an alcohol and drug-free environment. Recovery residences are designed to be financially self-sustaining through rent and fees paid by residents, and there is no limit on the length of stay for those who abide by the rules.

Section 397.311, F.S., defines a recovery residence as a residential dwelling unit, or other form of group housing, offered or advertised through any means, including oral, written, electronic, or printed means, by any person or entity as a residence that provides a peer-supported, alcohol-free, and drug-free living environment. A 2009 Connecticut study notes the following: “Sober houses do not provide treatment, [they are] just a place where people in similar circumstances can support one another in sobriety. Because they do not provide treatment, they typically are not subject to state regulation.”⁷

Voluntary Certification of Recovery Residences in Florida

Florida does not license recovery residences. Instead, in 2015 the Legislature enacted sections 397.487–397.4872, F.S., which establish voluntary certification programs for recovery residences and recovery residence administrators, implemented by private credentialing entities.

While certification is voluntary, Florida law incentivizes certification. Since July 1, 2016, Florida has prohibited licensed substance abuse service providers from referring patients to a recovery residence unless the recovery residence is certified and is actively managed by a certified recovery residence administrator.⁸ Referrals by licensed service providers to uncertified recovery residences are limited to those licensed service providers under contract with a managing entity as defined in s. 394.9082, F.S.; referrals by a recovery residence to a licensed service provider when the recovery residence or its owners, directors, operators, or employees do not benefit, directly or indirectly, from the referral; and referrals before July 1, 2018 by a licensed service provider to that licensed service provider’s wholly owned subsidiary.⁹

The DCF publishes a list of all certified recovery residences and recovery residence administrators on its website.¹⁰ As of February 13, 2019, there were 404 certified recovery residences in Florida.¹¹ The total number of available beds at these residences was 5,786 (2,915 men’s beds, 1,493 women’s, and 1,378 unisex).¹² As of January 2019, a total of 25 counties in Florida contained at least one certified recovery residence.¹³

⁷ *Id.*

⁸ S. 397.4873(1), F.S.

⁹ S. 397.4873(2), F.S.

¹⁰ S. 397.4872, F.S.

¹¹ Florida Association of Recovery Residences, *Certified Residences*,

<http://www.dcf.state.fl.us/programs/samh/docs/FARR%20Certified%20Recovery%20Residences.pdf> (last visited Mar. 8, 2019).

¹² *Id.*

¹³ *Id.*

Behavioral Health Workforce Shortage

Workforce issues for providers of substance use disorder and mental illness services, which have been of concern for decades, have taken on a greater sense of urgency with the passage of recent parity and health reform legislation.¹⁴ The Affordable Care Act increased the number of people who are eligible for health care coverage including behavioral health services. In addition, as screening for mental illness and substance abuse becomes more frequent in primary care, more people will need behavioral health services. Furthermore, workforce shortages will be impacted by additional demands that result from: (1) a large number of returning veterans in need of services; and (2) new state re-entry initiatives to reduce prison populations, a large majority of whom have mental or substance use disorders.¹⁵

Shortages of qualified behavioral health workers, recruitment and retention of staff and an aging workforce have long been cited as problems. Lack of workers in rural/frontier areas and the need for a workforce more reflective of the racial and ethnic composition of the U.S. population create additional barriers to accessing care for many. Recruitment and retention efforts are hampered by inadequate compensation, which discourages many from entering or remaining in the field. In addition, the misunderstanding and prejudice of persons with mental and substance use disorders can negatively affect the use of peer specialists.

Use of Peer Specialists

Research has shown that recovery from a substance use disorder or mental illness is facilitated by the use of social support provided by peers.¹⁶ The most recognized form of peer support is the 12-step programs of Alcoholics Anonymous and Narcotics Anonymous. More recently, peers or peer specialists, have been used to assist persons with serious mental illnesses.¹⁷

Research has identified four types of social support provided by peers:

- Emotional - where a peer demonstrates empathy, caring or concern to bolster a person's self-esteem. This is often provided by peer mentoring or peer-led support groups.
- Informational - where a peer shares knowledge and information to provide life or vocational skills training. Examples include parenting classes, job readiness training, or wellness seminars.
- Instrumental - where a peer provides concrete assistance to help others accomplish tasks. Examples include child care, transportation and help accessing health and human services.
- Affiliational - where a peer facilitates contacts with other people to promote learning of social skills, create a sense of community, and acquire a sense of belonging. Examples

¹⁴ U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. Report to Congress on the Nation's Substance Abuse and Mental Health Workforce Issues. January 24, 2013. Available at: https://www.cibhs.org/sites/main/files/file-attachments/samhsa_bhwork_0.pdf (last visited Apr. 2, 2019).

¹⁵ *Id.*

¹⁶ U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment. What Are Peer Recovery Support Services? Available at: <https://store.samhsa.gov/product/What-Are-Peer-Recovery-Support-Services-/sma09-4454> (last visited Mar. 8, 2019).

¹⁷ National Public Radio. In Texas, People with Mental Illness Are Finding Work Helping Peers. July 11, 2017. <http://www.npr.org/sections/health-shots/2017/07/11/536501069/in-texas-people-with-mental-illness-are-finding-work-helping-peers> (last visited Mar. 8, 2019).

include staffing recovery centers, sports league participation, and alcohol or drug free socialization.¹⁸

The Department of Children and Families (department) Florida Peer Services Handbook, defines a peer as an individual who has life experience with a mental health and/or substance use condition.¹⁹ Current department guidelines recommend that an individual be in recovery for at least two years to be considered for peer training. In Florida, family members or caregivers can also work and be certified as peer specialists.²⁰

The Florida Certification Board currently offers certification with three distinct endorsements for individuals with lived experience who wish to become certified as Peer Specialists. General requirements for certification include being age 18 or older, minimum education of high school diploma or equivalent, background screening, completion of a minimum of 40 hours of training, and passing a competency exam.

Barriers to the Use of Peer Specialists

Currently, there is a shortage of peers working within behavioral health services. As of June 2017, there were 418 individuals with active certification through the Florida Certification Board.²¹ There are two principal barriers to the use of peer specialists.

First, peer specialists often cannot pass background screening requirements in ss. 435.04 and 408.809, F.S. Persons who have recovered from a substance use disorder or mental illness often have a criminal history. Common offenses would include using and selling illegal substances, prostitution, or financial fraud. Section 435.04, F.S., allows persons with certain disqualifying offenses identified through background screening to apply to the respective state agency head (the Secretary of the Department of Children and Families or the Secretary of the Agency for Health Care Administration) for an exemption if it has been three or more years since their conviction. The applicant must produce all court records regarding their convictions, letters of recommendation, evidence of their rehabilitation, education documents, evidence of employment, and fill out a questionnaire. The requirements of this exemption often deter persons from becoming peer specialists.

Second, peer specialists have only recently been reimbursed as a behavioral health care service. Medicaid billing for peer support services began in Georgia in 1999, and quickly expanded nationally in 2007 after the Center for Medicare and Medicaid Services (CMS) sent guidelines to states on how to be reimbursed for services delivered by peer providers.²² In 2012, Georgia was approved as the first state to bill for a peer whole health and wellness service delivered by peer

¹⁸ U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment. What Are Peer Recovery Support Services? Available at: <http://www.npr.org/sections/health-shots/2017/07/11/536501069/in-texas-people-with-mental-illness-are-finding-work-helping-peers> (last visited Mar. 8, 2019).

¹⁹ Department of Children and Families, Florida Peer Services Handbook. Available at: <http://www.dcf.state.fl.us/programs/samh/publications/peer-services/DCF-Peer-Guidance.pdf> (last visited Mar. 8, 2019).

²⁰ *Id.*

²¹ *Id.*

²² U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services. SMDL #07-011. Aug. 15, 2007. Available at: <https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD081507A.pdf> (last visited Mar. 8, 2019).

providers. CMS' Clarifying Guidance on Peer Services Policy from May 2013 states that any peer provider must "complete training and certification as defined by the state" before providing billable services. Beginning January 1, 2014, CMS expanded the type of practitioners who can provide Medicaid prevention services beyond physicians and other licensed practitioners, at a state's discretion, which can include peer providers. Florida's Medicaid program currently covers peer recovery services. The department also allows the state's behavioral health managing entities to reimburse for these services.

Background Screening Requirements and Process Under Ch. 435, F.S.

Chapter 435, F.S., addresses background screening requirements for persons seeking employment or for employees in positions that require a background screening. An employer²³ may not hire, select, or otherwise allow an employee to have contact with a vulnerable person²⁴ that would place the employee in a role that requires a background screening until the screening process is completed and demonstrates the absence of any grounds for the denial or termination of employment. If the screening process shows any grounds for the denial or termination of employment, the employer may not hire, select, or otherwise allow the employee to have contact with any vulnerable person that would place the employee in a role that requires background screening unless the employee is granted an exemption for disqualification by the agency²⁵ as provided under s. 435.07, F.S.²⁶

If an employer becomes aware that an employee has been arrested for a disqualifying offense, the employer must remove the employee from contact with any vulnerable person that places the employee in a role that requires a background screening until the arrest is resolved in a way that the employer determines that the employee is still eligible for employment under ch. 435, F.S.²⁷ The employer must terminate the employment of any of its personnel found to be in noncompliance with the minimum standards of ch. 435, F.S., or place the employee in a position for which background screening is not required unless the employee is granted an exemption from disqualification pursuant to s. 435.07, F.S.²⁸

An employer may hire an employee to a position that requires a background screening before the employee completes the screening process for training and orientation purposes. However, the employee may not have direct contact with vulnerable persons until the screening process is completed and the employee demonstrates that he or she exhibits no behaviors that warrant the denial or termination of employment.²⁹

²³ "Employer" means any person or entity required by law to conduct screening of employees pursuant to ch. 435, F.S. See s. 435.02(3), F.S.

²⁴ Vulnerable persons are defined as minors in s. 1.01, F.S., or as vulnerable adults in s. 415.102, F.S.

²⁵ "Agency" means any state, county, or municipal agency that grants licenses or registration permitting the operation of an employer or is itself an employer or that otherwise facilitates the screening of employees pursuant to ch. 435, F.S. If there is no state agency or the municipal or county agency chooses not to conduct employment screening, "agency" means the DCF. See s. 435.02(1), F.S.

²⁶ Section 435.06(2)(a), F.S.

²⁷ Section 435.06(2)(b), F.S.

²⁸ Section 435.06(2)(c), F.S.

²⁹ Section 435.06(2)(d), F.S.

Sections 435.03 and 435.04, F.S., outline the screening requirements. There are two levels of background screening:

- Level 1 screening includes, at a minimum, employment history checks and statewide criminal correspondence checks through the Florida Department of Law Enforcement (FDLE) and a check of the Dru Sjodin National Sex Offender Public Website,³⁰ and may include criminal records checks through local law enforcement agencies.³¹
- Level 2 screening includes, but, is not limited to, fingerprinting for statewide criminal history records checks through the FDLE and national criminal history checks through the Federal Bureau of Investigation (FBI), and may include local criminal records checks through local law enforcement agencies.³²

The security background investigations under s. 435.04, F.S., for level 2 screening must ensure that no persons subject to this section have been arrested for and are awaiting final disposition of, have been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to, or have been adjudicated delinquent, and the record has not been sealed or expunged for, any offense listed in s. 435.04(2), F.S., or a similar law of another jurisdiction.³³ Additionally, such investigations must ensure that no person subject to s. 435.04, F.S., has been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to any offense that constitutes domestic violence in s. 741.28, F.S., whether such act was committed in this state or another jurisdiction.³⁴

For both levels of screening, the person required to be screened pursuant to ch. 435, F.S., must submit a complete set of information necessary to conduct a screening under ch. 435, F.S.,³⁵ and must supply any missing criminal or other necessary information upon request to the requesting employer or agency within 30 days after receiving the request for the information.³⁶ Every employee must attest, subject to penalty of perjury, to meeting the requirements for qualifying for employment pursuant ch. 435, F.S., and agreeing to inform the employer immediately if arrested for any of the disqualifying offenses while employed by the employer.³⁷

For level 1 screening, the employer must submit the information necessary for screening to the Florida Department of Law Enforcement (FDLE) within 5 working days after receiving it. The FDLE must conduct a search of its records and respond to the employer or agency. The employer must inform the employee whether screening has revealed any disqualifying information.³⁸

For level 2 screening, the employer or agency must submit the information necessary for screening to the FDLE within 5 working days after receiving it. The FDLE must perform a criminal history record check of its records and request that the FBI perform a national criminal

³⁰ The Dru Sjodin National Sex Offender Public Website is a U.S. government website that links public state, territorial, and tribal sex offender registries in one national search site. Available at <https://www.nsopw.gov/> (last visited Mar. 8, 2019).

³¹ Section 435.03(1), F.S.

³² Section 435.04(1)(a), F.S.

³³ Section 435.04(2), F.S.

³⁴ Section 435.04(3), F.S.

³⁵ Section 435.05(1)(a), F.S.

³⁶ Section 435.05(1)(d), F.S.

³⁷ Section 435.05(2), F.S.

³⁸ Section 435.05(1)(b), F.S.

history record check. The FDLE must respond to the employer or agency, and the employer or agency must inform the employee whether screening has revealed disqualifying information.³⁹

Each employer licensed or registered with an agency must conduct level 2 screening and must submit to the agency annually or at the time of license renewal, under penalty of perjury, a signed attestation attesting to compliance with the provisions of ch. 435, F.S.⁴⁰

Individuals Requiring Background Screening Under Ch. 397, F.S.

Only certain individuals affiliated with substance abuse treatment providers require background screening. Section 397.4073, F.S., requires all owners, directors, chief financial officers, and clinical supervisors of service providers, as well as all service provider personnel who have direct contact with children receiving services or with adults who are developmentally disabled receiving services to undergo level 2 background screening.

Regarding recovery residences, s. 397.487(6), F.S., and s. 397.4871(5), F.S., each require level 2 background screening for all recovery residence owners, directors, and chief financial officers, and for administrators seeking certification.

Exemptions from Disqualification for Employment

Section 435.07(1), F.S., authorizes the head of the appropriate agency to grant to any employee otherwise disqualified from employment due to certain disqualifying offenses an exemption from such disqualification. For a felony, three years must have elapsed since the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed. No waiting period applies to misdemeanors.

Additionally, s. 435.07(2), F.S., provides that persons employed, or applicants for employment, by treatment providers who treat adolescents 13 years of age and older who are disqualified from employment solely because of crimes under s. 817.563, F.S. (sale of imitation controlled substance), s. 893.13, F.S. (controlled substances offenses, excluding drug trafficking), or s. 893.147, F.S. (drug paraphernalia offenses) may be exempted from disqualification from employment pursuant to ch. 435, F.S., without application of the 3-year waiting period for felony offenses in s. 435.07(1)(a)1., F.S.

Section 397.4073(4), F.S., authorizes the DCF to grant any service provider personnel an exemption from disqualification as provided in s. 435.07, F.S. The DCF may grant exemptions from disqualification to service provider personnel whose backgrounds checks indicate crimes under s. 817.563, F.S., s. 893.13, F.S. (controlled substances offenses, excluding drug trafficking), or s. 893.147, F.S., or grant exemptions from disqualification which would limit service provider personnel to working with adults in substance abuse treatment facilities.

Section 397.4872(1), F.S., provides that the individual exemptions to staff disqualification or administrator ineligibility may be requested if a recovery residence deems the decision will

³⁹ Section 435.05(1)(c), F.S.

⁴⁰ Section 435.05(3), F.S.

benefit the program. Requests for exemptions must be submitted in writing to the DCF within 20 days after the denial by the credentialing entity and must include a justification for the exemption. Subsection (2) provides, with some exceptions, the DCF may exempt a person from ss. 397.487(6), and 397.4871(5), F.S., if it has been at least three years since the person has completed or been lawfully released from confinement, supervision, or sanction for the disqualifying offense.

As previously noted, substance abuse services are governed by ch. 394, F.S., and ch. 397, F.S. “The system of care provides services to children and adults with or at-risk of substance misuse/abuse problems or co-occurring substance abuse and mental health problems[.]”⁴¹ Section 394.4572(1)(a), F.S., requires a level 2 screening for mental health personnel,⁴² and s. 394.4572(1)(a), F.S., authorizes the DCF and the Agency for Health Care Administration (AHCA) to grant exemptions from disqualification as provided in ch. 435, F.S. However, s. 394.4572, F.S., does not specifically authorize the DCF or the AHCA to grant exemptions from disqualification for service provider personnel to work solely in mental health treatment programs or facilities or in programs or facilities that treat co-occurring substance use and mental health disorders.

III. Effect of Proposed Changes:

Section 1 amends s. 394.4572, F.S., to allow the DCF (or AHCA, as applicable) to grant exemptions from disqualification for service provider personnel to work solely in mental health treatment programs or facilities, or in programs that treat co-occurring substance abuse and mental health disorders.

Section 2 amends s. 397.311, F.S., providing definitions to Chapter 397 on Substance Abuse Services to include definitions for “clinical supervisors” and “peer specialists.” The bill also expands the definition of “recovery residence” to include all community housing.

Section 3 amends s. 397.321, F.S., to provide due process procedures via an internal department review and the administrative hearing process under chapter 120, F.S., for certified service provider personnel whose certification is denied, revoked, or suspended by the credentialing entity.

Section 4 amends s. 397.4073, F.S., relating to recovery residences, to require that beginning on July 1, 2019, peer specialists will be subject to level 2 background screenings, and, along with recovery residence owners, directors, chief financial officers, and clinical supervisors, will also be subject to background screenings for the offenses in s. 408.809, F.S. in addition to those in chapter 435, F.S. The bill also provides that for individuals who seek an exemption from disqualification for employment in substance abuse treatment following a level 2 background screening, the bill requires the DCF must render a decision on the application for exemption

⁴¹ Department of Children and Families, *Substance Abuse and Mental Health Services Plan 2014-2016*, p. 3, available at <http://www.dcf.state.fl.us/programs/samh/publications/2014-2016%20SAMH%20Services%20Plan.pdf> (last visited Mar. 8, 2019).

⁴² “Mental health personnel” includes all program directors, professional clinicians, staff members, and volunteers working in public or private mental health programs and facilities who have direct contact with individuals held for examination or admitted for mental health treatment. Section 394.4572(1)(a), F.S.

from disqualification within 60 days after the DCF receives the complete application. Additionally, the bill allows individuals to work under supervision for up to 90 days while the DCF evaluates their applications for an exemption from disqualification, so long as it has been five or more years since the individuals have completed all non-monetary conditions associated with their most recent disqualifying offense.

The bill also modifies current requirements relating to background screening and exemptions from disqualification from employment to add the following crimes for which service provider personnel may receive an exemption from disqualification without the statutorily imposed waiting period, if they are working with adolescents 13 years of age and older and adults with substance use disorders:

- Prostitution-related offenses under s. 796.07(2)(e), F.S.;
- Unarmed burglary of a conveyance or structure under s. 810.02(4), F.S.;
- Third degree grand theft under s. 812.014(2)(c), F.S.;
- Forgery under s. 831.01, F.S.;
- Offenses involving uttering or publishing a forged instrument under s. 832.02, F.S.; and
- Any attempt, solicitation, or conspiracy to commit any of these offenses or any offense currently listed in the section.

The bill permits the department to grant exemptions from disqualification for service provider personnel to work exclusively in substance use disorder treatment programs, facilities, or recovery residences or in programs or facilities that treat co-occurring substance use and mental health disorders, and provides that the department may further limit such exemptions from disqualification to working with adults in substance abuse treatment facilities.

Section 5 amends s. 397.4075, F.S., to increase criminal penalties relating to personnel from a first-degree misdemeanor to a third degree felony. Additionally, the bill creates a new offense for anyone who willfully, knowingly, or intentionally makes false statements, misrepresents, impersonates, fails to disclose, or otherwise fraudulently discloses inaccurate information on a licensure application when such fact is material to determining one's qualifications to be an owner, director, volunteer, or other personnel of a service provider.

Section 6 creates s. 397.417, F.S., providing that a person who has been in recovery from a substance use disorder or mental illness for the past two years or a family member or caregiver of such a person may seek certification as a peer specialist. The bill requires the DCF to approve training and continuing education programs for peer specialist certification. The DCF must designate one or more credentialing entities that have met nationally recognized standards for developing and administering certification programs to handle the training and certification of peer specialists. The bill intends to expand the use of peer specialists as a cost-effective behavioral health care service. The bill also encourages the department, behavioral health managing entity, or Medicaid to reimburse providers of this service.

The bill allows a peer specialist (who is not yet certified), to provide support services for up to a year while he or she is working towards certification; such peer specialists must be supervised by a qualified professional or a certified peer specialists with at least three years of full-time experience at a licensed behavioral health organization.

The bill also allows individuals who wish to become peer specialists but have certain disqualifying offenses in their background to request an exemption from disqualification pursuant to s. 435.07, F.S., from the department or the Agency for Health Care Administration, as applicable. The bill prohibits an individual who is not a certified peer specialist from advertising recovery services as a peer specialist, unless the individual is working toward certification and is supervised by a qualified professional as previously described.

Section 7 amends s. 397.487, F.S., relating to recovery residences, to require all owners, directors, and chief financial officers of a recovery residence applying for voluntary certification to undergo a background screening under s. 408.809, F.S. The bill also directs the credentialing entity for recovery residences to deny an application if any of these individuals has been found guilty of, plead nolo contendere to, or had an adjudication of guilt withheld for, any offense listed in s. 408.809(4), F.S., unless the department has issued an exemption under s. 397.4073, F.S.

The bill allows a certified recovery residence that has a discharge policy approved by the credentialing entity to transfer or discharge residents from the recovery residence in accordance with that policy under the following circumstances:

- The discharge or transfer is necessary for the resident's welfare.
- The resident's needs cannot be met at the recovery residence.
- The health and safety of other residents or recovery residence employees are at risk or would be at risk if the resident continues to live at the recovery residence.

This right to discharge or transfer a resident will supersede any landlord and tenant rights and obligations under chapter 83, F.S.

The bill provides that local governments are not prohibited from mandating certification of recovery residences, and requires the Sober Homes Task Force within the Office of the State Attorney for the Fifteenth Judicial Circuit to submit a report containing recommendations on statewide mandatory certification of sober homes to the President of the Senate and the Speaker of the House of Representatives by January 1, 2020.

Section 8 amends s. 397.4873, F.S., relating to referrals to or from recovery residences, to modify existing restrictions on referrals to or from recovery residences to allow referrals by a recovery residence that is democratically operated by its residents pursuant to a charter from a congressionally recognized or sanctioned entity (often referred to as an "Oxford House"). The bill permits licensed service providers to make referrals to or accept referrals from such entities so long as neither the residence itself, nor any individual residents therein, receive a direct or indirect benefit.

Section 9 amends s. 397.55, F.S., relating to prohibition of deceptive marketing practices, to require any organization that contracts for referral services with a recovery residence to disclose the nature of the referral and the list of the DCF's licensed service providers and certified recovery residences.

Section 10 amends s. 435.07, F.S., relating to exemptions from employment disqualification, to modify current requirements relating to background screening and exemptions from

disqualification from employment to add the following crimes for which service provider personnel may be exempted from employment disqualification when working with individuals 13 years of age or older:

- Prostitution-related offenses under s. 796.07(2)(e), F.S.;
- Unarmed burglary of a conveyance or structure under s. 810.02(4), F.S.;
- Third degree grand theft under s. 812.014(2)(c), F.S.;
- Forgery under s. 831.01, F.S.;
- Offenses involving uttering or publishing a forged instrument under s. 832.02, F.S.; and
- Any attempt, solicitation, or conspiracy to commit any of these offenses or any offense currently listed in the section.

Section 11 amends s. 553.80, F.S., relating to enforcement, to require that a single-family or two-family dwelling used as a recovery residence be classified as a single-family or two-family dwelling for purposes of the Florida Building Code.

Section 12 amends s. 212.055, F.S., relating to the county public hospital surtax to correct a cross reference to a definition in chapter 397, F.S. relating to substance abuse.

Section 13 amends s. 397.416, F.S., relating to substance use disorder treatment services to correct cross references to definitions.

Section 14 amends s. 440.102, F.S., relating drug-free workplace requirements to correct a cross reference to a definition.

Section 15 provides an effective date of July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

PCS/CS/SB 900 will allow additional peers to be employed to provide recovery services to persons suffering from substance use disorder to mental illnesses. Private insurers and Medicaid managed care plans may see a reduction in the cost of behavioral health care services if more health insurance providers make use of peer specialists.

C. Government Sector Impact:

The bill will result in the need for technology changes to the Care Provider Background Screening Clearinghouse system administered by the AHCA. The system changes are estimated to cost \$100,000. However, if Issue 36306C0 in the AHCA's Legislative Budget Request for the 2019-2020 fiscal year is funded, the technology changes can be incorporated into the clearinghouse system planned upgrade. Both SB 2500, the Senate's proposed 2019-2020 General Appropriations Bill and HB 5001, the House's proposed 2019-2020 General Appropriations Bill, include funding for the system upgrade.

The bill may result in additional background screenings if more persons apply to become peer specialists; however, the DCF currently licenses volunteers and personnel of recovery residences and additional screenings for peers would likely be insignificant.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 394.4572, 397.311, 397.321, 397.4073, 397.4075, 397.487, 397.4873, 397.55, 435.07, 553.80, 633.206, 212.055, 397.416, and 440.102.

This bill creates section 397.417 of the Florida Statutes.

A. Committee Substitute – Statement of Substantial Changes:

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

Recommended CS/CS by Appropriations Subcommittee on Health and Human Services on April 9, 2019:

The committee substitute removes the requirement that state uniform fire safety standards apply to recovery residences.

CS by Children, Families, and Elder Affairs on March 11, 2019:

The committee substitute:

- Expresses legislative intent to expand the use of peer specialists as a cost-effective means of providing services to those with substance use disorders and/or mental illness.
- Encourages that peer specialists be reimbursed as a recovery service through DCF, a managing entity, or Medicaid, and encourages Medicaid managed care plans to use peer specialists in providing recovery services.
- Specifies that local governments are not prohibited from mandatory certification of recovery residences.
- Mandates that the Sober Homes Task Force within the Office of the State Attorney of the Fifteenth Judicial Circuit submit a report to the President of the Senate and the Speaker of the House of Representatives containing recommendations on mandatory statewide certification by January 1, 2020.

B. Amendments:

None.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR GAYLE HARRELL
25th District

COMMITTEES:
Health Policy, *Chair*
Appropriations Subcommittee on Health
and Human Services, *Vice Chair*
Appropriations Subcommittee on Criminal
and Civil Justice
Children, Families, and Elder Affairs
Military and Veterans Affairs and Space

JOINT COMMITTEE:
Joint Committee on Public Counsel Oversight

March 13, 2019

Senator Aaron Bean
405 Senate Building
404 South Monroe Street
Tallahassee, FL 32399

Chair Bean,

I respectfully request that **SB 900 – Substance Abuse Services** be placed on the next available agenda for the Appropriations Subcommittee on Health and Human Services Meeting. **SB 900** passed its last committee stop unanimously.

Should you have any questions or concerns, please feel free to contact my office. Thank you in advance for your consideration.

Thank you,

A handwritten signature in blue ink that reads "Gayle".

Senator Gayle Harrell
Senate District 25

Cc: Tonya Kidd, Staff Director
Robin Jackson, Committee Administrative Assistant

REPLY TO:

- 215 SW Federal Highway, Suite 203, Stuart, Florida 34994 (772) 221-4019
- 310 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5025

Senate's Website: www.flsenate.gov

BILL GALVANO
President of the Senate

DAVID SIMMONS
President Pro Tempore

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19

Meeting Date

900

Bill Number (if applicable)

122872

Amendment Barcode (if applicable)

Topic Substance Abuse Services

Name Austin Stowers

Job Title Deputy Director of Legislative Affairs

Address PL 11, The Capitol

Street

Phone (850) 413-2890

Tallahassee

FL

32399

Email Austin.Stowers@MyFloridaCFO.com

City

State

Zip

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Department of Financial Services

Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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4/9/19
Meeting Date

SB 900
Bill Number (if applicable)

Topic SUBSTANCE ABUSE SERVICES

Amendment Barcode (if applicable)

Name NATALIE KELLY

Job Title CEO

Address 122 S. CALHOUN ST.
JALAHASSEE FL 32301
Street City State Zip

Phone 850-570-5747
Email NATALIE@FLMANAGINGENTITIES.COM

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing FLORIDA ASSOCIATION OF MANAGING ENTITIES

Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4-9-19

Meeting Date

CS/SB 900

Bill Number (if applicable)

Topic Substance Abuse Services

Amendment Barcode (if applicable)

Name MARK FONTAINE

Job Title DIRECTOR

Address 2868 MAHAN DRIVE

Phone 878-2196

Street
TALLAHASSEE FL 32308

City State Zip
Email mfontaine@fadaa.org

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing FLORIDA Alcohol + Drug Abuse Association

Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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4/2/19

900

Meeting Date

Bill Number (if applicable)

Topic Mental health

Amendment Barcode (if applicable)

Name Alisa LaPort

Job Title Lobbyist

Address PO Box 1344

Phone 850-443-1319

Street TLH

Email alisa@go4psail.com

City TLH

State FL

Zip 32302

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing National Alliance on Mental Illness - Palm Beach

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19

SB 900

Meeting Date

Bill Number (if applicable)

Topic Peer counselors

Amendment Barcode (if applicable)

Name Neal McGarry

Job Title CEO

Address 1715 South Gadsden Street

Phone 850-222-6314

Street

Tallahassee

Florida

32301

Email namcgarry@flcertificationboard.org

City

State

Zip

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Florida Certification Board

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19
Meeting Date

SB 900
Bill Number (if applicable)

Topic Substance Abuse Services

Amendment Barcode (if applicable)

Name Gemma Sunnergren

Job Title Student

Address 1505 W Tharpe St, Apt 1133

Phone 954-304-3773

allahassee FL 32803
City State Zip

Email gemmasunn@gmail.com

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing League of Women Voters of Florida

Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19
Meeting Date

900
Bill Number (if applicable)

Topic Substance Abuse Services

Amendment Barcode (if applicable)

Name Devon West

Job Title Legislative Policy Advisor

Address 100 S. Andrews Ave., Main Library, 8th FL Phone 954-789-9293

Ft. Lauderdale FL 33301 Email dewest@broward.org
City State Zip

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Broward County Bd. of County Cmsrs.

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19

Meeting Date

900

Bill Number (if applicable)

Topic Substance Abuse Services

Amendment Barcode (if applicable)

Name Rebecca Delarosa

Job Title Legislative Affairs Director

Address 309 N Olive Ave. 1101.3

Phone 850 284-7235

Street West Palm Beach, FL 33407

Email rdelarosa@pb.org

City State Zip

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Palm Beach County

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4.9.19
Meeting Date

SB 900
Bill Number (if applicable)

Topic Sober Homes

Amendment Barcode (if applicable)

Name David Bernhardt

Job Title V.P. State Fraternal Order Police

Address _____
Street

Phone _____

City _____ State _____ Zip _____

Email Bernhardt@fop.com

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing FOP

Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

By the Committee on Children, Families, and Elder Affairs; and
Senator Harrell

586-02927-19

2019900c1

1 A bill to be entitled
2 An act relating to substance abuse services; amending
3 s. 394.4572, F.S.; authorizing the Department of
4 Children and Families and the Agency for Health Care
5 Administration to grant exemptions from
6 disqualification for certain service provider
7 personnel; amending s. 397.311, F.S.; redefining the
8 terms "clinical supervisor" and "recovery residence";
9 defining the terms "clinical services supervisor,"
10 "clinical director," and "peer specialist"; amending
11 s. 397.321, F.S.; providing for the review of certain
12 decisions by a department-recognized certifying
13 entity; authorizing certain persons to request an
14 administrative hearing within a specified timeframe
15 and under certain circumstances; amending s. 397.4073,
16 F.S.; requiring individuals screened on or after a
17 specified date to undergo specified background
18 screening; requiring the department to grant or deny a
19 request for an exemption from qualification within a
20 certain timeframe; authorizing certain applicants for
21 an exemption to work under the supervision of certain
22 persons for a specified period of time while his or
23 her application is pending; authorizing certain
24 persons to be exempt from disqualification from
25 employment; authorizing the department to grant
26 exemptions from disqualification for service provider
27 personnel to work solely in certain treatment programs
28 and facilities; amending s. 397.4075, F.S.; increasing
29 the criminal penalty for certain unlawful activities

Page 1 of 21

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

586-02927-19

2019900c1

30 relating to personnel; providing a criminal penalty
31 for inaccurately disclosing certain facts in an
32 application for licensure; creating s. 397.417, F.S.;
33 providing legislative intent; authorizing an
34 individual to seek certification as a peer specialist
35 if he or she meets certain requirements; requiring the
36 department to approve one or more third-party
37 credentialing entities for specified purposes;
38 requiring the credentialing entity to demonstrate
39 compliance with certain standards in order to be
40 approved by the department; requiring an individual
41 providing department-funded recovery support services
42 as a peer specialist to be certified; authorizing an
43 individual who is not certified to provide recovery
44 support services as a peer specialist under certain
45 circumstances; prohibiting an individual who is not a
46 certified peer specialist from advertising or
47 providing recovery services unless the person is
48 exempt; providing criminal penalties; authorizing the
49 department, a behavioral health managing entity, or
50 the Medicaid program to reimburse peer specialist
51 services as a recovery service; encouraging Medicaid
52 managed care plans to use peer specialists in
53 providing recovery services; amending s. 397.487,
54 F.S.; revising legislative findings relating to
55 voluntary certification of recovery residences;
56 revising background screening requirements for owners,
57 directors, and chief financial officers of recovery
58 residences; authorizing a certified recovery residence

Page 2 of 21

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2019900c1

59 to immediately discharge or transfer residents under
 60 certain circumstances; specifying that a local
 61 governmental entity is not prohibited from requiring
 62 mandatory certification of recovery residences for
 63 certain purposes; requiring the Sober Homes Task Force
 64 within the Office of the State Attorney of the
 65 Fifteenth Judicial Circuit to submit a report to the
 66 Legislature containing certain recommendations;
 67 amending s. 397.4873, F.S.; expanding the exceptions
 68 to limitations on referrals by recovery residences to
 69 licensed service providers; amending s. 397.55, F.S.;
 70 revising the requirements for a service provider,
 71 operator of a recovery residence, or certain third
 72 parties to enter into certain contracts with marketing
 73 providers; amending s. 435.07, F.S.; authorizing the
 74 exemption of certain persons from disqualification
 75 from employment; amending s. 553.80, F.S.; requiring
 76 that a single-family or two-family dwelling used as a
 77 recovery residence be deemed a single-family or two-
 78 family dwelling for purposes of the Florida Building
 79 Code; amending s. 633.206, F.S.; requiring the
 80 Department of Financial Services to establish uniform
 81 firesafety standards for recovery residences;
 82 exempting a single-family or two-family dwelling used
 83 as a recovery residence from the uniform firesafety
 84 standards; requiring that such dwellings be deemed a
 85 single-family or two-family dwelling for the purposes
 86 of the Life Safety Code and Florida Fire Prevention
 87 Code; amending ss. 212.055, 397.416, and 440.102,

Page 3 of 21

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586-02927-19

2019900c1

88 F.S.; conforming cross-references; providing an
 89 effective date.

90
 91 Be It Enacted by the Legislature of the State of Florida:

92
 93 Section 1. Subsection (2) of section 394.4572, Florida
 94 Statutes, is amended to read:

95 394.4572 Screening of mental health personnel.—

96 (2) (a) The department or the Agency for Health Care
 97 Administration may grant exemptions from disqualification as
 98 provided in chapter 435.

99 (b) The department or the Agency for Health Care
 100 Administration, as applicable, may grant exemptions from
 101 disqualification for service provider personnel to work solely
 102 in mental health treatment programs or facilities, or in
 103 programs or facilities that treat co-occurring substance use and
 104 mental health disorders.

105 Section 2. Present subsections (30) through (49) of section
 106 397.311, Florida Statutes, are redesignated as subsections (31)
 107 through (50), respectively, subsection (8) and present
 108 subsection (37) of that section are amended, and subsection (30)
 109 is added to that section, to read:

110 397.311 Definitions.—As used in this chapter, except part
 111 VIII, the term:

112 (8) “Clinical supervisor,” “clinical services supervisor,”
 113 or “clinical director” means a person who meets the requirements
 114 of a qualified professional and who manages personnel who
 115 provide direct clinical services, or who maintains lead
 116 responsibility for the overall coordination and provision of

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117 clinical services treatment.

118 (30) "Peer specialist" means a person who has been in
 119 recovery from a substance use disorder or mental illness for at
 120 least 2 years and who uses his or her personal experience to
 121 provide services in behavioral health settings, supporting
 122 others in their recovery; or a person who has at least 2 years
 123 of experience as a family member or caregiver of an individual
 124 who has a substance use disorder or mental illness. The term
 125 does not include a qualified professional or a person otherwise
 126 certified under chapter 394 or chapter 397.

127 (38)(37) "Recovery residence" means a residential dwelling
 128 unit, or other form of group housing, including group housing
 129 that is part of any licensable community housing component
 130 established by rule or statute, which ~~that~~ is offered or
 131 advertised through any means, including oral, written,
 132 electronic, or printed means, by any person or entity as a
 133 residence that provides a peer-supported, alcohol-free, and
 134 drug-free living environment.

135 Section 3. Subsection (15) of section 397.321, Florida
 136 Statutes, is amended to read:

137 397.321 Duties of the department.—The department shall:

138 (15) Recognize a statewide certification process for
 139 addiction professionals and identify and endorse one or more
 140 agencies responsible for such certification of service provider
 141 personnel. Any decision by a department-recognized certifying
 142 entity to deny, revoke, or suspend a certification, or otherwise
 143 impose sanctions on an individual who is certified, is
 144 reviewable by the department. Upon receiving an adverse
 145 determination, the person aggrieved may request an

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146 administrative hearing conducted pursuant to ss. 120.569 and
 147 120.57(1) within 30 days after completing any appeals process
 148 offered by the credentialing entity or the department, as
 149 applicable.

150 Section 4. Paragraphs (a), (f), and (g) of subsection (1),
 151 and subsection (4) of section 397.4073, Florida Statutes, are
 152 amended to read:

153 397.4073 Background checks of service provider personnel.—

154 (1) PERSONNEL BACKGROUND CHECKS; REQUIREMENTS AND
 155 EXCEPTIONS.—

156 (a) For all individuals screened on or after July 1, 2019,
 157 background checks shall apply as follows:

158 1. All owners, directors, chief financial officers, and
 159 clinical supervisors of service providers are subject to level 2
 160 background screening as provided under chapter 435 and s.
 161 408.809. Inmate substance abuse programs operated directly or
 162 under contract with the Department of Corrections are exempt
 163 from this requirement.

164 2. All service provider personnel who have direct contact
 165 with children receiving services or with adults who are
 166 developmentally disabled receiving services are subject to level
 167 2 background screening as provided under chapter 435 and s.
 168 408.809.

169 3. All peer specialists who have direct contact with
 170 individuals receiving services are subject to level 2 background
 171 screening as provided under chapter 435 and s. 408.809.

172 (f) Service provider personnel who request an exemption
 173 from disqualification must submit the request within 30 days
 174 after being notified of the disqualification. The department

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175 shall grant or deny the request within 60 days after receipt of
 176 a complete application.

177 (g) If 5 years or more have elapsed since an applicant for
 178 an exemption from disqualification has completed or has been
 179 lawfully released from confinement, supervision, or a
 180 nonmonetary condition imposed by a court for the applicant's
 181 most recent disqualifying offense, the applicant may work with
 182 adults with substance use disorders or co-occurring disorders
 183 under the supervision of persons who meet all personnel
 184 requirements of this chapter for up to 90 days after being
 185 notified of his or her disqualification or until the department
 186 makes a final determination regarding his or her request for an
 187 exemption from disqualification, whichever is earlier the most
 188 recent disqualifying offense, service provider personnel may
 189 work with adults with substance use disorders under the
 190 supervision of a qualified professional licensed under chapter
 191 490 or chapter 491 or a master's-level-certified addictions
 192 professional until the agency makes a final determination
 193 regarding the request for an exemption from disqualification.

194 (h)(g) The department may not issue a regular license to
 195 any service provider that fails to provide proof that background
 196 screening information has been submitted in accordance with
 197 chapter 435.

198 (4) EXEMPTIONS FROM DISQUALIFICATION.—

199 (a) The department may grant to any service provider
 200 personnel an exemption from disqualification as provided in s.
 201 435.07.

202 (b) Since rehabilitated substance abuse impaired persons
 203 are effective in the successful treatment and rehabilitation of

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204 individuals with substance use disorders, for service providers
 205 which treat adolescents 13 years of age and older, service
 206 provider personnel whose background checks indicate crimes under
 207 s. 796.07(2)(e), s. 810.02(4), s. 812.014(2)(c), s. 817.563, s.
 208 831.01, s. 831.02, s. 893.13, or s. 893.147, and any related
 209 criminal attempt, solicitation, or conspiracy under s. 777.04,
 210 may be exempted from disqualification from employment pursuant
 211 to this paragraph.

212 (c) The department may grant exemptions from
 213 disqualification for service provider personnel to work solely
 214 in substance use disorder treatment programs, facilities, or
 215 recovery residences or in programs or facilities that treat co-
 216 occurring substance use and mental health disorders. The
 217 department may further limit such grant exemptions from
 218 disqualification which would limit service provider personnel to
 219 working with adults in substance abuse treatment facilities.

220 Section 5. Section 397.4075, Florida Statutes, is amended
 221 to read:

222 397.4075 Unlawful activities relating to personnel;
 223 penalties.—It is a felony of the third misdemeanor of the first
 224 degree, punishable as provided in s. 775.082 or s. 775.083, for
 225 any person willfully, knowingly, or intentionally to:

226 (1) Inaccurately disclose by false statement,
 227 misrepresentation, impersonation, or other fraudulent means, or
 228 fail to disclose, in any application for licensure or voluntary
 229 or paid employment, any fact which is material in making a
 230 determination as to the person's qualifications to be an owner,
 231 a director, a volunteer, or other personnel of a service
 232 provider;

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233 (2) Operate or attempt to operate as a service provider
 234 with personnel who are in noncompliance with the minimum
 235 standards contained in this chapter; or

236 (3) Use or release any criminal or juvenile information
 237 obtained under this chapter for any purpose other than
 238 background checks of personnel for employment.

239 Section 6. Section 397.417, Florida Statutes, is created to
 240 read:

241 397.417 Peer Specialists.-

242 (1) The Legislature intends to expand the use of peer
 243 specialists as a cost-effective means of providing services by
 244 ensuring that peer specialists meet specified qualifications,
 245 meet modified background screening requirements, and are
 246 adequately reimbursed for their services.

247 (2) An individual may seek certification as a peer
 248 specialist if he or she has been in recovery from a substance
 249 use disorder or mental illness for at least 2 years, or if he or
 250 she has at least 2 years of experience as a family member or
 251 caregiver of a person with a substance use disorder or mental
 252 illness.

253 (3) The department shall approve one or more third-party
 254 credentialing entities for the purposes of certifying peer
 255 specialists, approving training programs for individuals seeking
 256 certification as peer specialists, approving continuing
 257 education programs, and establishing the minimum requirements
 258 and standards that applicants must achieve to maintain
 259 certification. To obtain approval, the third-party credentialing
 260 entity must demonstrate compliance with nationally recognized
 261 standards for developing and administering professional

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262 certification programs to certify peer specialists.

263 (4) An individual providing department-funded recovery
 264 support services as a peer specialist shall be certified
 265 pursuant to subsection (3). An individual who is not certified
 266 may provide recovery support services as a peer specialist for
 267 up to 1 year if he or she is working toward certification and is
 268 supervised by a qualified professional or by a certified peer
 269 specialist who has at least 3 years of full-time experience as a
 270 peer specialist at a licensed behavioral health organization.

271 (5) An individual who is not a certified peer specialist
 272 may not advertise recovery services to the public in any way, or
 273 by any medium; or provide recovery services as a peer
 274 specialist, unless the person is exempt under subsection (4).
 275 Any individual who violates this subsection commits a
 276 misdemeanor of the first degree, punishable as provided in s.
 277 775.082 or s. 775.083.

278 (6) Peer specialist services may be reimbursed as a
 279 recovery service through the department, a behavioral health
 280 managing entity, or the Medicaid program. Medicaid managed care
 281 plans are encouraged to use peer specialists in providing
 282 recovery services.

283 Section 7. Subsections (1) and (6) of section 397.487,
 284 Florida Statutes, are amended, and subsections (11), (12), and
 285 (13) are added to that section, to read:

286 397.487 Voluntary certification of recovery residences.-

287 (1) The Legislature finds that a person suffering from
 288 addiction has a higher success rate of achieving long-lasting
 289 sobriety when given the opportunity to build a stronger
 290 foundation by living in a recovery residence while receiving

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291 treatment or after completing treatment. The Legislature further
 292 finds that this state and its subdivisions have a legitimate
 293 state interest in protecting these persons, who represent a
 294 vulnerable consumer population in need of adequate housing. It
 295 is the intent of the Legislature to protect persons who reside
 296 in a recovery residence.

297 (6) All owners, directors, and chief financial officers of
 298 an applicant recovery residence are subject to level 2
 299 background screening as provided under chapter 435 and s.
 300 408.809. A recovery residence is ineligible for certification,
 301 and a credentialing entity shall deny a recovery residence's
 302 application, if any owner, director, or chief financial officer
 303 has been found guilty of, or has entered a plea of guilty or
 304 nolo contendere to, regardless of adjudication, any offense
 305 listed in s. 435.04(2) or s. 408.809(4) unless the department
 306 has issued an exemption under s. 397.4073 or s. 397.4872. In
 307 accordance with s. 435.04, the department shall notify the
 308 credentialing agency of an owner's, director's, or chief
 309 financial officer's eligibility based on the results of his or
 310 her background screening.

311 (11) Notwithstanding any landlord and tenant rights and
 312 obligations under chapter 83, a recovery residence that is
 313 certified under this section and that has a discharge policy
 314 approved by a credentialing entity may immediately discharge or
 315 transfer a resident under any of the following circumstances:

316 (a) The discharge or transfer is necessary for the
 317 resident's welfare.

318 (b) The resident's needs cannot be met at the recovery
 319 residence.

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320 (c) The health and safety of other residents or recovery
 321 residence employees is at risk or would be at risk if the
 322 resident continues to live at the recovery residence.

323 (12) This section does not prohibit a local governmental
 324 entity from requiring mandatory certification of recovery
 325 residences as part of a reasonable accommodation process to
 326 protect the health and safety of the residents.

327 (13) By January 1, 2020, the Sober Homes Task Force within
 328 the Office of the State Attorney of the Fifteenth Judicial
 329 Circuit shall submit a report to the President of the Senate and
 330 the Speaker of the House of Representatives which contains
 331 recommendations on mandatory statewide certification of recovery
 332 residences.

333 Section 8. Paragraph (d) is added to subsection (2) of
 334 section 397.4873, Florida Statutes, and subsection (1) of that
 335 section is republished, to read:

336 397.4873 Referrals to or from recovery residences;
 337 prohibitions; penalties.—

338 (1) A service provider licensed under this part may not
 339 make a referral of a prospective, current, or discharged patient
 340 to, or accept a referral of such a patient from, a recovery
 341 residence unless the recovery residence holds a valid
 342 certificate of compliance as provided in s. 397.487 and is
 343 actively managed by a certified recovery residence administrator
 344 as provided in s. 397.4871.

345 (2) Subsection (1) does not apply to:

346 (d) The referral of a patient to, or acceptance of a
 347 referral of such a patient from, a recovery residence that has
 348 no direct or indirect financial or other referral relationship

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349 with the provider and that is democratically operated by its
 350 residents pursuant to a charter from an entity recognized or
 351 sanctioned by Congress, and where the residence or any resident
 352 of the residence does not receive a benefit, directly or
 353 indirectly, for the referral.

354 Section 9. Paragraph (d) of subsection (1) of section
 355 397.55, Florida Statutes, is amended to read:

356 397.55 Prohibition of deceptive marketing practices.—

357 (1) The Legislature recognizes that consumers of substance
 358 abuse treatment have disabling conditions and that such
 359 consumers and their families are vulnerable and at risk of being
 360 easily victimized by fraudulent marketing practices that
 361 adversely impact the delivery of health care. To protect the
 362 health, safety, and welfare of this vulnerable population, a
 363 service provider, an operator of a recovery residence, or a
 364 third party who provides any form of advertising or marketing
 365 services to a service provider or an operator of a recovery
 366 residence may not engage in any of the following marketing
 367 practices:

368 (d) Entering into a contract with a marketing provider who
 369 agrees to generate referrals or leads for the placement of
 370 patients with a service provider or in a recovery residence
 371 through a call center or a web-based presence, unless the
 372 contract requires such agreement and the marketing provider
 373 ~~service provider or the operator of the recovery residence~~
 374 discloses the following to the prospective patient so that the
 375 patient can make an informed health care decision:

376 1. Information about the specific licensed service
 377 providers or recovery residences that are represented by the

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378 marketing provider and pay a fee to the marketing provider,
 379 including the identity of such service providers or recovery
 380 residences; and

381 2. Clear and concise instructions that allow the
 382 prospective patient to easily access lists of licensed service
 383 providers and recovery residences on the department website.

384 Section 10. Subsection (2) of section 435.07, Florida
 385 Statutes, is amended to read:

386 435.07 Exemptions from disqualification.—Unless otherwise
 387 provided by law, the provisions of this section apply to
 388 exemptions from disqualification for disqualifying offenses
 389 revealed pursuant to background screenings required under this
 390 chapter, regardless of whether those disqualifying offenses are
 391 listed in this chapter or other laws.

392 (2) Persons employed, or applicants for employment, by
 393 treatment providers who treat adolescents 13 years of age and
 394 older who are disqualified from employment solely because of
 395 crimes under s. 796.07(2)(e), s. 810.02(4), s. 812.014(2)(c), s.
 396 817.563, s. 831.01, s. 831.02, s. 893.13, or s. 893.147, or any
 397 related criminal attempt, solicitation, or conspiracy under s.
 398 777.04, may be exempted from disqualification from employment
 399 pursuant to this chapter without application of the waiting
 400 period in subparagraph (1)(a)1.

401 Section 11. Subsection (9) is added to section 553.80,
 402 Florida Statutes, to read:

403 553.80 Enforcement.—

404 (9) If a single-family or two-family dwelling is used as a
 405 recovery residence, as defined in s. 397.311, such dwelling
 406 shall be deemed a single-family or two-family dwelling for

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407 purposes of the Florida Building Code.

408 Section 12. Paragraph (b) of subsection (1) of section
409 633.206, Florida Statutes, is amended, and subsection (5) is
410 added to that section, to read:

411 633.206 Uniform firesafety standards—The Legislature hereby
412 determines that to protect the public health, safety, and
413 welfare it is necessary to provide for firesafety standards
414 governing the construction and utilization of certain buildings
415 and structures. The Legislature further determines that certain
416 buildings or structures, due to their specialized use or to the
417 special characteristics of the person utilizing or occupying
418 these buildings or structures, should be subject to firesafety
419 standards reflecting these special needs as may be appropriate.

420 (1) The department shall establish uniform firesafety
421 standards that apply to:

422 (b) All new, existing, and proposed hospitals, nursing
423 homes, assisted living facilities, adult family-care homes,
424 recovery residences, correctional facilities, public schools,
425 transient public lodging establishments, public food service
426 establishments, elevators, migrant labor camps, mobile home
427 parks, lodging parks, recreational vehicle parks, recreational
428 camps, residential and nonresidential child care facilities,
429 facilities for the developmentally disabled, motion picture and
430 television special effects productions, tunnels, and self-
431 service gasoline stations, of which standards the State Fire
432 Marshal is the final administrative interpreting authority.

433
434 In the event there is a dispute between the owners of the
435 buildings specified in paragraph (b) and a local authority

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436 requiring a more stringent uniform firesafety standard for
437 sprinkler systems, the State Fire Marshal shall be the final
438 administrative interpreting authority and the State Fire
439 Marshal's interpretation regarding the uniform firesafety
440 standards shall be considered final agency action.

441 (5) If a single-family or two-family dwelling is used as a
442 recovery residence, as defined in s. 397.311, such dwelling is
443 exempt from the uniform firesafety standards for recovery
444 residences and shall be deemed a single-family or two-family
445 dwelling for the purposes of the Life Safety Code and Florida
446 Fire Prevention Code.

447 Section 13. Paragraph (e) of subsection (5) of section
448 212.055, Florida Statutes, is amended to read:

449 212.055 Discretionary sales surtaxes; legislative intent;
450 authorization and use of proceeds.—It is the legislative intent
451 that any authorization for imposition of a discretionary sales
452 surtax shall be published in the Florida Statutes as a
453 subsection of this section, irrespective of the duration of the
454 levy. Each enactment shall specify the types of counties
455 authorized to levy; the rate or rates which may be imposed; the
456 maximum length of time the surtax may be imposed, if any; the
457 procedure which must be followed to secure voter approval, if
458 required; the purpose for which the proceeds may be expended;
459 and such other requirements as the Legislature may provide.
460 Taxable transactions and administrative procedures shall be as
461 provided in s. 212.054.

462 (5) COUNTY PUBLIC HOSPITAL SURTAX.—Any county as defined in
463 s. 125.011(1) may levy the surtax authorized in this subsection
464 pursuant to an ordinance either approved by extraordinary vote

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465 of the county commission or conditioned to take effect only upon
 466 approval by a majority vote of the electors of the county voting
 467 in a referendum. In a county as defined in s. 125.011(1), for
 468 the purposes of this subsection, "county public general
 469 hospital" means a general hospital as defined in s. 395.002
 470 which is owned, operated, maintained, or governed by the county
 471 or its agency, authority, or public health trust.

472 (e) A governing board, agency, or authority shall be
 473 chartered by the county commission upon this act becoming law.
 474 The governing board, agency, or authority shall adopt and
 475 implement a health care plan for indigent health care services.
 476 The governing board, agency, or authority shall consist of no
 477 more than seven and no fewer than five members appointed by the
 478 county commission. The members of the governing board, agency,
 479 or authority shall be at least 18 years of age and residents of
 480 the county. No member may be employed by or affiliated with a
 481 health care provider or the public health trust, agency, or
 482 authority responsible for the county public general hospital.
 483 The following community organizations shall each appoint a
 484 representative to a nominating committee: the South Florida
 485 Hospital and Healthcare Association, the Miami-Dade County
 486 Public Health Trust, the Dade County Medical Association, the
 487 Miami-Dade County Homeless Trust, and the Mayor of Miami-Dade
 488 County. This committee shall nominate between 10 and 14 county
 489 citizens for the governing board, agency, or authority. The
 490 slate shall be presented to the county commission and the county
 491 commission shall confirm the top five to seven nominees,
 492 depending on the size of the governing board. Until such time as
 493 the governing board, agency, or authority is created, the funds

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494 provided for in subparagraph (d)2. shall be placed in a
 495 restricted account set aside from other county funds and not
 496 disbursed by the county for any other purpose.

497 1. The plan shall divide the county into a minimum of four
 498 and maximum of six service areas, with no more than one
 499 participant hospital per service area. The county public general
 500 hospital shall be designated as the provider for one of the
 501 service areas. Services shall be provided through participants'
 502 primary acute care facilities.

503 2. The plan and subsequent amendments to it shall fund a
 504 defined range of health care services for both indigent persons
 505 and the medically poor, including primary care, preventive care,
 506 hospital emergency room care, and hospital care necessary to
 507 stabilize the patient. For the purposes of this section,
 508 "stabilization" means stabilization as defined in s. 397.311 ~~or~~
 509 ~~397.311(45)~~. Where consistent with these objectives, the plan
 510 may include services rendered by physicians, clinics, community
 511 hospitals, and alternative delivery sites, as well as at least
 512 one regional referral hospital per service area. The plan shall
 513 provide that agreements negotiated between the governing board,
 514 agency, or authority and providers shall recognize hospitals
 515 that render a disproportionate share of indigent care, provide
 516 other incentives to promote the delivery of charity care to draw
 517 down federal funds where appropriate, and require cost
 518 containment, including, but not limited to, case management.
 519 From the funds specified in subparagraphs (d)1. and 2. for
 520 indigent health care services, service providers shall receive
 521 reimbursement at a Medicaid rate to be determined by the
 522 governing board, agency, or authority created pursuant to this

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523 paragraph for the initial emergency room visit, and a per-member
 524 per-month fee or capitation for those members enrolled in their
 525 service area, as compensation for the services rendered
 526 following the initial emergency visit. Except for provisions of
 527 emergency services, upon determination of eligibility,
 528 enrollment shall be deemed to have occurred at the time services
 529 were rendered. The provisions for specific reimbursement of
 530 emergency services shall be repealed on July 1, 2001, unless
 531 otherwise reenacted by the Legislature. The capitation amount or
 532 rate shall be determined before program implementation by an
 533 independent actuarial consultant. In no event shall such
 534 reimbursement rates exceed the Medicaid rate. The plan must also
 535 provide that any hospitals owned and operated by government
 536 entities on or after the effective date of this act must, as a
 537 condition of receiving funds under this subsection, afford
 538 public access equal to that provided under s. 286.011 as to any
 539 meeting of the governing board, agency, or authority the subject
 540 of which is budgeting resources for the retention of charity
 541 care, as that term is defined in the rules of the Agency for
 542 Health Care Administration. The plan shall also include
 543 innovative health care programs that provide cost-effective
 544 alternatives to traditional methods of service and delivery
 545 funding.

546 3. The plan's benefits shall be made available to all
 547 county residents currently eligible to receive health care
 548 services as indigents or medically poor as defined in paragraph
 549 (4) (d).

550 4. Eligible residents who participate in the health care
 551 plan shall receive coverage for a period of 12 months or the

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552 period extending from the time of enrollment to the end of the
 553 current fiscal year, per enrollment period, whichever is less.

554 5. At the end of each fiscal year, the governing board,
 555 agency, or authority shall prepare an audit that reviews the
 556 budget of the plan, delivery of services, and quality of
 557 services, and makes recommendations to increase the plan's
 558 efficiency. The audit shall take into account participant
 559 hospital satisfaction with the plan and assess the amount of
 560 poststabilization patient transfers requested, and accepted or
 561 denied, by the county public general hospital.

562 Section 14. Section 397.416, Florida Statutes, is amended
 563 to read:

564 397.416 Substance abuse treatment services; qualified
 565 professional.—Notwithstanding any other provision of law, a
 566 person who was certified through a certification process
 567 recognized by the former Department of Health and Rehabilitative
 568 Services before January 1, 1995, may perform the duties of a
 569 qualified professional with respect to substance abuse treatment
 570 services as defined in this chapter, and need not meet the
 571 certification requirements contained in s. 397.311(35) ~~s.~~
 572 ~~397.311(34)~~.

573 Section 15. Paragraphs (d) and (g) of subsection (1) of
 574 section 440.102, Florida Statutes, are amended to read:

575 440.102 Drug-free workplace program requirements.—The
 576 following provisions apply to a drug-free workplace program
 577 implemented pursuant to law or to rules adopted by the Agency
 578 for Health Care Administration:

579 (1) DEFINITIONS.—Except where the context otherwise
 580 requires, as used in this act:

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581 (d) "Drug rehabilitation program" means a service provider
582 ~~as defined in s. 397.311 which, established pursuant to s.~~
583 ~~397.311(43), that~~ provides confidential, timely, and expert
584 identification, assessment, and resolution of employee drug
585 abuse.

586 (g) "Employee assistance program" means an established
587 program capable of providing expert assessment of employee
588 personal concerns; confidential and timely identification
589 services with regard to employee drug abuse; referrals of
590 employees for appropriate diagnosis, treatment, and assistance;
591 and followup services for employees who participate in the
592 program or require monitoring after returning to work. If, in
593 addition to the above activities, an employee assistance program
594 provides diagnostic and treatment services, these services shall
595 in all cases be provided by service providers as defined in s.
596 397.311 pursuant to s. 397.311(43).

597 Section 16. This act shall take effect July 1, 2019.



312576

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
04/10/2019	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services
(Harrell) recommended the following:

Senate Amendment (with directory and title amendments)

Delete lines 323 - 326.

===== **D I R E C T O R Y C L A U S E A M E N D M E N T**=====

And the directory clause is amended as follows:

Delete lines 284 - 285

and insert:

Florida Statutes, are amended, and subsections (11) and (12) are
added to that section, to read:



312576

11
12
13
14
15
16
17

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

And the title is amended as follows:

Delete lines 60 - 63

and insert:

 certain circumstances; requiring the Sober Homes Task
 Force



839894

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
04/10/2019	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services (Book)
recommended the following:

- 1 **Senate Substitute for Amendment (312576)**
- 2
- 3 Delete line 326
- 4 and insert:
- 5 ensure the health and safety of the residents.



122872

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/10/2019	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services
(Harrell) recommended the following:

Senate Amendment (with title amendment)

Delete lines 408 - 446.

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

And the title is amended as follows:

Delete lines 79 - 87

and insert:

Code; amending ss. 212.055, 397.416, and 440.102,

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL: PCS/CS/SB 1218 (253314)

INTRODUCER: Appropriations Subcommittee on Health and Human Services; Children, Families, and Elder Affairs Committee; and Senator Book

SUBJECT: Homelessness

DATE: April 11, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Delia</u>	<u>Hendon</u>	<u>CF</u>	<u>Fav/CS</u>
2.	<u>Sneed</u>	<u>Kidd</u>	<u>AHS</u>	<u>Recommend: Fav/CS</u>
3.	<u> </u>	<u> </u>	<u>AP</u>	<u> </u>

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 1218 creates a dedicated revenue source for challenge grants provided to the State Office on Homelessness and local homeless continuums of care (CoC), which are dedicated to preventing and ending homelessness throughout the state. The bill also increases the amount of funds each CoC may receive annually through challenge grants.

The bill makes a number of changes to chapter 420, F.S., relating to homelessness, with the aim of bringing state law in line with corresponding federal statutes in order to eliminate outdated provisions and allow sources of federal funding matches to be accessed on an expedited basis.

The bill, subject to appropriation, may reduce funding available in the State and Local Housing Trust Funds and, if appropriated, direct the transfer of those funds (up to \$10 million annually) to the Grants and Donations Trust Fund in the Department of Children and Families for challenge grants. See Section V.

The bill takes effect July 1, 2019.

II. Present Situation:

Housing for Individuals with Lower Incomes

In 1986¹ the Legislature found that:

- Decent, safe, and sanitary housing for individuals of very low income, low income, and moderate income is a critical need in the state;
- New and rehabilitated housing must be provided at a cost affordable to such persons in order to alleviate this critical need;
- Special programs are needed to stimulate private enterprise to build and rehabilitate housing in order to help eradicate slum conditions and provide housing for very-low-income persons, low-income persons, and moderate-income persons as a matter of public purpose; and
- Public-private partnerships are an essential means of bringing together resources to provide affordable housing.²

As a result of these findings, the Legislature determined that legislation was urgently needed to alleviate crucial problems related to housing shortages for individuals with very low,³ low⁴ and moderate⁵ incomes. In 1986, part VI of ch. 420, F.S., was titled as the “Florida Affordable Care Act of 1986”⁶ and programs and funding mechanisms were created over the years to help remedy low-income housing issues.

State Office on Homelessness

In 2001, the Legislature created the State Office on Homelessness within the Department of Children and Families (DCF) to serve as a central point of contact within state government on issues relating to homelessness. The state office is responsible for coordinating resources and programs across all levels of government, and with private providers that serve the homeless. It also manages targeted state grants to support the implementation of local homeless service continuum of care plans.⁷

¹ Chapter 86-192, Laws of Fla.

² Section 420.6015, F.S.

³ “Very-low-income persons” means one or more persons or a family, the total annual adjusted gross household income of which does not exceed 50 percent of the median annual adjusted gross income for households within the state, or 50 percent of the median annual adjusted gross income for households within the metropolitan statistical area (MSA) or within the county in which the person or family resides, whichever is greater.

⁴ “Low-income persons” means one or more persons or a family, the total annual adjusted gross household income of which does not exceed 80 percent of the median annual adjusted gross income for households within the state, or 80 percent of the median annual adjusted gross income for households within the metropolitan statistical area (MSA) or within the county in which the person or family resides, whichever is greater.

⁵ “Moderate-income persons” means one or more persons or a family, the total annual adjusted gross household income of which is less than 120 percent of the median annual adjusted gross income for households within the state, or 120 percent of the median annual adjusted gross income for households within the metropolitan statistical area (MSA) or within the county in which the household is located, whichever is greater.

⁶ Chapter 86-192, Laws of Fla., Part VI, was subsequently renamed the “Affordable Housing Planning and Community Assistance Act.” Chapter 92-317, Laws of Fla.

⁷ Section 420.622(1), F.S.

Council on Homelessness

The Legislature also created the inter-agency Council on Homelessness in 2001. The 17-member council develops recommendations on how to reduce homelessness statewide and advises the State Office on Homelessness.⁸ The council includes:

- The Secretary of Children and Families, or his or her designee;
- The executive director of the Department of Economic Opportunity, or his or her designee, who shall advise the council on issues related to rural development;
- The State Surgeon General, or his or her designee;
- The Executive Director of Veterans' Affairs, or his or her designee;
- The Secretary of Corrections, or his or her designee;
- The Secretary of Health Care Administration, or his or her designee;
- The Commissioner of Education, or his or her designee;
- The Director of CareerSource Florida, Inc., or his or her designee;
- One representative of the Florida Association of Counties;
- One representative of the Florida League of Cities;
- One representative of the Florida Supportive Housing Coalition;
- The Executive Director of the Florida Housing Finance Corporation, or his or her designee;
- One representative of the Florida Coalition for the Homeless; and
- Four members appointed by the Governor.⁹

Local Coalitions for the Homeless

DCF is required to establish local coalitions to plan, network, coordinate, and monitor the delivery of services to the homeless.¹⁰ Groups and organizations provided the opportunity to participate in such coalitions include:

- Organizations and agencies providing mental health and substance abuse services;
- County health departments and community health centers;
- Organizations and agencies providing food, shelter, or other services targeted to the homeless;
- Local law enforcement agencies;
- Local workforce development boards;
- County and municipal governments;
- Local public housing authorities;
- Local school districts;
- Local organizations and agencies serving specific subgroups of the homeless population such as veterans, victims of domestic violence, persons with HIV/AIDS, and runaway youth; and
- Local community-based care alliances.¹¹

Local Homeless Assistance Continuum of Care

A local homeless assistance continuum of care is a framework for a comprehensive and seamless array of emergency, transitional, and permanent housing, and services to address the

⁸ *Id.*

⁹ Section 420.622(2), F.S.

¹⁰ Section 420.623, F.S.

¹¹ *Id.*

various needs of the homeless and those at risk of homelessness. The purpose of a local homeless assistance continuum of care is to help communities or regions envision, plan, and implement comprehensive and long-term solutions to the problem of homelessness in a community or region.¹²

DCF interacts with the state's 27 CoCs through the State Office on Homelessness, which serves as the state's central point of contact on homelessness. The state office has designated local entities to serve as lead agencies for local planning efforts to create homeless assistance CoC systems. The state office has made these designations in consultation with the local homeless coalitions and the Florida offices of the federal Department of Housing and Urban Development (HUD).

The CoC planning effort is an ongoing process that addresses all subpopulations of the homeless. The development of a local CoC plan is a prerequisite to applying for federal housing grants through HUD. The plan also makes the community eligible to compete for the state's Challenge Grants and Homeless Housing Assistance Grants.¹³

Challenge Grants

The State Office on Homelessness is authorized to accept and administer moneys appropriated to it to provide challenge Grants annually to the designated CoC lead agencies.¹⁴ The State Office on Homelessness may award grants in an amount of up to \$500,000 per lead agency.¹⁵ A lead agency may spend a maximum of 8 percent of its funding on administrative costs. To qualify for a challenge Grant, the lead agency must develop and implement a local homeless assistance continuum of care plan for its designated area.¹⁶ There is no dedicated revenue for these grants which in the past have been funded by the Sadowski State and Local Housing Trust Funds, general revenue, and various state trust funds.

Pursuant to s. 420.624, F.S., the DCF provides funding for local homeless assistance CoC, which is a framework for providing an array of emergency, transitional, and permanent housing, and services to address the various needs of homeless persons and persons at risk of becoming homeless.

In 2017, the Collier homeless coalition used the challenge grant to help the Shelter for Abused Women & Children with staffing of two case managers who work in outreach and transitional housing, and the remainder of the funds provided emergency rental or utility assistance to nearly 89 adults and 129 children.¹⁷ The Volusia/Flagler coalition has utilized challenge grant funding to help lower-income residents pay rent following job losses, car accidents, and other costly

¹² *Id.*

¹³ Florida Department of Children and Families, *Lead Agencies*, available at: <http://www.myflfamilies.com/service-programs/homelessness/> (last visited April 3, 2019).

¹⁴ "Section 420.621(1), F.S., defines "Continuum of Care" to mean the community components needed to organize and deliver housing and services to meet the specific needs of people who are homeless as they move to stable housing and maximum self-sufficiency. It includes action steps to end homelessness and prevent a return to homelessness."

¹⁵ Section 420.622, F.S.

¹⁶ *Id.*

¹⁷ <https://www.news-press.com/story/news/2018/07/04/gov-rick-scott-acts-resolve-homeless-grant-funding-southwest-florida-agencies/757846002/> (last visited April 3, 2019).

expenses.¹⁸ The Tampa-Hillsborough Homeless Initiative has used challenge grant money to establish a financial incentive program for developers, landlords, and property owners which has been successful at reducing levels of homelessness throughout Hillsborough County.¹⁹

Rapid ReHousing

Rapid ReHousing is a model for providing housing for individuals and families who are homeless. The model places a priority on moving a family or individual experiencing homelessness into permanent housing as quickly as possible, ideally within 30 days. While originally focused primarily on people experiencing homelessness due to short-term financial crises, programs across the country have begun to assist individuals and families who are traditionally perceived as more difficult to serve. This includes people with limited or no income, survivors of domestic violence, and those with substance abuse issues. Although the duration of financial assistance may vary, many programs find that, on average, four to six months of financial assistance is sufficient to stably re-house a household.²⁰

Since federal funding for Rapid ReHousing first became available in 2008, a number of Florida communities, including Palm Beach County, that prioritized Rapid ReHousing as a response to homelessness, have seen decreases in the amount of time households are homeless, less recidivism, and improved permanent housing outcomes relative to other available interventions.²¹

There are three core components of Rapid ReHousing programs:

- Housing identification services: Households are matched to appropriate and affordable housing in the community.
- Financial assistance for housing related expenses: Time-limited financial assistance is provided to get individuals and families back on their feet.
- Case management services: Case management services are provided to help households address barriers that prevent access to or stability in stable housing.²²

While all three components are present and available in effective Rapid ReHousing programs, there are instances where the components are provided by different entities or agencies, or where a household does not utilize all three.²³ A key element of Rapid ReHousing is the “Housing First” philosophy, which offers housing without preconditions such as employment, income, lack of a criminal background, or sobriety. If issues such as these need to be addressed, the household can address them most effectively once they are in housing.²⁴

¹⁸ <https://www.gainesville.com/news/20180703/state-moves-to-fund-homeless-programs> (last visited April 3, 2019).

¹⁹ The University of Tampa, *Cypress Landing Cost-Benefit Analysis Report*, (2015), on file with the Senate Children, Families, and Elder Affairs Committee.

²⁰ National Alliance to End Homelessness, *Rapid ReHousing: A History and Core Components*, (2014), available at: <http://www.endhomelessness.org/library/entry/rapid-re-housing-a-history-and-core-components> (last visited March 15, 2019).

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ The Florida Legislature expressed the intent to encourage homeless continuums of care to adopt the Housing First approach to ending homelessness for individuals and families in 2009. See s. 420.6275, F.S.

III. Effect of Proposed Changes:

Section 1 amends s. 201.15, F.S., requiring that, subject to appropriation, up to \$10 million of all document stamp tax money collected annually by the state may be transferred to the Grants and Donations Trust Fund in the Department of Children and Families (DCF) for the Challenge Grant program.

Section 2 amends s. 420.621, F.S., modifying the definition of ‘continuum of care’ to mean a group organized to carry out responsibilities pursuant to ch. 420, F.S., to coordinate, plan, and pursue ending homelessness in a designated catchment area. The bill provides that a CoC should be comprised of local community organizations to the extent that they are represented within the catchment area and available to participate.

The bill defines “continuum of care lead agency” or “continuum of care collaborative applicant” as the organization designated by a CoC pursuant to s. 420.6225, F.S.

The bill also redefines ‘homeless’ to mean either:

- An individual or family who lacks a fixed, regular, and adequate nighttime residence *as defined under “homeless”* as defined in 24 C.F.R. 578.3.²⁵
- An individual or family who will immediately lose their primary nighttime residence *as defined under “homeless”* as defined in 24 C.F.R. 578.3.²⁶

Section 3 amends s. 420.622, F.S., adding one representative of the Florida Housing Coalition and the Secretary of the Department of Elder Affairs, or his or her designee, to the Council on Homelessness. The bill provides that members of the council are encouraged to have experience in the administration or provision of resources, services, or housing that addresses the needs of persons experiencing homelessness.

The bill replaces the term “regionally developed plans” with the term “local continuum of care plans” to bring state statute in line with federal law. The bill also requires the State Office on Homelessness to collect, maintain, and make available information concerning persons who are

²⁵ “Homeless” is defined in 24 C.F.R. 578.3 as:

- (1) An individual or family who lacks a fixed, regular, and adequate nighttime residence, meaning:
 - (i) An individual or family with a primary nighttime residence that is a public or private place not designed for or ordinarily used as a regular sleeping accommodation for human beings, including a car, park, abandoned building, bus or train station, airport, or camping ground;
 - (ii) An individual or family living in a supervised publicly or privately operated shelter designated to provide temporary living arrangements (including congregate shelters, transitional housing, and hotels and motels paid for by charitable organizations or by federal, State, or local government programs for low-income individuals); or
 - (iii) An individual who is exiting an institution where he or she resided for 90 days or less and who resided in an emergency shelter or place not meant for human habitation immediately before entering that institution.

²⁶ “Homeless” is defined in 24 C.F.R. 578.3 as:

- (2) An individual or family who will imminently lose their primary nighttime residence, provided that:
 - (i) The primary nighttime residence will be lost within 14 days of the date of application for homeless assistance;
 - (ii) No subsequent residence has been identified; and
 - (iii) The individual or family lacks the resources or support networks, *e.g.*, family, friends, faith-based or other social networks, needed to obtain other permanent housing.

homeless, including summary demographics information drawn from the local continuum of care Housing Inventory Chart required by HUD. The bill replaces all instances of the term “local homeless continuum of care” and “local homeless assistance coalition” with ‘continuum of care.’”

The bill also revises the goals of the State Office on Homelessness to promote a federal policy agenda that is responsive to the needs of those who are homeless or at risk of homelessness, rather than only the current homeless population. The bill modifies policy objectives to reflect an emphasis on ending homelessness in the state, as opposed to meeting the needs of the homeless.

The bill increases the amount of funds available to each CoC for challenge grants from \$500,000 to \$750,000 per continuum of care lead agency, and requires each CoC lead agency to document the commitment of local government or private organizations to provide matching funds or in-kind support in an amount equal to 25 percent of the grant requested.

Section 4 creates s. 420.6225, to provide that the purpose of a CoC is to coordinate community efforts to prevent and end homelessness in its catchment area. The bill requires each CoC to designate a collaborative applicant that is responsible for submitting a CoC funding application for the designated catchment area to HUD. The bill provides that the collaborative applicant will be serve as the point of contact to the State Office on Homelessness. The bill also requires CoC catchment areas to be designated and revised as necessary by the State Office on Homelessness, and the catchment areas must be consistent with the CoC catchment areas recognized by HUD. The bill provides that the State Office on Homelessness must recognize only one CoC lead agency for each catchment area.

The bill requires each CoC to create a ‘continuum of care plan,’ which must include outreach to unsheltered individuals and families, a coordinated entry system for services, identification of emergency shelters, identification of permanent supportive housing, Rapid Rehousing, and an ongoing planning mechanism to homelessness for all subpopulations of persons experiencing homelessness.

The bill also requires CoCs to promote participation by all interested individuals and organizations and may not exclude anyone on the basis of race, color, national origin, sex, handicap, familial status, or religion. The bill provides for coordination of these individuals and organizations, to the extent possible, with other mainstream health and social services.

Section 5 creates s. 420.6227, F.S., to create a new version of the grant-in-aid program existing under current law in s. 420.625, F.S. The new section replaces references to “local agencies” with references to “continuums of care” in order to bring the state grant-in-aid program in line with federal statutes and ultimately allow federal matching dollars to be drawn down more efficiently. The bill provides that the purpose of the grant-in-aid program is to assist individuals who are or may become homeless, and to help homeless households move to permanent housing as quickly as possible.

Section 6 repeals s. 420.623, F.S., relating to local coalitions for the homeless.

Section 7 repeals s. 420.624, F.S., relating to local homeless assistance continuums of care.

Section 8 repeals s. 420.625, F.S., relating to the grant-in-aid program.

Section 9 amends s. 420.626, F.S., making technical revisions to discharge guidelines for homelessness facilities and institutions.

Section 10 amends s. 420.6265, F.S., to revise legislative intent with respect to Rapid ReHousing. The bill provides that Rapid ReHousing should employ temporary financial assistance for the purposes of both quickly moving families and individuals into permanent housing and using housing stabilization support services to help them remain stably housed. The bill provides legislative findings and intent that Rapid ReHousing has proven to be a cost-effective approach to ending homelessness, and is demonstrably proven to be more cost-effective than alternative approaches.

Section 11 amends s. 420.6275, F.S., to revise legislative intent with respect to the Housing First methodology. The bill provides findings that Housing First is a cost-effective approach to ending homelessness and reducing the length of time of homelessness for many individuals and families. The bill also provides legislative intent to emphasize maintaining stable housing under the Housing First approach.

Section 12 amends s. 420.507, F.S., to correct cross references.

Section 13 provides an effective date of July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

PCS/CS/SB 1218 will direct \$10 million annually from the State and Local Housing Trust Funds to the Department of Children and Families (DCF) for challenge grants, if an appropriation is made to do so.

B. Private Sector Impact:

None.

C. Government Sector Impact:

Subject to an appropriation, the bill will reduce the funding available in the State and Local Housing Trust Funds and directs those funds (up to \$10 million annually) be transferred to the Grants and Donations Trust Fund in the DCF for challenge grants. Funding for Challenge Grants totaled \$4.1 million statewide for the 2018-2019 fiscal year.²⁷

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 201.15, 420.621, 420.622, 420.626, 420.6265, 420.6275, and 420.507.

This bill creates the following sections of the Florida Statutes: 420.6225 and 420.6227.

This bill repeals the following sections of the Florida Statutes: 420.623, 420.624, and 420.625.

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

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

Recommended CS/CS by Appropriations Subcommittee on Health and Human Services on April 9, 2019:

The committee substitute makes the transfer to the Grants and Donations Trust Fund in the DCF for challenge grants subject to appropriation.

²⁷ Specific Appropriation 345, General Appropriations Act, Ch. 2018-9, Laws of Fla.

CS by Children, Families, and Elder Affairs on March 25, 2019:

- The committee substitute removes the ability of the Florida Housing Finance Corporation to add additional populations to the definition of homelessness.

B. Amendments:

None.

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



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Children, Families, and Elder Affairs, *Chair*
Appropriations
Appropriations Subcommittee on Education
Appropriations Subcommittee on Health and Human
Services
Health Policy
Rules

JOINT COMMITTEE:

Joint Legislative Budget Commission

SENATOR LAUREN BOOK

32nd District

March 28, 2018

Chair Aaron Bean
Appropriations Subcommittee on Health and Human Services
201 The Capitol
404 S. Monroe Street
Tallahassee, FL 32399-1100

Chair Bean:

I respectfully request that **CS/SB 1218—Homelessness** be placed on the agenda for the next Appropriations Subcommittee on Health and Human Services meeting.

Should you have any questions or concerns, please feel free to contact my office or me. Thank you in advance for your consideration.

Thank you,

A handwritten signature in cursive script that reads "Lauren Book".

Senator Lauren Book
Senate District 32

Cc: Allen Brown, Staff Director
Celia Georgiades, Administrative Assistant

REPLY TO:

- 967 Nob Hill Road, Plantation, Florida 33324 (954) 424-6674
- 202 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5032

Senate's Website: www.flsenate.gov

BILL GALVANO
President of the Senate

DAVID SIMMONS
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19
Meeting Date

SBI218
Bill Number (if applicable)

Topic Homelessness

Amendment Barcode (if applicable)

Name Lauren Jackson

Job Title

Address 205 S. Adams St.

Phone 931-265-8999

Tallahassee FL 32301
City State Zip

Email Lauren@ericksconsultants.com

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing FL Association of Counties

Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19
Meeting Date

SB 1218
Bill Number (if applicable)

Topic Homelessness

Amendment Barcode (if applicable)

Name Robert Beck

Job Title Partner, PinPoint Results

Address 150 S. Monroe Suite 303

Phone 766 1410

Tall FL 32301
City State Zip

Email Robert@PinPointResults.com

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Florida Coalition for the Homeless

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19
Meeting Date

1218
Bill Number (if applicable)

Topic Homelessness

Amendment Barcode (if applicable)

Name Devon West

Job Title Legislative Policy Advisor

Address 100 S. Andrews Ave, Main Library, 9th Fl Phone 954-789-9293

Ft. Lauderdale FL 33301 Email dewest@broward.org
City State Zip

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Broward County Bd. of County Comrs.

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

By the Committee on Children, Families, and Elder Affairs; and
Senator Book

586-03487-19

20191218c1

1 A bill to be entitled
2 An act relating to homelessness; amending s. 201.15,
3 F.S.; requiring that certain taxes of a specified
4 amount be transferred annually to the Grants and
5 Donations Trust Fund within the Department of Children
6 and Families for the purpose of funding challenge
7 grants; amending s. 420.621, F.S.; revising, adding,
8 and deleting defined terms; amending s. 420.622, F.S.;
9 increasing the number of members on the Council on
10 Homelessness to include a representative of the
11 Florida Housing Coalition and the Secretary of the
12 Department of Elder Affairs or his or her designee;
13 providing that appointed council members are
14 encouraged to have certain experience; revising the
15 duties of the State Office on Homelessness; revising
16 requirements for the state's system of homeless
17 programs; requiring entities that receive state
18 funding to provide summary aggregated data to assist
19 the council in providing certain information; removing
20 the requirement that the office have the concurrence
21 of the council to accept and administer moneys
22 appropriated to it to provide certain annual challenge
23 grants to continuums of care lead agencies; clarifying
24 the source of such appropriation; increasing the
25 maximum amount of grant awards per continuum of care
26 lead agency; conforming provisions to changes made by
27 the act; revising requirements for use of grant funds
28 by continuum of care lead agencies; revising
29 preference criteria for certain grants; increasing the

Page 1 of 29

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

586-03487-19

20191218c1

30 maximum percentage of its funding which a continuum of
31 care lead agency may spend on administrative costs;
32 requiring such agencies to submit a final report to
33 the Department of Children and Families documenting
34 certain outcomes achieved by grant-funded programs;
35 removing the requirement that the office have the
36 concurrence of the council to administer moneys given
37 to it to provide homeless housing assistance grants
38 annually to certain continuum of care lead agencies to
39 acquire, construct, or rehabilitate permanent housing
40 units for homeless persons; conforming a provision to
41 changes made by the act; requiring grant applicants to
42 be ranked competitively based on criteria determined
43 by the office; deleting preference requirements;
44 increasing the minimum number of years for which
45 projects must reserve certain units acquired,
46 constructed, or rehabilitated; increasing the maximum
47 percentage of funds the office and each applicant may
48 spend on administrative costs; revising certain
49 performance measure requirements; authorizing, instead
50 of requiring, the Department of Children and Families,
51 with input from the council, to adopt rules relating
52 to certain grants and related issues; revising
53 requirements for an annual report the council must
54 submit to the Governor, Legislature, and Secretary of
55 Children and Families; authorizing the office to
56 administer moneys appropriated to it for distribution
57 among certain designated continuum of care lead
58 agencies and entities; creating s. 420.6225, F.S.;

Page 2 of 29

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

586-03487-19

20191218c1

59 specifying the purpose of a continuum of care;
 60 requiring each continuum of care, pursuant to federal
 61 law, to designate a collaborative applicant that is
 62 responsible for submitting the continuum of care
 63 funding application for the designated catchment area
 64 to the United States Department of Housing and Urban
 65 Development; providing requirements for such
 66 designated collaborative applicants; authorizing the
 67 applicant to be referred to as the continuum of care
 68 lead agency; providing requirements for continuum of
 69 care catchment areas and lead agencies; requiring that
 70 each continuum of care create a continuum of care plan
 71 for specified purposes; specifying requirements for
 72 such plans; requiring continuums of care to promote
 73 participation by all interested individuals and
 74 organizations, subject to certain requirements;
 75 creating s. 420.6227, F.S.; providing legislative
 76 findings and program purpose; establishing a grant-in-
 77 aid program to help continuums of care prevent and end
 78 homelessness, which may include any aspect of the
 79 local continuum of care plan; requiring continuums of
 80 care to submit an application for grant-in-aid funds
 81 to the office for review; requiring the office to
 82 develop guidelines for the development, evaluation,
 83 and approval of spending plans; requiring grant-in-aid
 84 funds for continuums of care to be administered by the
 85 office and awarded on a competitive basis; requiring
 86 the office to distribute such funds to local agencies
 87 to fund programs that are required by the local

Page 3 of 29

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

586-03487-19

20191218c1

88 continuum of care plan, based on certain
 89 recommendations; limiting the percentage of the total
 90 state funds awarded under a spending plan which may be
 91 used by the continuum of care lead agency for staffing
 92 and administrative expenditures; requiring entities
 93 contracting with local agencies to provide services
 94 through certain financial assistance programs to
 95 provide a specified minimum percentage of the funding
 96 necessary for the support of project operations;
 97 authorizing in-kind contributions to be evaluated and
 98 counted as part or all of the required local funding,
 99 at the discretion of the office; repealing s. 420.623,
 100 F.S., relating to local coalitions for the homeless;
 101 repealing s. 420.624, F.S., relating to local homeless
 102 assistance continuums of care; repealing s. 420.625,
 103 F.S., relating to a grant-in-aid program; amending s.
 104 420.626, F.S.; revising procedures that certain
 105 facilities and institutions are encouraged to develop
 106 and implement to reduce the discharge of persons into
 107 homelessness when such persons are admitted or housed
 108 for a specified period at such facilities or
 109 institutions; amending s. 420.6265, F.S.; revising
 110 legislative findings and intent for Rapid ReHousing;
 111 revising the Rapid ReHousing methodology; amending s.
 112 420.6275, F.S.; revising legislative findings relating
 113 to Housing First; revising the Housing First
 114 methodology to reflect current practice; amending s.
 115 420.507, F.S.; conforming cross-references; providing
 116 an effective date.

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

Section 1. Paragraph (c) of subsection (4) of section 201.15, Florida Statutes, is amended, and subsection (5) of that section is republished, to read:

201.15 Distribution of taxes collected.—All taxes collected under this chapter are hereby pledged and shall be first made available to make payments when due on bonds issued pursuant to s. 215.618 or s. 215.619, or any other bonds authorized to be issued on a parity basis with such bonds. Such pledge and availability for the payment of these bonds shall have priority over any requirement for the payment of service charges or costs of collection and enforcement under this section. All taxes collected under this chapter, except taxes distributed to the Land Acquisition Trust Fund pursuant to subsections (1) and (2), are subject to the service charge imposed in s. 215.20(1). Before distribution pursuant to this section, the Department of Revenue shall deduct amounts necessary to pay the costs of the collection and enforcement of the tax levied by this chapter. The costs and service charge may not be levied against any portion of taxes pledged to debt service on bonds to the extent that the costs and service charge are required to pay any amounts relating to the bonds. All of the costs of the collection and enforcement of the tax levied by this chapter and the service charge shall be available and transferred to the extent necessary to pay debt service and any other amounts payable with respect to bonds authorized before January 1, 2017, secured by revenues distributed pursuant to this section. All

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taxes remaining after deduction of costs shall be distributed as follows:

(4) After the required distributions to the Land Acquisition Trust Fund pursuant to subsections (1) and (2) and deduction of the service charge imposed pursuant to s. 215.20(1), the remainder shall be distributed as follows:

(c) Eleven and twenty-four hundredths percent of the remainder in each fiscal year shall be paid into the State Treasury to the credit of the State Housing Trust Fund. Of such funds, the first \$35 million shall be transferred annually, subject to any distribution required under subsection (5), to the State Economic Enhancement and Development Trust Fund within the Department of Economic Opportunity. The next \$10 million shall be transferred annually, subject to any distribution required under subsection (5), to the Grants and Donations Trust Fund within the Department of Children and Families for the purpose of funding the challenge grants established in s. 420.622(4). The remainder shall be used as follows:

1. Half of that amount shall be used for the purposes for which the State Housing Trust Fund was created and exists by law.

2. Half of that amount shall be paid into the State Treasury to the credit of the Local Government Housing Trust Fund and used for the purposes for which the Local Government Housing Trust Fund was created and exists by law.

(5) Distributions to the State Housing Trust Fund pursuant to paragraphs (4)(c) and (d) must be sufficient to cover amounts required to be transferred to the Florida Affordable Housing Guarantee Program's annual debt service reserve and guarantee

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175 fund pursuant to s. 420.5092(6) (a) and (b) up to the amount
 176 required to be transferred to such reserve and fund based on the
 177 percentage distribution of documentary stamp tax revenues to the
 178 State Housing Trust Fund which is in effect in the 2004-2005
 179 fiscal year.

180 Section 2. Section 420.621, Florida Statutes, is amended to
 181 read:

182 420.621 Definitions.—As used in ss. 420.621-420.628, the
 183 term:

184 (1) "Continuum of care" means the group organized to carry
 185 out the responsibilities imposed under ss. 420.621-420.628 to
 186 coordinate, plan, and pursue ending homelessness in a designated
 187 catchment area. The group is composed of representatives from
 188 certain organizations, including, but not limited to, nonprofit
 189 homeless providers, victim service providers, faith-based
 190 organizations, governments, businesses, advocates, public
 191 housing agencies, school districts, social service providers,
 192 mental health agencies, hospitals, universities, affordable
 193 housing developers, law enforcement, organizations that serve
 194 homeless and formerly homeless veterans, and organizations that
 195 serve homeless and formerly homeless persons, to the extent that
 196 these organizations are represented within the designated
 197 catchment area and are available to participate the community
 198 components needed to organize and deliver housing and services
 199 to meet the specific needs of people who are homeless as they
 200 move to stable housing and maximum self-sufficiency. It includes
 201 action steps to end homelessness and prevent a return to
 202 homelessness.

203 (2) "Continuum of care lead agency" or "continuum of care

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204 collaborative applicant" means the organization designated by a
 205 continuum of care pursuant to s. 420.6225.

206 ~~(3)(2)~~ "Council on Homelessness" means the council created
 207 in s. 420.622.

208 ~~(4)(3)~~ "Department" means the Department of Children and
 209 Families.

210 ~~(4) "District" means a service district of the department,~~
 211 ~~as set forth in s. 20.19.~~

212 (5) "Homeless," means any of the following:

213 (a) An individual or family who lacks a fixed, regular, and
 214 adequate nighttime residence as defined under "homeless" in 24
 215 C.F.R. 578.3.

216 (b) An individual or family who will imminently lose their
 217 primary nighttime residence as defined under "homeless" in 24
 218 C.F.R. 578.3 applied to an individual, or "individual
 219 experiencing homelessness" means an individual who lacks a
 220 fixed, regular, and adequate nighttime residence and includes an
 221 individual who:

222 ~~(a) Is sharing the housing of other persons due to loss of~~
 223 ~~housing, economic hardship, or a similar reason;~~

224 ~~(b) Is living in a motel, hotel, travel trailer park, or~~
 225 ~~camping ground due to a lack of alternative adequate~~
 226 ~~accommodations;~~

227 ~~(c) Is living in an emergency or transitional shelter;~~

228 ~~(d) Has a primary nighttime residence that is a public or~~
 229 ~~private place not designed for, or ordinarily used as, a regular~~
 230 ~~sleeping accommodation for human beings;~~

231 ~~(e) Is living in a car, park, public space, abandoned~~
 232 ~~building, bus or train station, or similar setting; or~~

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233 ~~(f) Is a migratory individual who qualifies as homeless~~
 234 ~~because he or she is living in circumstances described in~~
 235 ~~paragraphs (a) - (e).~~
 236
 237 ~~The terms do not refer to an individual imprisoned pursuant to~~
 238 ~~state or federal law or to individuals or families who are~~
 239 ~~sharing housing due to cultural preferences, voluntary~~
 240 ~~arrangements, or traditional networks of support. The terms~~
 241 ~~include an individual who has been released from jail, prison,~~
 242 ~~the juvenile justice system, the child welfare system, a mental~~
 243 ~~health and developmental disability facility, a residential~~
 244 ~~addiction treatment program, or a hospital, for whom no~~
 245 ~~subsequent residence has been identified, and who lacks the~~
 246 ~~resources and support network to obtain housing.~~
 247 (6) "Local coalition for the homeless" means a coalition
 248 established pursuant to s. 420.623.
 249 (7) "New and temporary homeless" means individuals or
 250 families who are homeless due to societal factors.
 251 (6)(8) "State Office on Homelessness" means the state
 252 office created in s. 420.622.
 253 Section 3. Section 420.622, Florida Statutes, is amended to
 254 read:
 255 420.622 State Office on Homelessness; Council on
 256 Homelessness.—
 257 (1) The State Office on Homelessness is created within the
 258 Department of Children and Families to provide interagency,
 259 council, and other related coordination on issues relating to
 260 homelessness.
 261 (2) The Council on Homelessness is created to consist of 19

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262 ~~17~~ representatives of public and private agencies who shall
 263 develop policy and advise the State Office on Homelessness. The
 264 council members shall be: the Secretary of Children and
 265 Families, or his or her designee; the executive director of the
 266 Department of Economic Opportunity, or his or her designee, who
 267 shall advise the council on issues related to rural development;
 268 the State Surgeon General, or his or her designee; the Executive
 269 Director of Veterans' Affairs, or his or her designee; the
 270 Secretary of Corrections, or his or her designee; the Secretary
 271 of Health Care Administration, or his or her designee; the
 272 Commissioner of Education, or his or her designee; the Director
 273 of CareerSource Florida, Inc., or his or her designee; one
 274 representative of the Florida Association of Counties; one
 275 representative of the Florida League of Cities; one
 276 representative of the Florida Supportive Housing Coalition; one
 277 representative of the Florida Housing Coalition; the Executive
 278 Director of the Florida Housing Finance Corporation, or his or
 279 her designee; one representative of the Florida Coalition for
 280 the Homeless; the Secretary of the Department of Elder Affairs,
 281 or his or her designee; and four members appointed by the
 282 Governor. The council members shall be nonpaid volunteers and
 283 shall be reimbursed only for travel expenses. The appointed
 284 members of the council shall be appointed to staggered 2-year
 285 terms, ~~and are encouraged to have experience in the~~
 286 administration or provision of resources, services, or housing
 287 that addresses the needs of persons experiencing homelessness.
 288 The council shall meet at least four times per year. The
 289 importance of minority, gender, and geographic representation
 290 shall be considered in appointing members to the council.

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291 (3) The State Office on Homelessness, pursuant to the
 292 policies set by the council and subject to the availability of
 293 funding, shall:

294 (a) Coordinate among state, local, and private agencies and
 295 providers to produce a statewide consolidated inventory for the
 296 state's entire system of homeless programs which incorporates
 297 local continuum of care plans regionally developed plans. Such
 298 programs include, but are not limited to:

299 1. Programs authorized under the McKinney-Vento Homeless
 300 Assistance Stewart B. McKinney Homeless Assistance Act of 1987,
 301 as amended by the Homeless Emergency Assistance and Rapid
 302 Transition to Housing (HEARTH) Act of 2009, 42 U.S.C. ss. 11302
 303 ss. 11371 et seq., and carried out under funds awarded to this
 304 state; and

305 2. Programs, components thereof, or activities that assist
 306 persons who are homeless or at risk for homelessness.

307 (b) Collect, maintain, and make available information
 308 concerning persons who are homeless ~~or at risk for homelessness,~~
 309 including summary demographics information drawn from the local
 310 continuum of care Homeless Management Information System or the
 311 annual Point-in-Time Count, current services and resources
 312 available and the local continuum of care Housing Inventory
 313 Chart required by the Department of Housing and Urban
 314 Development, the cost and availability of services and programs,
 315 and the met and unmet needs of this population. All entities
 316 that receive state funding must provide summary aggregated
 317 ~~access to all data they maintain in summary form,~~ with no
 318 individual identifying information, to assist the council in
 319 providing this information. The State Office on Homelessness, in

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320 consultation with the designated lead agencies for a ~~local~~
 321 ~~homeless~~ continuum of care and with the Council on Homelessness,
 322 shall develop a process by which summary data is collected the
 323 ~~system and process of data collection~~ from all lead agencies for
 324 the purpose of analyzing trends and assessing impacts in the
 325 ~~statewide homeless delivery system~~ for delivering services to
 326 the homeless. ~~Any statewide homelessness survey and database~~
 327 ~~system must comply with all state and federal statutory and~~
 328 ~~regulatory confidentiality requirements.~~

329 (c) Annually evaluate state and continuum of care system
 330 programs local services and resources and develop a consolidated
 331 plan for addressing the needs of the homeless or those at risk
 332 for homelessness.

333 (d) Explore, compile, and disseminate information regarding
 334 public and private funding sources for state and local programs
 335 serving the homeless and provide technical assistance in
 336 applying for such funding.

337 (e) Monitor and provide recommendations for coordinating
 338 the activities and programs of local continuums of care
 339 ~~coalitions for the homeless~~ and promote the effectiveness of
 340 programs to prevent and end homelessness in the state addressing
 341 ~~the needs of the homeless.~~

342 (f) Provide technical assistance to facilitate efforts to
 343 support and strengthen establish, maintain, and expand local
 344 ~~homeless assistance~~ continuums of care.

345 (g) Develop and assist in the coordination of policies and
 346 procedures relating to the discharge or transfer from the care
 347 or custody of state-supported or state-regulated entities
 348 persons who are homeless or at risk for homelessness.

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349 (h) Spearhead outreach efforts for maximizing access by
350 people who are homeless or at risk for homelessness to state and
351 federal programs and resources.

352 (i) Promote a federal policy agenda that is responsive to
353 the needs of those who are homeless or at risk of homelessness
354 ~~the homeless population~~ in this state.

355 (j) Review reports on continuum of care system performance
356 measures and ~~Develop outcome and accountability measures and~~
357 ~~promote and~~ use such measures to evaluate program effectiveness
358 and make recommendations for improving current practices to work
359 toward ending homelessness in this state in order to best meet
360 the needs of the homeless.

361 (k) Formulate policies and legislative proposals aimed at
362 preventing and ending homelessness in this state to address more
363 ~~effectively the needs of the homeless~~ and coordinate the
364 implementation of state and federal legislative policies.

365 (l) Convene meetings and workshops of state and local
366 agencies, continuum of care local coalitions and programs, and
367 other stakeholders for the purpose of developing and reviewing
368 policies, services, activities, coordination, and funding of
369 efforts to end homelessness ~~meet the needs of the homeless.~~

370 (m) With the input of the continuum of care, conduct or
371 promote research on the effectiveness of current programs and
372 propose pilot projects aimed at ending homelessness ~~improving~~
373 ~~services.~~

374 (n) Serve as an advocate for issues relating to
375 homelessness.

376 (o) Investigate ways to improve access to participation in
377 state funding and other programs for prevention and reduction

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378 ~~alleviation~~ of homelessness to faith-based organizations and
379 collaborate and coordinate with faith-based organizations.

380 (4) The State Office on Homelessness, ~~with the concurrence~~
381 ~~of the Council on Homelessness~~, shall accept and administer
382 moneys appropriated to it pursuant to s. 201.15(4)(c) to provide
383 annual "challenge grants" to lead agencies of ~~homeless~~
384 ~~assistance~~ continuums of care designated by the State Office on
385 Homelessness pursuant to s. 420.6225 ~~s. 420.624~~. The department
386 shall establish varying levels of grant awards up to \$750,000
387 ~~\$500,000~~ per continuum of care lead agency. The department, in
388 consultation with the Council on Homelessness, shall specify a
389 grant award level in the notice of the solicitation of grant
390 applications.

391 (a) To qualify for the grant, a continuum of care lead
392 agency must develop and implement a local ~~homeless assistance~~
393 continuum of care plan for its designated catchment area. The
394 services and housing funded through the grant must be
395 implemented through the continuum of care's ~~continuum of care~~
396 ~~plan must implement a~~ coordinated assessment or central intake
397 entry system as provided in s. 420.6225(5)(b) and must be
398 designed to screen, assess, and refer persons seeking assistance
399 to the appropriate housing intervention and service provider.
400 The continuum of care lead agency shall also document the
401 commitment of local government or private organizations to
402 provide matching funds or in-kind support in an amount equal to
403 25 percent of the grant requested. Expenditures of leveraged
404 funds or resources, including third-party cash or in-kind
405 contributions, are authorized only for eligible activities
406 carried out in connection with a ~~committed on one~~ project in

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407 which such funds or resources have not been used as leverage or
 408 match for any other project or program, and The expenditures
 409 must be certified through a written commitment.

410 (b) Preference must be given to those continuum of care
 411 lead agencies that have demonstrated the ability of their
 412 continuum of care to help households move out of homelessness
 413 ~~provide quality services to homeless persons and the ability to~~
 414 ~~leverage federal homeless assistance funding under the Stewart~~
 415 ~~B. McKinney Act with local government funding or private funding~~
 416 ~~for the provision of services to homeless persons.~~

417 ~~(c) Preference must be given to lead agencies in catchment~~
 418 ~~areas with the greatest need for the provision of housing and~~
 419 ~~services to the homeless, relative to the population of the~~
 420 ~~catchment area.~~

421 (c)(d) The grant may be used to fund any of the housing,
 422 program, or service needs included in the local ~~homeless~~
 423 ~~assistance~~ continuum of care plan. The continuum of care lead
 424 agency may allocate the grant to programs, services, or housing
 425 providers that implement the local ~~homeless assistance~~ continuum
 426 of care plan. The lead agency may provide subgrants to a local
 427 agency to implement programs or services or provide housing
 428 identified for funding in the lead agency's application to the
 429 department. A lead agency may spend a maximum of 10 ~~8~~ percent of
 430 its funding on administrative costs.

431 (d)(e) The continuum of care lead agency shall submit a
 432 final report to the department documenting the outcomes achieved
 433 by the grant-funded programs ~~grant~~ in enabling persons who are
 434 homeless to return to permanent housing, thereby ending such
 435 person's episode of homelessness.

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436 (5) The State Office on Homelessness, ~~with the concurrence~~
 437 ~~of the Council on Homelessness,~~ may administer moneys given
 438 ~~appropriated~~ to it to provide homeless housing assistance grants
 439 annually to continuum of care lead agencies ~~for local homeless~~
 440 ~~assistance continuum of care,~~ as recognized by the State Office
 441 on Homelessness, to acquire, construct, or rehabilitate
 442 ~~transitional or~~ permanent housing units for homeless persons.
 443 These moneys shall consist of any sums that the state may
 444 appropriate, as well as money received from donations, gifts,
 445 bequests, or otherwise from any public or private source, which
 446 are intended to acquire, construct, or rehabilitate ~~transitional~~
 447 ~~or~~ permanent housing units for homeless persons.

448 (a) Grant applicants shall be ranked competitively based on
 449 criteria determined by the State Office on Homelessness.
 450 ~~Preference must be given to applicants who leverage additional~~
 451 ~~private funds and public funds, particularly federal funds~~
 452 ~~designated for the acquisition, construction, or rehabilitation~~
 453 ~~of transitional or permanent housing for homeless persons; who~~
 454 ~~acquire, build, or rehabilitate the greatest number of units; or~~
 455 ~~who acquire, build, or rehabilitate in catchment areas having~~
 456 ~~the greatest need for housing for the homeless relative to the~~
 457 ~~population of the catchment area.~~

458 (b) Funding for any particular project may not exceed
 459 \$750,000.

460 (c) Projects must reserve, for a minimum of 20 ~~10~~ years,
 461 the number of units acquired, constructed, or rehabilitated
 462 through homeless housing assistance grant funding to serve
 463 persons who are homeless at the time they assume tenancy.

464 (d) No more than two grants may be awarded annually in any

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465 given ~~local homeless assistance~~ continuum of care catchment
466 area.

467 (e) A project may not be funded which is not included in
468 the local ~~homeless assistance~~ continuum of care plan, as
469 recognized by the State Office on Homelessness, for the
470 catchment area in which the project is located.

471 (f) The maximum percentage of funds that the State Office
472 on Homelessness and each applicant may spend on administrative
473 costs is 10 ~~5~~ percent.

474 (6) The State Office on Homelessness, in conjunction with
475 the Council on Homelessness, shall establish performance
476 measures related to state funding provided through the State
477 Office on Homelessness and utilize those grant-related measures
478 to and specific objectives by which it may evaluate the
479 performance and outcomes of continuum of care lead agencies that
480 receive state grant funds. Challenge Grants made through the
481 State Office on Homelessness shall be distributed to lead
482 agencies based on their overall performance and their
483 achievement of specified objectives. Each lead agency for which
484 grants are made under this section shall provide the State
485 Office on Homelessness a thorough evaluation of the
486 effectiveness of the program in achieving its stated purpose. In
487 evaluating the performance of the lead agencies, the State
488 Office on Homelessness shall base its criteria upon the program
489 objectives, goals, and priorities that were set forth by the
490 lead agencies in their proposals for funding. Such criteria may
491 include, but are not limited to, the number of persons or
492 households that are no longer homeless, the rate of recidivism
493 to homelessness, and the number of persons who obtain gainful

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494 ~~employment.~~

495 (7) The State Office on Homelessness must monitor the
496 challenge grants and homeless housing assistance grants to
497 ensure proper expenditure of funds and compliance with the
498 conditions of the applicant's contract.

499 (8) The Department of Children and Families, with input
500 from the Council on Homelessness, may ~~must~~ adopt rules relating
501 to the challenge grants and the homeless housing assistance
502 grants and related issues consistent with the purposes of this
503 section.

504 (9) The council shall, by June 30 of each year, provide to
505 the Governor, the Legislature, and the Secretary of Children and
506 Families a report summarizing the extent of homelessness in the
507 state and the council's recommendations for ending ~~reducing~~
508 homelessness in this state.

509 (10) The State Office on Homelessness may administer moneys
510 appropriated to it for distribution among the ~~28 local homeless~~
511 continuum of care continuum of care lead agencies and entities
512 funded in the 2017-2018 state fiscal year which are designated
513 by the office as local coalitions for the homeless designated by
514 the Department of Children and Families.

515 Section 4. Section 420.6225, Florida Statutes, is created
516 to read:

517 420.6225 Continuum of care.—

518 (1) The purpose of a continuum of care, as defined in s.
519 420.621, is to coordinate community efforts to prevent and end
520 homelessness in its catchment area designated as provided in
521 subsection (3) and to fulfill the responsibilities set forth in
522 this chapter.

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523 (2) Pursuant to the federal HEARTH Act of 2009, each
 524 continuum of care is required to designate a collaborative
 525 applicant that is responsible for submitting the continuum of
 526 care funding application for the designated catchment area to
 527 the United States Department of Housing and Urban Development.
 528 The continuum of care designated collaborative applicant shall
 529 serve as the point of contact to the State Office on
 530 Homelessness, is accountable for representations made in the
 531 application, and, in carrying out responsibilities under this
 532 chapter, may be referred to as the continuum of care lead
 533 agency.

534 (3) Continuum of care catchment areas must be designated
 535 and revised as necessary by the State Office on Homelessness and
 536 must be consistent with the continuum of care catchment areas
 537 recognized by the United States Department of Housing and Urban
 538 Development for the purposes of awarding federal homeless
 539 assistance funding for continuum of care programs.

540 (4) The State Office on Homelessness shall recognize only
 541 one continuum of care lead agency for each designated catchment
 542 area. Such continuum of care lead agency must be consistent with
 543 the continuum of care collaborative applicant designation
 544 recognized by the United States Department of Housing and Urban
 545 Development in the awarding of federal funds to continuums of
 546 care.

547 (5) Each continuum of care shall create a continuum of care
 548 plan, the purpose of which is to implement an effective and
 549 efficient housing crisis response system to prevent and end
 550 homelessness in the continuum of care catchment area. A
 551 continuum of care plan must include all of the following

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552 components:

553 (a) Outreach to unsheltered individuals and families to
 554 link them with appropriate housing interventions.

555 (b) A coordinated entry system, compliant with the
 556 requirements of the federal HEARTH Act of 2009, which is
 557 designed to coordinate intake, utilize common assessment tools,
 558 prioritize households for housing interventions, and refer
 559 households to the appropriate housing intervention.

560 (c) Emergency shelter, designed to provide safe temporary
 561 shelter while the household is in the process of obtaining
 562 permanent housing.

563 (d) Supportive services, designed to maximize housing
 564 stability once the household is in permanent housing.

565 (e) Permanent supportive housing, designed to provide long-
 566 term affordable housing and support services to persons with
 567 disabilities who are moving out of homelessness.

568 (f) Rapid ReHousing, as specified in s. 420.6265.

569 (g) Permanent housing, including linkages to affordable
 570 housing, subsidized housing, long-term rent assistance, housing
 571 vouchers, and mainstream private sector housing.

572 (h) An ongoing planning mechanism to end homelessness for
 573 all subpopulations of persons experiencing homelessness.

574 (6) Continuums of care must promote participation by all
 575 interested individuals and organizations and may not exclude
 576 individuals and organizations on the basis of race, color,
 577 national origin, sex, handicap, familial status, or religion.
 578 Faith-based organizations, local governments, and persons who
 579 have experienced homelessness are encouraged to participate. To
 580 the extent possible, these individuals and organizations must be

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581 coordinated and integrated with other mainstream health, social
 582 services, and employment programs for which homeless populations
 583 may be eligible, including, but not limited to, Medicaid, the
 584 State Children's Health Insurance Program, the Temporary
 585 Assistance for Needy Families Program, the Food Assistance
 586 Program, and services funded through the Mental Health and
 587 Substance Abuse Block Grant, the Workforce Innovation and
 588 Opportunity Act, and the welfare-to-work grant program.

589 Section 5. Section 420.6227, Florida Statutes, is created
 590 to read:

591 420.6227 Grant-in-aid program.-

592 (1) LEGISLATIVE FINDINGS.-The Legislature hereby finds and
 593 declares that many services for households experiencing
 594 homelessness have been provided by local communities through
 595 voluntary private agencies and religious organizations and that
 596 those resources have not been sufficient to prevent and end
 597 homelessness in Florida. The Legislature recognizes that the
 598 level of need and types of problems associated with homelessness
 599 may vary from community to community, due to the diversity and
 600 geographic distribution of the homeless population and the
 601 resulting differing needs of particular communities.

602 (2) PURPOSE.-The principal purpose of the grant-in-aid
 603 program is to provide needed assistance to continuums of care to
 604 enable them to do all of the following:

605 (a) Assist persons in their communities who have become, or
 606 may likely become, homeless.

607 (b) Help homeless households move to permanent housing as
 608 quickly as possible.

609 (3) ESTABLISHMENT.-There is hereby established a state

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610 grant-in-aid program to help continuums of care prevent and end
 611 homelessness, which may include any aspect of the local
 612 continuum of care plan, as described in s. 420.6225.

613 (4) APPLICATION PROCEDURE.-Continuums of care that intend
 614 to apply for the grant-in-aid program must submit an application
 615 for grant-in-aid funds to the State Office on Homelessness for
 616 review.

617 (5) SPENDING PLANS.-The State Office on Homelessness shall
 618 develop guidelines for the development, evaluation, and approval
 619 of spending plans that are created by local continuum of care
 620 lead agencies.

621 (6) ALLOCATION OF GRANT FUNDS.-The State Office on
 622 Homelessness shall administer state grant-in-aid funds for
 623 continuums of care, which must be awarded on a competitive
 624 basis.

625 (7) DISTRIBUTION TO LOCAL AGENCIES.-The State Office on
 626 Homelessness shall distribute funds awarded under subsection (6)
 627 to local agencies to fund programs that are required by the
 628 local continuum of care plan, as described in s. 420.6225 and
 629 provided in subsection (3), based upon the recommendations of
 630 the local continuum of care lead agencies, in accordance with
 631 spending plans that are developed by the lead agencies and
 632 approved by the office. Not more than 10 percent of the total
 633 state funds awarded under a spending plan may be used by the
 634 continuum of care lead agency for staffing and administrative
 635 expenditures.

636 (8) LOCAL MATCHING FUNDS.-If an entity contracts with local
 637 agencies to provide services and receives financial assistance
 638 obtained under this section, the entity must provide a minimum

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639 of 25 percent of the funding necessary for the support of
 640 project operations. In-kind contributions, including, but not
 641 limited to, materials, commodities, transportation, office
 642 space, other types of facilities, or personal services may be
 643 evaluated and counted as part or all of the required local
 644 funding, at the discretion of the State Office on Homelessness.

645 Section 6. Section 420.623, Florida Statutes, is repealed.

646 Section 7. Section 420.624, Florida Statutes, is repealed.

647 Section 8. Section 420.625, Florida Statutes, is repealed.

648 Section 9. Subsection (3) of section 420.626, Florida
 649 Statutes, is amended, and subsection (2) of that section is
 650 republished, to read:

651 420.626 Homelessness; discharge guidelines.—

652 (2) The following facilities and institutions are
 653 encouraged to develop and implement procedures designed to
 654 reduce the discharge of persons into homelessness when such
 655 persons are admitted or housed for more than 24 hours at such
 656 facilities or institutions: hospitals and inpatient medical
 657 facilities; crisis stabilization units; residential treatment
 658 facilities; assisted living facilities; and detoxification
 659 centers.

660 (3) The procedures should include all of the following:

661 (a) Development and implementation of a screening process
 662 or other mechanism for identifying persons to be discharged from
 663 the facility or institution who are at considerable risk for
 664 homelessness or face some imminent threat to health and safety
 665 upon discharge.↗

666 (b) Development and implementation of a discharge plan
 667 addressing how identified persons will secure housing and other

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668 needed care and support upon discharge.↗

669 (c) ~~Communication with Assessment of the capabilities of~~
 670 the entities to whom identified persons may potentially be
 671 discharged to determine their capability to serve such persons
 672 and their acceptance of such discharge into their programs, and
 673 selection of the entity determined to be best equipped to
 674 provide or facilitate the provision of suitable care and
 675 support.↗

676 (d) Coordination of effort and sharing of information with
 677 entities that are expected to bear the responsibility for
 678 providing care or support to identified persons upon discharge.↗
 679 ~~and~~

680 (e) Provision of sufficient medication, medical equipment
 681 and supplies, clothing, transportation, and other basic
 682 resources necessary to assure that the health and well-being of
 683 identified persons are not jeopardized upon their discharge.

684 Section 10. Section 420.6265, Florida Statutes, is amended
 685 to read:

686 420.6265 Rapid ReHousing.—

687 (1) LEGISLATIVE FINDINGS AND INTENT.—

688 (a) The Legislature finds that Rapid ReHousing is a
 689 strategy of using temporary financial assistance ~~and case~~
 690 ~~management~~ to quickly move an individual or family out of
 691 homelessness and into permanent housing, and using housing
 692 stabilization support services to help them remain stably
 693 housed.

694 (b) The Legislature also finds that public and private
 695 solutions to homelessness in the past have focused on providing
 696 individuals and families who are experiencing homelessness with

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697 emergency shelter, transitional housing, or a combination of
 698 both. While emergency shelter and transitional housing programs
 699 may provide critical access to services for individuals and
 700 families in crisis, the programs often fail to address permanent
 701 housing their long-term needs and may unnecessarily extend their
 702 episodes of homelessness.

703 (c) The Legislature further finds that most households
 704 become homeless as a result of a financial crisis that prevents
 705 individuals and families from paying rent or a domestic conflict
 706 that results in one member being ejected or leaving without
 707 resources or a plan for housing.

708 (d) The Legislature further finds that Rapid ReHousing has
 709 proven to be a cost-effective is an alternative approach to
 710 ending homelessness which reduces to the current system of
 711 emergency shelter or transitional housing which tends to reduce
 712 the length of time that a person is homeless and is demonstrably
 713 has proven to be more cost effective than alternative
 714 approaches.

715 (e) It is therefore the intent of the Legislature to
 716 encourage ~~homeless~~ continuums of care to adopt the Rapid
 717 ReHousing approach to ending preventing homelessness for
 718 individuals and families who do not require the intensive
 719 ~~intense~~ level of supports provided in the permanent supportive
 720 housing model.

721 (2) RAPID REHOUSING METHODOLOGY.—

722 (a) The Rapid ReHousing response to homelessness differs
 723 from traditional approaches to addressing homelessness by
 724 focusing on each individual's or family's barriers to housing.
 725 By using this approach, communities can significantly reduce the

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726 amount of time that individuals and families are homeless and
 727 prevent further episodes of homelessness.

728 (b) In Rapid ReHousing, when an individual or a family is
 729 identified as being homeless, the individual or family is
 730 assessed and prioritized for housing through the continuum of
 731 care's coordinated entry system, temporary assistance is
 732 provided to allow the individual or family to obtain permanent
 733 housing as quickly as possible, and necessary, ~~if needed,~~
 734 assistance is provided to allow the individual or family to
 735 retain housing.

736 (c) The objective of Rapid ReHousing is to provide
 737 assistance for as short a term as possible so that the
 738 individual or family receiving assistance attains stability and
 739 integration into the community as quickly as possible ~~does not~~
 740 ~~develop a dependency on the assistance.~~

741 Section 11. Section 420.6275, Florida Statutes, is amended
 742 to read:

743 420.6275 Housing First.—

744 (1) LEGISLATIVE FINDINGS AND INTENT.—

745 (a) The Legislature finds that many communities plan to
 746 manage homelessness rather than ~~plan~~ to end it.

747 (b) The Legislature also finds that for nearly most of the
 748 ~~past~~ two decades, public and private solutions to homelessness
 749 ~~have~~ focused on providing individuals and families who ~~were~~ are
 750 experiencing homelessness with emergency shelter, transitional
 751 housing, or a combination of both. This strategy failed to
 752 recognize that, while emergency shelter programs may provide
 753 critical access to services for individuals and families in
 754 crisis, they often fail to address their long-term needs.

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755 (c) The Legislature further finds that Housing First is a
 756 cost-effective ~~an alternative approach to the current system of~~
 757 ~~emergency shelter or transitional housing which tends to ending~~
 758 homelessness and reducing ~~reduce~~ the length of time of
 759 homelessness for many individuals and families ~~and has proven to~~
 760 ~~be cost-effective.~~

761 (d) It is therefore the intent of the Legislature to
 762 encourage ~~homeless~~ continuums of care to adopt the Housing First
 763 approach to ending homelessness for individuals and families.

764 (2) HOUSING FIRST METHODOLOGY.—

765 (a) The Housing First approach to homelessness provides
 766 permanent ~~differs from traditional approaches by providing~~
 767 housing assistance, followed by case management, and support
 768 services responsive to individual or family needs once after
 769 housing is obtained. By using this approach ~~when appropriate,~~
 770 communities can significantly reduce the amount of time that
 771 individuals and families are homeless and prevent further
 772 episodes of homelessness. Housing First emphasizes that social
 773 services provided to enhance individual and family well-being
 774 can be more effective when people are in their own home, and:

775 1. The housing is not time-limited.

776 2. The housing is not contingent on compliance with
 777 services. Instead, participants must comply with a standard
 778 lease agreement.

779 3. Individuals and families ~~and~~ are provided with
 780 individualized ~~the~~ services and support ~~that are~~ necessary to
 781 help them maintain stable housing ~~do so successfully.~~

782 3. ~~A background check and any rehabilitation necessary to~~
 783 ~~combat an addiction related to alcoholism or substance abuse has~~

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784 ~~been completed by the individual for whom assistance or support~~
 785 ~~services are provided.~~

786 (b) The Housing First approach addresses the societal
 787 causes of homelessness and advocates for the immediate return of
 788 individuals and families into housing and communities. Housing
 789 First links affordable housing with community-based social
 790 service and health care organizations ~~Housing First provides a~~
 791 ~~critical link between the emergency and transitional housing~~
 792 ~~system and community-based social service, educational, and~~
 793 ~~health care organizations~~ and consists of four components:

794 1. Crisis intervention and short-term stabilization.

795 2. Screening, intake, and needs assessment.

796 3. Provision of housing resources.

797 4. Provision of case management.

798 Section 12. Paragraph (d) of subsection (22) of section
 799 420.507, Florida Statutes, is amended to read:

800 420.507 Powers of the corporation.—The corporation shall
 801 have all the powers necessary or convenient to carry out and
 802 effectuate the purposes and provisions of this part, including
 803 the following powers which are in addition to all other powers
 804 granted by other provisions of this part:

805 (22) To develop and administer the State Apartment
 806 Incentive Loan Program. In developing and administering that
 807 program, the corporation may:

808 (d) In counties or rural areas of counties that do not have
 809 existing units set aside for homeless persons, forgive
 810 indebtedness for loans provided to create permanent rental
 811 housing units for persons who are homeless, as defined in s.
 812 420.621 s. ~~420.621(5)~~, or for persons residing in time-limited

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813 transitional housing or institutions as a result of a lack of
814 permanent, affordable housing. Such developments must be
815 supported by a ~~local homeless assistance~~ continuum of care
816 developed under s. 420.6225 ~~s. 420.624~~, be developed by
817 nonprofit applicants, be small properties as defined by
818 corporation rule, and be a project in the local housing
819 assistance continuum of care plan recognized by the State Office
820 on Homelessness.

821 Section 13. This act shall take effect July 1, 2019.



235940

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/09/2019	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services (Book)
recommended the following:

Senate Amendment

Delete lines 158 - 159
and insert:
the Department of Economic Opportunity. Subject to an
appropriation, up to the next \$10 million may be transferred,
subject to any distribution

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL: PCS/CS/SB 1460 (263332)

INTRODUCER: Appropriations Subcommittee on Health and Human Services; Health Policy Committee; and Senator Book and others

SUBJECT: Stroke Centers

DATE: April 11, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	Fav/CS
2.	Gerbrandt	Kidd	AHS	Recommend: Fav/CS
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 1460 revises the criteria under which a hospital qualifies as a stroke center and adds a new class of stroke centers to the current-law list of stroke centers that the Agency for Health Care Administration (AHCA) is required to maintain and make available on its website and to the Department of Health (DOH).

The bill directs the AHCA to include thrombectomy-capable stroke centers (TSC) in its list of stroke centers, in addition to acute stroke-ready centers (ASRC), primary stroke centers (PSC), and comprehensive stroke centers (CSC) that current law requires the AHCA to include in the list.

The bill eliminates a hospital's ability to be included in the AHCA's list of stroke centers by attesting with an affidavit that it meets the criteria for qualifying as a stroke center or that it has been certified as a stroke center by a nationally recognized accrediting organization. Under the bill, in order to be included in the AHCA's list, a hospital must submit documentation verifying its certification as a stroke center, which may include offering and performing endovascular therapy consistent with standards identified by a nationally recognized, guidelines-based organization approved by the AHCA.

The bill also prohibits a hospital from advertising that it is a state-listed stroke center unless the hospital has submitted verifying documentation to the AHCA, as opposed to merely notifying the AHCA as under current law.

The bill directs the DOH to include data from TSCs in its annual list to the medical directors of licensed emergency medical service (EMS) providers and directs the medical directors to develop and implement transportation and rerouting protocols for stroke patients with the intent to reroute them to ASRCs, PSCs, CSCs, and TSCs.

The bill has an insignificant fiscal impact on the AHCA.

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

II. Present Situation:

What is a Stroke?

A stroke is a serious medical condition that occurs when the blood supply to the brain is interrupted or severely reduced, depriving brain tissue of oxygen and nutrients.¹ The brain needs a constant supply of oxygen and nutrients in order to function.² Even a brief interruption in blood supply from a stroke can cause significant problems.

There are two main types of strokes: an ischemic stroke and a hemorrhagic stroke. The former is the most common type and occurs when an artery in the brain becomes blocked. The latter occurs when a brain artery leaks blood or ruptures.³

There are two types of ischemic strokes: thrombotic and embolic.⁴ In a thrombotic stroke, a blood clot (thrombus) forms in an artery that supplies blood to the brain.⁵ In an embolic stroke, a blood clot or other substance, such as plaque or fatty material, travels through the bloodstream to an artery in the brain.⁶ With both types of ischemic stroke, the blood clot or other substance blocks the flow of oxygenated blood to a portion of the brain.⁷

The two types of hemorrhagic stroke are intracerebral and subarachnoid.⁸ In an intracerebral hemorrhage, a blood vessel inside the brain leaks blood or ruptures.⁹ In a subarachnoid hemorrhage, a blood vessel on the surface of the brain leaks blood or ruptures, and bleeding occurs between the inner and middle layers of the membrane that covers the brain.¹⁰ In both

¹ The Mayo Clinic, *Stroke*, available at: <http://www.mayoclinic.org/diseases-conditions/stroke/home/ovc-20117264>, (last visited Mar. 29, 2019).

² UCLA Health, *What is a Stroke?* available at: <http://stroke.ucla.edu/what-is-a-stroke>, (last visited Mar. 29, 2019).

³ Id.

⁴ Id.

⁵ Id.

⁶ Id. The blood clot or other substance traveling through the bloodstream is called an embolus.

⁷ Id.

⁸ Id.

⁹ Id.

¹⁰ Id.

types of hemorrhagic stroke, the leaked blood causes swelling of the brain and increased pressure in the skull. This swelling and pressure causes brain damage.¹¹

Stroke Treatment

Time is of the essence in the treatment of a stroke. Medical personnel begin treatment in the ambulance on the way to the hospital.¹² Treatment for a stroke depends on how much time has elapsed since the symptoms began to appear and whether the stroke is ischemic or hemorrhagic.¹³

Treatment for an ischemic stroke may include medicines,¹⁴ such as antiplatelet medicines and blood thinners, and medical procedures, but a hemorrhagic stroke may require surgery to find and stop the bleeding.¹⁵ In addition to emergency care to treat a stroke, an individual may also receive treatment to prevent another stroke and rehabilitation to treat the side effects of the stroke.¹⁶ According to the federal Centers for Disease Control and Prevention (CDC), research indicates that patients receiving care at a Primary Stroke Center (PSC) have a higher survival and recovery rate than those treated in hospitals without this type of specialized care.¹⁷

Stroke Centers in Florida

Florida first enacted legislation relating to PSCs and CSCs in 2004.¹⁸ In 2017, the Legislature added ASRCs to the list of PSCs and CSCs, which is made available to licensed emergency medical services (EMS) providers.¹⁹ The AHCA has adopted a rule establishing the criteria for ASRCs, PSCs, and CSCs.²⁰

There are currently no Florida hospitals designated as ASRCs, 114 designated as PSCs in 40 counties, and 48 CSCs in 22 counties.²¹

¹¹ Id.

¹² Center for Disease Control and Prevention, *Stroke Treatment* (updated May. 18, 2017) available at: <https://www.cdc.gov/stroke/treatments.htm>, (last visited Mar. 29, 2019).

¹³ National Institutes of Health, National Heart, Lung and Blood Institute, *Treatment*, available at: <https://www.nhlbi.nih.gov/health/health-topics/topics/stroke/treatment> (last visited Mar. 29, 2019).

¹⁴ Id. Such medication includes a tissue plasminogen activator (TPA), which dissolves, or breaks up the clot. TPA is an injection which must be given within 4 hours of stroke symptoms onset.

¹⁵ Id.

¹⁶ *Supra* note 122.

¹⁷ Centers for Disease Control and Prevention, *A Summary Of Primary Stroke Center Policy In The United States* (2011), available at: https://www.cdc.gov/dhdsp/pubs/docs/primary_stroke_center_report.pdf, (last visited Mar. 29, 2019)

¹⁸ Section 3, ch. 2004-325, Laws of Fla.

¹⁹ Chapter 2017-172, Laws of Fla.

²⁰ *See* s. 395.3038(3), F.S. and rule 59A-3.246(4), F.A.C.

²¹ Agency for Health Care Administration, Hospital & Outpatient Service Unit, Reports, *Stroke Centers* (updated Mar. 1, 2019), available at: http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/Reports.shtml (last visited Mar. 29, 2019).

National Accrediting Organizations

The Joint Commission, the Healthcare Facilities Accreditation Program, and the DNV GL (formerly known as Det Norske Veritas) offer certifications to hospitals as an ASRC, PSC, CSC, and TSC.²²

Licensure

A hospital may apply for designation as an ASRC, PSC, or CSC by submitting a hospital licensure application²³ and attaching a License Application Stroke Center Affidavit, both of which must be signed by the hospital's chief executive officer, attesting that the stroke program meets:

- The criteria for one of the designations as specified by rule, or
- Is certified as a stroke center by The Joint Commission, the Health Facilities Accreditation Program, or DNV GL.²⁴

A hospital seeking stroke center certification must establish specific procedures for screening patients to recognize that numerous conditions, including cardiac disorders, often mimic stroke in children. Medical staff must ensure that transfer to an appropriate facility for specialized care is provided to children and young adults with known childhood diagnoses.²⁵

Acute Stroke Ready Centers (ASRC)

An ASRC is a hospital that is designated by the AHCA as meeting Florida regulation requirements based on national guidelines to meet the initial needs of stroke patients and support better outcomes for stroke care as part of a stroke care system.²⁶ A hospital with an ASRC certification is required to notify the ACHA if it no longer meets the criteria.²⁷

Many patients with an acute stroke live in areas without ready access to a PSC or CSC; more than half the U.S. population lives more than an hour away from a stroke center.²⁸ Hospitals in areas with low population densities and relatively small numbers of patients with strokes may be less likely to have the resources to become a stroke center and may lack the experience and

²²The Joint Commission, *Certification for Acute Stroke Ready Center*, available at:

https://www.jointcommission.org/certification/acute_stroke_ready_hospitals.aspx; *Certification Comprehensive Stroke Center*, available at:

https://www.jointcommission.org/certification/advanced_certification_comprehensive_stroke_centers.aspx; *Certification for Primary Stroke Centers*, available at: https://www.jointcommission.org/certification/primary_stroke_centers.aspx;

Certification for Thrombectomy-Capable Stroke Centers, available at:

https://www.jointcommission.org/certification/certification_for_thrombectomycapable_stroke_centers.aspx, (last visited Mar. 29, 2019).

²³ Fla. Admin. Code R. 59A-3.066(2), (2019).

²⁴ Fla. Admin. Code R. 59A-3.246(4)(a), (2019).

²⁵ Fla. Admin. Code R. 59A-3.346(4)(b), (2019).

²⁶ Agency for Health Care Administration, Facility/Provider Definitions, *Acute Stroke Ready Center*, available at: <http://www.floridahealthfinder.gov/about-ahca/facility-locator-glossary.aspx> (last visited Mar. 29, 2019).

²⁷ Section 395.3038, F.S.

²⁸ Mark J. Alberts, et al, *Formation and Function of Acute Stroke-Ready Hospitals Within a Stroke System of Care Recommendations From the Brain Attack Coalition*, *Stroke*, Vol. 44, Issue 12 (Nov. 25, 2013), available at: <http://stroke.ahajournals.org/content/44/12/3382.full>, (last visited Mar. 29, 2019).

expertise to provide ongoing care for a stroke.²⁹ In such settings, there is a need to distinguish between those that offer enhanced care and expertise for acute stroke versus those with only basic or no organized abilities and expertise.³⁰

An ASRC must have an acute stroke team available 24 hours a day, 7 days a week, and be capable of responding to patients who are in the emergency department or an inpatient unit within 15 minutes of being called. An ASRC team must consist of a physician and one or more of the following:

- A registered professional nurse;
- An advanced registered nurse practitioner; or
- A physician assistant.

An ASRC must designate a physician with knowledge of cerebrovascular disease to serve as the ASRC medical director. The medical director is responsible for implementing the stroke services protocols. The qualifications for the medical director of an ASRC are determined by the hospital governing board.

An ASRC must have the following services available 24 hours a day, 7 days a week:

- A dedicated emergency department;
- Clinical laboratory services;³¹
- Diagnostic imaging capability for a head computed tomography (CT) and magnetic resonance imaging (MRI);
- Intravenous thrombolytics available;
- Anticoagulate reversal medication available;
- Neurologist services available in person or via telemedicine; and
- A transfer agreement with a PSC or CSC.³²

Primary Stroke Centers (PSC)

A PSC certification recognizes hospitals that meet standards to support better outcomes for stroke care.³³ Such hospitals must have:

- A dedicated stroke-focused program;
- Be staffed by qualified medical professionals trained in stroke care; and
- Provide individualized care to meet stroke patients' needs based on recommendations of the Brain Attack Coalition and guidelines published by the American Heart Association and American Stroke Association or equivalent guidelines.³⁴

These hospitals must also collect and utilize performance data to improve quality of care for stroke patients.³⁵

²⁹ Id.

³⁰ Id.

³¹ Fla. Admin. Code R. 59A-3.255(6)(g), (2019).

³² Fla. Admin. Code R. 59A-3.246(4)(c),5., (2019).

³³ American Heart Association, *Facts: Primary Stroke Centers*, available at: <https://www.yourethecure.org/facts-primary-stroke-centers> (last visited Mar. 29, 2019).

³⁴ Id.

³⁵ *Supra* note 28.

In order for the AHCA to designate a hospital program as a PSC, the hospital program must be certified by the Joint Commission as a PSC or meet the certification criteria applicable to PSCs as outlined in the Joint Commission Disease-Specific Care Certification Manual, 2nd Edition.³⁶ The manual requires a PSC to:³⁷

- Use a standardized method of delivering care;
- Support patient self-management activities;
- Tailor treatment and intervention to individual needs;
- Promote the flow of patient information across settings and providers, while protecting patient rights, security and privacy;
- Analyze and use standardized performance measure data to continually improve treatment plans; and
- Demonstrate the hospital's application of and compliance with clinical practice guidelines published by the American Heart Association and American Stroke Association or equivalent, evidence-based guidelines.³⁸

A PSC must have an acute stroke team available 24 hours a day, 7 days a week, capable of responding to patients who are in the emergency department or an inpatient unit within 15 minutes of being called. A PSC team must consist of a physician and one or more of the following:

- A registered professional nurse;
- An advanced registered nurse practitioner; or
- A physician assistant.

A PSC must designate a physician with knowledge of cerebrovascular disease to serve as the PSC medical director. The medical director is responsible for implementing the stroke services protocols. The qualifications for the medical director are determined by the hospital's governing board.

A PSC must have the following services available 24 hours a day, 7 days a week:

- A dedicated emergency department;
- Clinical laboratory services;³⁹
- Diagnostic imaging to include head CT, CT angiography (CTA), brain and cardiac magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), and transthoracic and/or transesophageal echocardiography;
- Intravenous thrombolytics;
- Anticoagulate reversal medication available for administration; and
- Neurologist services, available in person or via tele-medicine.

³⁶ The standards are published in the 2019 *Disease-Specific Care Review Process Guide*, available at: https://www.jointcommission.org/assets/1/6/2019_Disease_Specific_Care_Organization_RPG.pdf (last visited Mar. 29, 2019).

³⁷ *Id.*

³⁸ The Joint Commission, *Discover the Most Comprehensive Stroke Certifications* (March, 2019), available at: https://www.jointcommission.org/certification/primary_stroke_centers.aspx (last visited Mar. 29, 2019).

³⁹ See Fla. Admin. Code R. 59A-3.255(6)(g), (2019), for specific laboratory requirements.

The following services may be available on-site or via a transfer agreement:

- Neurosurgical services within two hours of being deemed clinically necessary;
- Physical, occupational, or speech therapy; and
- Neurovascular interventions for aneurysms, stenting of carotid arteries, carotid endarterectomy, and endovascular therapy.

A PSC must develop a quality improvement program designed to analyze data, correct errors, identify system improvements, and ongoing improvement in patient care and delivery of services.

A multidisciplinary institutional Quality Improvement Committee must monitor quality benchmarks and review clinical complications on a regular basis. Specific benchmarks, outcomes, and indicators must be defined, monitored, and reviewed by the Quality Improvement Committee on a regular basis for quality assurance purposes.⁴⁰

Comprehensive Stroke Centers (CSC)

A CSC certification recognizes hospitals that meet standards to treat the most complex stroke cases.⁴¹ These hospitals must meet all the criteria of a PSC. They must also have advanced imaging techniques and personnel trained in vascular neurology, neurosurgery, and endovascular procedures available 24 hours a day, 7 days a week, as well as neuroscience intensive care unit (ICU) and experience and expertise treating patients with large ischemic strokes, intracerebral hemorrhage, and subarachnoid hemorrhage.

In order for the AHCA to designate a hospital program as a CSC, the hospital program must have received PSC designation and also have the following:

- Personnel with clinical expertise in specified disciplines available;⁴²
- Advanced diagnostic capabilities;⁴³
- Neurosurgical and endovascular interventions available;⁴⁴
- Specialized infrastructure; and
- Quality improvement and clinical outcomes measurements.⁴⁵

The specialized infrastructure includes extensive requirements that the EMS and CSC leadership are linked to ensure:

- EMS use a stroke triage assessment tool;
- EMS patient assessment and management at the scene is consistent with evidence-based practice;
- Inter-facility transfers; and

⁴⁰ Fla. Admin. Code R.59A-3.246(4)(d), (2019).

⁴¹ The American Heart Association, *Get with the Guidelines – Stroke Clinical Tools*, available at: <https://www.heart.org/en/professional/quality-improvement/get-with-the-guidelines/get-with-the-guidelines-stroke/get-with-the-guidelines-stroke-clinical-tools> (last visited Mar. 29, 2019).

⁴² See Fla. Admin. Code R. 59A-3.246(4)(e), (2019), for specific qualifications. Medical personnel with neurosurgical expertise must be available in a CSC on a 24 hours per day, 7 days per week basis and in-house within two hours, and neurologist(s) with special expertise in the management of stroke patients should be available 24 hours per day, 7 days per week.

⁴³ Id.

⁴⁴ *Supra* note 38.

⁴⁵ Id.

- Ongoing communication with EMS providers regarding availability of services.

A CSC must maintain:

- An acute stroke team available 24 hours a day, 7 days a week;
- A system for facilitating inter-facility transfers;
- Defined access telephone numbers in a system for accepting appropriate transfers;
- Specialized inpatient units including an ICU with medical and nursing personnel who have special training, skills, and knowledge in the management of patients with all forms of neurological or neurosurgical conditions that require intensive care;
- An acute stroke unit with medical and nursing personnel who have training, skills, and knowledge sufficient to care for patients with neurological conditions, particularly acute stroke patients, and who are appropriately trained in neurological assessment and management;
- Inpatient post-stroke rehabilitation and ensure continuing arrangements post-discharge for rehabilitation needs and medical management;
- The education of its medical and paramedical professionals by offering ongoing professional education for all disciplines;
- An ongoing effort to educate inpatients, their families, and the public about risk factor reduction or management, primary and secondary prevention, the warning signs and symptoms of stroke, and medical management and rehabilitation for stroke patients;
- A career development track to develop neuroscience nursing, particularly in the area of cerebrovascular disease; and
- Professional and administrative infrastructure necessary to conduct clinical trials and should have participated in stroke clinical trials within the last year and actively participate in ongoing clinical stroke trials.⁴⁶

Thrombectomy-Capable Stroke Centers (TSC)

The Joint Commission, in collaboration with the American Heart Association and American Stroke Association, is offering a new advanced stroke certification for TSCs in response to the need to identify hospitals that meet rigorous standards for performing endovascular thrombectomy (EVT).⁴⁷

To achieve TSC certification, a hospital must:

- Demonstrate compliance with the new standards for TSC certification;⁴⁸

⁴⁶ Id.

⁴⁷ The Joint Commission, *Certification for Thrombectomy-Capable Stroke Centers*, available at: https://www.jointcommission.org/certification/certification_for_thrombectomycapable_stroke_centers.aspx (last visited Mar. 29, 2019)

⁴⁸ All certified Thrombectomy-Capable Stroke Center (TSC) programs will be required to collect and report data for the eight Joint Commission stroke (STK) measures in addition to five selected comprehensive stroke (CSTK) measures relating to ischemic strokes for a total performance measurement requirement of 13 measures. In addition to collecting and reporting this data, organizations are expected to use this information for ongoing performance improvement efforts. The Joint Commission, *Thrombectomy-Capable Stroke Performance Measurement Requirements*, available at: https://www.jointcommission.org/certification/thrombectomycapable_stroke_performance_measurement_requirements.aspx (last visited Mar. 29, 2019)

- Meet the minimum mechanical thrombectomy volume requirements, outlined in the following chart:

Joint Commission Quality Measures for Disease-Specific Care Certification⁴⁹

Measure Set No.	Measure Short Name	Ischemic Stroke	Hemorrhagic Stroke
STK-1	Venous Thromboembolism (VTE) Prophylaxis	X	X
STK-2	Discharged on Antithrombotic Therapy	X	
STK-3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	X	
STK-4	Thrombolytic Therapy	X	
STK-5	Antithrombotic Therapy By End of Hospital Day 2	X	
STK-6	Discharged on Statin Medication	X	
STK-8	Stroke Education	X	X
STK-10	Assessed for Rehabilitation	X	X

- Demonstrate the ability to perform mechanical thrombectomy, 24 hours a day, 7 days a week;
- Maintain dedicated intensive care beds for acute ischemic stroke patients;
- Meet the expectations for the availability of staff and practitioners closely aligned with CSC expectations;
- Collect and review data regarding adverse patient outcomes following mechanical thrombectomy; and
- Collect data for 13 standardized performance measures listed in the chart above.⁵⁰

Stroke Center Inventory

The AHCA maintains a list of hospitals offering stroke services.⁵¹ The list of hospitals meeting the criteria as a ASRC, PSC, or CSC is published on the AHCA’s website.^{52,53} There are also 286 EMS providers⁵⁴ that report patient stroke data to the DOH.⁵⁵ However, the data are not standardized, and many of the data that the DOH currently collects come from voluntary participation in the DOH’s EMS Tracking and Reporting System (EMSTARS) program⁵⁶ and

⁴⁹ Id.

⁵⁰ *Infra* note 51.

⁵¹ Section 395.3038, F.S.

⁵² *Supra* note 211.

⁵³ Id. A list of hospitals with a stroke center designation is also available through the facility locator tool on: www.floridahealthfinder.gov, (last visited Mar. 12, 2019).

⁵⁴ Department of Health, *EMS Provider Licensure Report*, available at: <http://www.floridahealth.gov/licensing-and-regulation/ems-service-provider-regulation-and-compliance/ems-providers.html> (last visited Mar. 29, 2019).

⁵⁵ Agency For Health Care Administration, *Hospital ER Services*, available at: http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Hospital_ER_Services.pdf, (last visited Mar. 29, 2019).

⁵⁶ The EMSTARS program allows emergency medical providers to capture incident level patient care records for every emergency activation.

only includes data on response, provider impression, procedures and medication, and destination.⁵⁷

Health care records submitted to the DOH from licensed EMS providers are confidential and exempt from public records requests under s. 401.30(4), F.S.

Stroke Patient Transportation

The DOH has also developed a stroke assessment tool.⁵⁸ The tool is available on the DOH's website and is provided to EMS providers.⁵⁹ Each licensed EMS provider must use a stroke triage assessment tool that is substantially similar to the DOH's stroke triage assessment tool.⁶⁰ Annually, by June 1, the DOH sends the list of ASRCs, PSCs, and CSCs to the medical director of each licensed EMS provider in Florida.⁶¹

III. Effect of Proposed Changes:

Section 1 amends s. 395.3038, F.S., to add Thrombectomy-Capable Stroke Centers (TSC) to the AHCA's list of certified stroke centers.

The bill requires that listed hospitals must be certified by a nationally recognized certifying organization as meeting the criteria for an ASRC, PSC, TSC, or CSC. The AHCA's list must include only those hospitals that have submitted documentation to the AHCA verifying their certification as an ASRC, PSC, TSC or CSC. That documentation may include, but is not limited to, any stroke center that offers and performs mechanical endovascular therapy (EVT) consistent with the standards identified by a nationally recognized, guidelines-based organization approved by the AHCA. The bill requires hospitals that have previously attested in an affidavit to the agency that it meets the criteria as a certain stroke center, to be certified by a nationally recognized accrediting organization by July 1, 2021.

The bill eliminates the use of an affidavit attesting that the hospital's stroke program meets the criteria for one of the stroke center designations, as specified by AHCA rule, as an alternate method for the hospital to be listed.

The bill directs that if a hospital chooses to no longer be certified by a nationally recognized certifying organization, or has not attained national certification as an ASRC, PSC, CSC, or TSC, the hospital must notify the AHCA and the AHCA must immediately remove the hospital from its list of stroke centers.

The bill removes AHCA's rule-making authority to establish criteria for an ASRC, PSC, and CSC, which were required to be substantially similar to the certification standards for the same categories of stroke centers of a nationally recognized accrediting organization.

⁵⁷ *Supra* note 55.

⁵⁸ Section 395.3041(2), F.S.

⁵⁹ Section 395.3041(2), F.S.

⁶⁰ *Id.*

⁶¹ Section 395.3041(1), F.S.

Section 2 amends s. 395.30381, F.S., to require that TCSs, in addition to ASRCs, PSCs, and CSCs, regularly report information containing nationally recognized stroke performance measures to the statewide stroke registry.

Section 3 amends s. 395.3039, F.S., to prohibit a hospital from advertising that it is a state-listed ASRC, PSC, CSC, or TSC, unless the hospital has submitted documentation to the AHCA verifying that it is certified and meets the certification criteria of a nationally recognized certifying organization.

Section 4 amends s. 395.3041, F.S., to direct the DOH to include data from TSCs in its annual list to the medical directors of licensed EMS providers. The bill directs the medical directors of licensed EMS providers to develop and implement transportation and rerouting protocols, in addition to assessment and treatment protocols, for stroke patients with the intent to reroute them to ASRCs, PSCs, CSCs, and TSCs. The protocols must include plans for the triage and transport of suspected stroke patients, including, but not limited to, patients who may have an emergent large vessel occlusion, to an appropriate facility within a specified timeframe after such patients exhibit the sudden onset of stroke-related symptoms.

The bill directs the medical directors of licensed EMS providers to specifically consider the capability of an emergency receiving facility to improve outcomes for patients who are suspected, based on clinical severity, of having an emergent large vessel occlusion in developing the protocols.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

Hospitals that maintain ASRCs, PSCs, CSCs, or TSCs, are required under PCS/CS/SB 1460 to be certified by a nationally recognized certifying organization and may incur a cost for their application for certification. They may need to purchase new software and incur labor costs to collect, maintain, and send the required data to the DOH. Such costs, if any, are indeterminate.

C. Government Sector Impact:

The bill has an insignificant fiscal impact on the Agency for Health Care Administration.⁶²

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.3038, 395.30381, 395.3039, and 395.3041.

IX. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**

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

Recommended CS/CS by Appropriations Subcommittee on Health and Human Services on April 4, 2019:

The committee substitute requires hospitals that have previously attested in an affidavit to the AHCA that it meets certain criteria as a certain stroke center, to be certified by a nationally recognized accrediting organization by July 1, 2021. The CS also removes the DOH's role in the development of protocols of relating to emergency medical service providers.

⁶² Agency for Health Care Administration, *SB 1460 2019 Agency Legislative Bill Analysis- Fiscal Analysis* (February 26, 2019) (on file with the Appropriations Subcommittee on Health and Human Services).

CS by Health Policy on March 18, 2019:

The CS:

- Removes specific entities that may certify that an ASRCs, PSCs, CSCs, or TSCs meets the standards of a specific type of stroke center and requires only that the certifying entity must be a nationally recognized, guidelines-based organization approved by the AHCA; and
- Removes the DOH from the protocol development and implementation process with licensed EMS medical directors for transportation and rerouting of stroke patients with the intent to reroute them to ASRCs, PSCs, CSCs, and TSCs.

B. Amendments:

None.

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19

Meeting Date

1460

Bill Number (if applicable)

Topic Stroke Centers

Amendment Barcode (if applicable)

Name Mark Landreth

Job Title G.R.D.

Address 2851 Rumpkin Green Cir #A

Phone 552 544 3376

Street

City

State

Zip

37308

Email Mark.Landreth@heart.org

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing American Heart Association

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19

Meeting Date

1460

Bill Number (if applicable)

Topic Stroke Centers

Amendment Barcode (if applicable)

Name Kelly Mallette

Job Title _____

Address 104 W. Jefferson Street

Phone (850) 224-3427

Street

Tallahassee, FL

City

State

Zip

Email Kelly@rtbackpa.com

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Society For Neurointerventional Surgery

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

By the Committee on Health Policy; and Senators Book and Powell

588-03172-19

20191460c1

A bill to be entitled

An act relating to stroke centers; amending s. 395.3038, F.S.; revising the criteria for hospitals to be included on the state list of stroke centers by the Agency for Health Care Administration; removing provisions requiring the agency to adopt rules establishing the criteria for such list; amending s. 395.30381, F.S.; revising provisions relating to the statewide stroke registry to conform to changes made by the act; amending s. 395.3039, F.S.; revising provisions prohibiting the advertisement of a hospital as a state-listed stroke center, unless certain conditions are met, to conform to changes made by the act; amending s. 395.3041, F.S.; requiring the medical director of each licensed emergency medical services provider to develop and implement protocols for the assessment, treatment, transport, and rerouting of suspected stroke patients to certain stroke centers; requiring that such protocols include specified plans for the triage and transport of suspected stroke patients; providing an effective date.

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

Section 1. Subsection (1), paragraph (a) of subsection (2), and subsection (3) of section 395.3038, Florida Statutes, are amended to read:

395.3038 State-listed stroke centers; notification of hospitals.-

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CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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(1) The agency shall make available on its website and to the department a list of the name and address of each hospital that is certified by a nationally recognized certifying organization as meets the criteria for an acute stroke ready center, a primary stroke center, a thrombectomy-capable stroke center, or a comprehensive stroke center. The list of stroke centers must include only those hospitals that have submitted documentation to the agency verifying their certification as an acute stroke ready center, a primary stroke center, a thrombectomy-capable stroke center, or a comprehensive stroke center, which may include, but is not limited to, any stroke center that offers and performs mechanical endovascular therapy consistent with the standards identified by a nationally recognized guidelines-based organization approved by the agency that attest in an affidavit submitted to the agency that the hospital meets the named criteria, or those hospitals that attest in an affidavit submitted to the agency that the hospital is certified as an acute stroke ready center, a primary stroke center, or a comprehensive stroke center by a nationally recognized accrediting organization.

(2) (a) If a hospital no longer chooses to be certified by a nationally recognized certifying organization or has not attained certification consistent with meet the criteria in subsection (1) as for an acute stroke ready center, a primary stroke center, a thrombectomy-capable stroke center, or a comprehensive stroke center, the hospital shall notify the agency and the agency shall immediately remove the hospital from the list of stroke centers.

~~(3) The agency shall adopt by rule criteria for an acute~~

Page 2 of 5

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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59 ~~stroke ready center, a primary stroke center, and a~~
60 ~~comprehensive stroke center which are substantially similar to~~
61 ~~the certification standards for the same categories of stroke~~
62 ~~centers of a nationally recognized accrediting organization.~~

63 Section 2. Section 395.30381, Florida Statutes, is amended
64 to read:

65 395.30381 Statewide stroke registry.—

66 (1) Subject to a specific appropriation, the department
67 shall contract with a private entity to establish and maintain a
68 statewide stroke registry to ensure that the stroke performance
69 measures required to be submitted under subsection (2) are
70 maintained and available for use to improve or modify the stroke
71 care system, ensure compliance with standards and nationally
72 recognized guidelines, and monitor stroke patient outcomes.

73 (2) Each acute stroke ready center, primary stroke center,
74 thrombectomy-capable stroke center, and comprehensive stroke
75 center shall regularly report to the statewide stroke registry
76 information containing specified by the department, including
77 nationally recognized stroke performance measures.

78 (3) The department shall require the contracted private
79 entity to use a nationally recognized platform to collect data
80 from each stroke center on the stroke performance measures
81 required in subsection (2). The contracted private entity shall
82 provide regular reports to the department on the data collected.

83 (4) A ~~No~~ liability of any kind or character for damages or
84 other relief shall not arise or be enforced against any acute
85 stroke ready center, primary stroke center, thrombectomy-capable
86 stroke center, or comprehensive stroke center by reason of
87 having provided such information to the statewide stroke

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88 registry.

89 Section 3. Section 395.3039, Florida Statutes, is amended
90 to read:

91 395.3039 Advertising restrictions.—A person may not
92 advertise to the public, by way of any medium whatsoever, that a
93 hospital is a state-listed ~~primary or comprehensive~~ stroke
94 center unless the hospital has submitted documentation to the
95 agency verifying that it is certified and meets the criteria
96 ~~provided notice to the agency as required in s. 395.3038 by this~~
97 ~~act.~~

98 Section 4. Subsections (1), (3), and (4) of section
99 395.3041, Florida Statutes, are amended to read:

100 395.3041 Emergency medical services providers; triage and
101 transportation of stroke victims to a stroke center.—

102 (1) By June 1 of each year, the department shall send the
103 list of acute stroke ready centers, primary stroke centers,
104 thrombectomy-capable stroke centers, and comprehensive stroke
105 centers to the medical director of each licensed emergency
106 medical services provider in the ~~this~~ state.

107 (3) The medical director of each licensed emergency medical
108 services provider shall develop and implement assessment,
109 treatment, transport, and rerouting ~~transport-destination~~
110 protocols for stroke patients with the intent to assess, treat,
111 ~~and transport~~, and reroute stroke patients to acute stroke ready
112 centers, primary stroke centers, thrombectomy-capable stroke
113 centers, and comprehensive stroke centers. The protocols must
114 include plans for the triage and transport of suspected stroke
115 patients, including, but not limited to, patients who may have
116 an emergent large vessel occlusion, to an appropriate facility

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117 within a specified timeframe after such patients exhibit the
118 sudden onset of stroke-related symptoms. In developing the
119 protocols, the department and the medical director of each
120 licensed emergency medical services provider must consider the
121 capability of an emergency receiving facility to improve
122 outcomes for patients who are suspected, based on clinical
123 severity, of having an emergent large vessel occlusion ~~the most~~
124 ~~appropriate hospital.~~

125 (4) Each emergency medical services provider licensed under
126 chapter 401 must comply with all ~~sections of this section and~~
127 ss. 395.3038-395.3039 ~~act.~~

128 Section 5. This act shall take effect July 1, 2019.



538518

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/09/2019	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services (Book)
recommended the following:

Senate Amendment

Delete lines 43 - 49
and insert:
organization approved by the agency. Each hospital that has
attested in an affidavit to the agency that it meets the
criteria in this subsection must be certified ~~that attest in an
affidavit submitted to the agency that the hospital meets the
named criteria, or those hospitals that attest in an affidavit
submitted to the agency that the hospital is certified as an~~



538518

11 ~~acute stroke ready center, a primary stroke center, or a~~
12 ~~comprehensive stroke center~~ by a nationally recognized
13 accrediting organization by July 1, 2021.



835638

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/09/2019	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services (Book)
recommended the following:

Senate Amendment

Delete line 119
and insert:
protocols, the medical director of each

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL: PCS/CS/SB 1518 (418074)

INTRODUCER: Appropriations Subcommittee on Health and Human Services; Health Policy Committee; and Senator Wright and others

SUBJECT: Alternative Treatment Options for Veterans

DATE: April 11, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Williams</u>	<u>Brown</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>Gerbrandt</u>	<u>Kidd</u>	<u>AHS</u>	<u>Recommend: Fav/CS</u>
3.	_____	_____	<u>AP</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 1518 authorizes the Florida Department of Veterans' Affairs (FDVA) to contract with one state university or Florida College System institution to furnish alternative treatment options for veterans who have been diagnosed by a health care practitioner with service-connected posttraumatic stress disorder or a traumatic brain injury under certain conditions. The provision of the alternative treatment services must be under the direction and supervision of an individual licensed as an medical physician, an osteopathic physician, a chiropractor, a psychologist, a clinical social worker, a marriage and family therapist, a nurse, or a mental health counselor, and participating providers must agree to provide certain data.

The bill requires the FDVA to compile specified data into an annual report for submission to the Governor, the President of the Senate, and the Speaker of the House Representatives. The bill authorizes the FDVA to adopt rules for purposes of implementing the bill.

Implementation of the bill is subject to an appropriation; however, SB 2500, First Engrossed, the Senate's General Appropriations Bill for the 2019-2020 fiscal year, provides \$50,000 in nonrecurring funds from the General Revenue Fund to the University of South Florida for "Alternative Treatment for Veterans." See Section V.

The bill takes effect July 1, 2019.

II. Present Situation:

Veterans' Health Care Services

Veterans of the United States Armed Forces may be eligible for a range of benefits, which are codified in Title 38 of the United States Code. Certain former members of the Reserves or National Guard who were called to active duty may also be eligible for benefits.¹ The federal Department of Veterans Affairs (VA) is required by law to provide eligible veterans hospital care and outpatient care services that are defined as “needed.” The VA defines “needed” as care or services that will promote, preserve, and restore health. This includes treatment, procedures, supplies, or services. This decision of need will be based on the judgment of the veteran’s health care provider and in accordance with generally accepted standards of clinical practice.

There are also specific health programs for which veterans may be eligible, including treatment relating to:

- Blindness rehabilitation;
- Post-traumatic stress;
- Traumatic brain injury;
- Agent Orange exposure;
- Gulf War Syndrome and related illnesses;
- Radiation exposure; and,
- HIV/AIDS.²

If a person served in the active military service and was separated under any condition other than “dishonorable,” that individual may be eligible for health care and other benefits under the federal Veterans Health Administration (VHA) through the VA. Most veterans who enlisted after September 7, 1980, or entered active duty after October 16, 1981, must have served at least 24 continuous months; however, this time standard may not apply to those veterans who were discharged due to a disability that was caused or aggravated in the line of duty or under other exceptions.³

Veterans must register or apply for health care benefits through the VHA. Certain categories of veterans are provided enhanced enrollment, such as veterans who:

- Are former prisoners of war;
- Are Purple Heart Medal recipients;
- Are Medal of Honor recipients;
- Are classified as having compensable VA-awarded, service-connected disability⁴ representing 10 percent or more of the veteran’s functional capacity;

¹ U.S. Department of Veterans Affairs, Health Benefits, available at: <https://www.va.gov/HEALTHBENEFITS/apply/veterans.asp> (last visited April 4, 2019).

² U.S. Department of Veterans Affairs, Veteran’s Health Care overview, available at: <https://www.military.com/benefits/veterans-health-care/veterans-health-care-overview.html#1> (last visited April 4, 2019).

³ *Supra* note 1.

⁴ A service-connected disability is an injury or illness that was incurred or aggravated during active military service. Compensation may also be paid for post-service disabilities that are considered related or secondary to disabilities occurring in service or presumed to be related to circumstances of military services, even if they arise after military service. To be eligible for compensation, the veteran must

- Receive a VA pension;
- Were discharged from the military because of a disability (not pre-existing), early out, or hardship;
- Served in a theater of operations for five years post discharge;
- Served in the Republic of Vietnam from January 9, 1962, to May 7, 1975;
- Served in the Persian Gulf from August 2, 1990 to November 11, 1998;
- Were stationed or resided at Camp Lejeune for 30 days or more between August 1, 1953, and December 31, 1987;
- Were found catastrophically disabled by the VA; or
- Have a household income that is below the VA's national income or geographical-adjusted thresholds.⁵

Only certain veterans are required to provide income information to the VA as part of the application process. Veterans who do not have a VA-service connected disability, do not receive a VA pension, or have a special eligibility are required to participate in the financial assessment. While many Veterans qualify for enrollment and cost-free health care services based on a compensable, service-connected condition or other qualifying factors, certain veterans will be asked to complete a financial assessment at the time of enrollment to determine their eligibility for free medical care, medications and/or travel benefits. The assessment is based on the previous year's gross household income of the veteran and his or her spouse and dependents, if any.

This financial information may be used to determine the veteran's enrollment priority group. The gross household income amounts that are used to determine priority groups or eligibility for cost-free care are adjusted annually. These amounts can also vary by geographic based assessments. Unreimbursed medical expenses are deducted from the veteran's gross income, including medical-travel related expenses, health insurance premiums, and prescriptions.⁶

When a veteran enrolls for benefits, he or she is assigned to one of eight priority groups that the VA uses to balance the demand for services with available resources. Priority groupings are based on the need for services, level of disability, discharge status, and income.⁷ The highest priority group are those veterans with service-related injuries with at least a 50 percent service-connected disability and/or the veteran has been determined unemployable.⁸ The lowest priority group includes those veterans whose gross household incomes are above the VA national income threshold and who agree to pay copayments.

have been separated or discharged under conditions other than dishonorable. See <https://www.benefits.va.gov/compensation/> (last visited April 4, 2019).

⁵ *Supra* note 1.

⁶ See U.S. Department of Veterans Affairs, Basic Eligibility for VA Health Care (last updated April 2, 2018) available at: https://www.va.gov/healthbenefits/resources/publications/hbco/hbco_basic_eligibility.asp (last visited April 4, 2019).

⁷ *Supra* note 2.

⁸ *Id.*

Florida Veterans

The federal VA system serves more than 1.5 million Floridians, which is the third highest population of veterans in the country behind California and Texas.⁹ Over half of the state's veterans are aged 65 and older, with the majority of those veterans having served during the Vietnam and Gulf Wars eras, as noted in the chart below.

Period of Service	Number of Veterans 9/30/2017
WWII	75,794
Korea	153,562
Vietnam	532,691
Gulf Wars	500,269
Other	297,462
Total	1,559,778

In Florida, 733,037 individuals were enrolled in VA health services and over 500,000 unique enrollees received treatment in Fiscal Year 2017. The VHA operates 9 VA inpatient facilities, 69 outpatient facilities, and 24 Vet Centers in the state. For 2016, the VHA reported expending \$6,371,816 for medical care in Florida. Besides health care benefits, over 348,000 Florida veterans also receive disability compensation payments.¹¹

Veterans' Health Care Delivery System

Nationally, the VA has 155 inpatient sites and over 1,000 outpatient sites with another 300 Vet Centers that provide counseling services, outreach, and referral services to veterans and their families. Veterans can receive health care services at any VA health care facility in the country. Health care enrollment and utilization has increased with outpatient visits growing from 46.5 million visits in 2002 to 95.2 million visits in 2015.¹²

Health care is primarily delivered through 21 regional networks know as Veterans Integrated Service Networks, or VISNs, nationwide. For Florida, two networks cover the state with one responsible for 60 counties in the northern, central, and southern regions of the state¹³ and the other network covering the remaining seven counties in northwest Florida.¹⁴

⁹ See U.S. Department of Veterans Affairs, State Profile (as of September 30, 2017), available at: https://www.va.gov/vetdata/docs/SpecialReports/State_Summaries_Florida.pdf (last visited April 4, 2019).

¹⁰ U.S. Department of Veterans Affairs, *Veteran Population*, (updated November 23, 2018), available at: https://www.va.gov/vetdata/Veteran_Population.asp (last visited April 4, 2019). The "Other" category includes veterans of multiple more recent conflicts as well as those with no war-time service.

¹¹ *Supra* note 9.

¹² U.S. Department of Veterans Affairs, *Selected Veterans Health Administration Characteristics, FY 2001 to FY 2015*, available at: <https://www.va.gov/vetdata/Expenditures.asp> (last visited April 4, 2019).

¹³ VISN 8 is the Sunshine Healthcare Network and covers 60 Florida counties, 19 rural counties in South Georgia, and Puerto Rico and the U.S. Virgin Islands. VISN 8 includes seven outpatient clinics of which six are located in Florida and one is located in Puerto Rico. For more information on VISN 8, see <https://www.visn8.va.gov/VISN8/about/index.asp> (last visited April 4, 2019).

¹⁴ VISN 16 is the South Central VA Health Care Network and serve veterans in Arkansas, Louisiana, Mississippi, and parts of Texas, Missouri, Alabama, Oklahoma, and Florida. VISN 16 has eight Veterans Affairs Medical Centers (VAMC) of which none are located in

Veterans Choice Program

Congress directed the VA through the Veterans Access, Choice, and Accountability Act of 2014 (VACCA)¹⁵, and specifically, the Veterans Choice Program (VCP), to furnish hospital care and medical services through alternative means when veterans could not access services in a timely manner. To be eligible, a veteran may optionally enroll if he or she faces an unacceptable burden in accessing a provider of more than 40 miles driving distance to the nearest VA medical facility and has been identified to have an appointment more than 30 days out from a preferred appointment date; faces other geographic challenges; encounters environmental challenges; or has a medical condition that impairs the veterans ability to travel.

When a veteran attempts to schedule an appointment at a VHA medical facility or meets the driving condition or one of the other special circumstances and cannot be seen within 30 days, the veteran is placed on the Veterans Choice List (VCL). Once the veteran is placed on this list, the veteran has the ability to opt into the program and receive care from the designated third party administrator (TPA) managed provider network.

The VACCA also mandated other changes such as requiring the use of electronic waiting lists , making such waiting lists accessible so veterans can make informed choices about whether to receive care at such facilities, requiring VCP cards be issued to certain veterans, requiring non-VA health care providers to have the same credentials as VA health care providers, requiring the establishment of performance metrics, setting appointment access standards, requiring a number of reports, and publishing wait times of VA facilities publicly.

The VCP was initially funded by Congress with \$10 billion. The legislation would sunset upon either the exhaustion of the funds or three years from the its enactment, whichever occurred first.¹⁶ Before either event could happen, the program's termination date was removed and additional funds were authorized in 2017.¹⁷

Patient Centered Community Care Program

Existing prior to VCP, if care was not readily available either because of time or geography, a veteran's health care facility could and still can use a Patient Centered Community Care Contract (PC3) to purchase care from a non-VA provider. More than 3.5 million authorizations for services under PC3 contracts were made from September 1, 2015 through August 31, 2016, a 13 percent increase over the same period in 2014-2015.¹⁸ In comparison, internal VA appointments for 2015-2016 were 58.3 million.¹⁹

Florida, one outpatient clinic in Texas, and 68 outpatient sites or Vet Centers of which six are located in Florida. For more information on VISN 16, see <https://www.visn16.va.gov/about/> (last visited April 4, 2019).

¹⁵ Pub. Law No. 113-146.

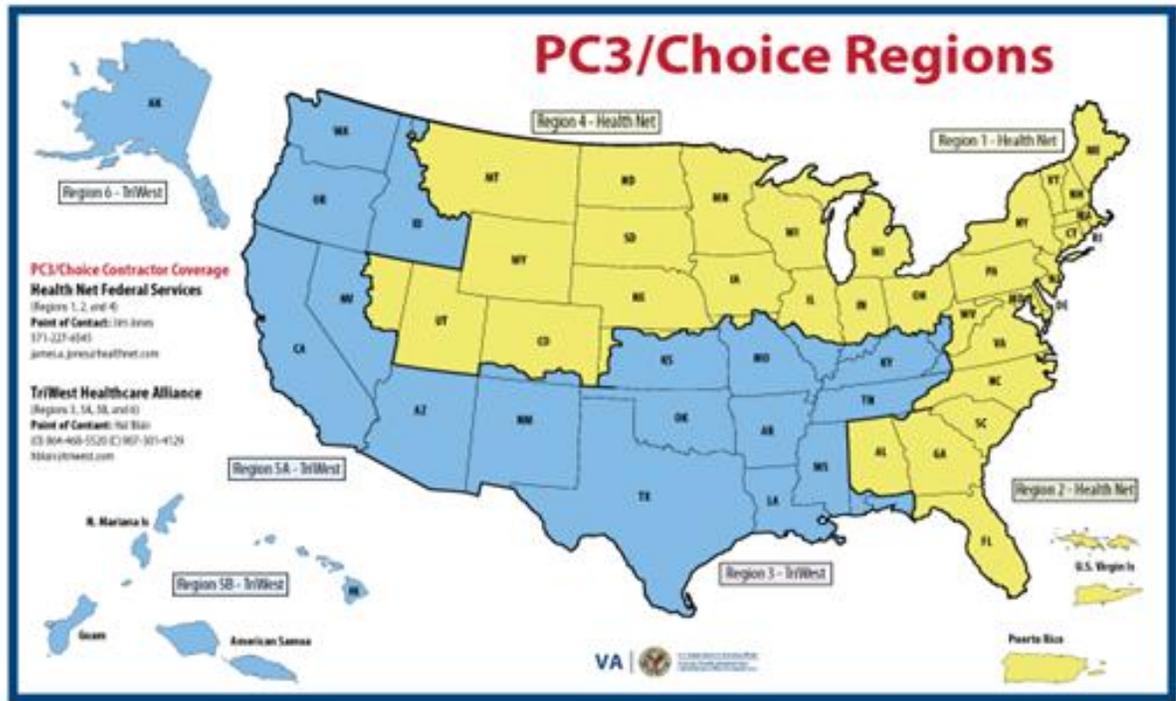
¹⁶ Veterans Access, Choice, and Accountability Act of 2014, Pub. Law No. 113-146, s. 101(p) (August 7, 2014), 128 STAT. 1763 (August 7, 2014).

¹⁷ VA Choice and Quality Employment Act of 2017, Pub. Law No. 115-26, 131 STAT. 129-130 (April 19, 2017).

¹⁸ U.S. Department of Veterans Affairs, Special Medical Advisory Group (SMAG) *Progress Report 2016*, p. 5, available at: https://www.va.gov/health/smag_report/smag_progress_report_2016.asp (last visited Mar. 21, 2019).

¹⁹ *Id.*

Florida is covered by two different health network contracts: Health Net Federal Services and TriWest Healthcare Alliance.²⁰ A map of the regions covered by the contracts is shown below.



The PC3 program does not provide coverage for all benefits. Coverage is limited only to primary care, limited emergency care, mental health care, inpatient and outpatient specialty care, and limited newborn care for enrolled female veterans following the birth of a child.²¹ Services are managed nationally by one of two TPA managed provider networks based on where the veteran is located.

The Veterans Choice Programs

Collectively known as the Veterans Choice Programs , the VA provides veterans with options under the VCP, the PC3, and non-VA fee programs for pre-authorized medical care only. Millions of appointments had been provided under the programs and billions of dollars had been expended in health care funds with an additional \$235 million spent on administrative costs to the health care networks over a several year time span.²²

The Inspector General (IG) of the VA reported on contacts received by its office from October 1, 2015, through January 31, 2017, and noted they fell into four general complaint categories:

- 48 percent had concerns about appointments and scheduling;

²⁰ U.S. Department of Veterans Affairs, *VHA Office of Community Care, Patient Centered Community Care (PC3)*, (last updated May 11, 2017), available at: <https://www.va.gov/COMMUNITYCARE/programs/veterans/pccc/index.asp> (last visited April 4, 2019).

²¹ *Id.*

²² Testimony of Michael J. Missal, Inspector General of U.S. Department of Veterans Affairs before the Committee on Veterans’ Affairs, U.S. House of Representatives, Hearing on “Shaping the Future: Consolidating and Improving VA Community Care,” (March 7, 2017), p. 2, available at: <https://www.va.gov/oig/pubs/statements/VAOIG-Statement-20170307-missal.pdf> (last visited April 4, 2019).

- 35 percent had concerns about referrals, authorizations, or consults;
- 12 percent had concerns about veteran and provider payments; and
- 5 percent had concerns about program eligibility or enrollment.²³

The IG reviewed appointment wait times, authorization practices, scheduling procedures, and timeliness of care of various offices and facilities. Several barriers to care were found, including 1.2 million appointments from November 1, 2014, through September 30, 2015 for veterans in the various VHA programs waiting over 30 days for care at VHA medical facilities.²⁴ In the October 2016 report, the IG published its review of the Phoenix, Arizona VA Health System in which it had determined that more than 22,000 patients had 34,000 open consults. One patient waited in excess of 300 days for a consult.²⁵ The review of the Phoenix office included services delivered in both the traditional and non-traditional VA care settings.

In February 2016, another IG report looked at timely care in Colorado Springs. Out of 450 consults and appointments, 288 veterans in Colorado Springs encountered wait times in excess of 30 days. Of those 288 who had wait times in excess of 30 days, none of those 288 veterans were added to the VCL or were not added in a timely manner, which would make them eligible to receive services under that program.²⁶

Access to Care in Florida

News reports and other OIG reports indicate that the VA struggled to implement the new Choice programs from November 1, 2014, through September 30, 2015, including the special OIG Choice Implementation report requested by Congress.²⁷ Within this audit, one Florida facility was included, the North Florida/South Georgia Veterans Health System. The audit noted the struggles of the VA to meet the expedited 90-day implementation timeline of the original 2014 legislation, inadequate provider networks once the program was implemented, third party liability concerns by veterans for non-payment of medical bills to providers, appointment wait times in excess of 30 days, and provider administrative burden issues.²⁸

In its response to the audit report, the Secretary of the VA noted that the Choice programs have changed dramatically since implementation and had seen a growth rate in authorizations from October 2015 to March 2016 of 103 percent.²⁹ The VA requested authorization to consolidate all of the Community Care Programs into a singular authority tied to Medicare reimbursement for like services to address issues related to provider network adequacy and administrative burdens on both the DVA and the provider.³⁰

²³ *Id.*

²⁴ *Id.* at 3.

²⁵ *Id.* at 4. The publication title of the report is *Review of Alleged Consult Mismanagement of the Phoenix VA Health Care System (PVAHCS)*, VA Office of Inspector General, Office of Audits and Evaluation, (October 4, 2016), Report 15-046720342, available at: <https://www.va.gov/oig/pubs/VAOIG-15-04672-342.pdf> (last visited April 4, 2019).

²⁶ U.S. Department of Veterans Affairs, VA Office of Inspector General Office of Audits and Evaluation, *Veterans Health Administration – Review of the Alleged Untimely Care at the Community Based Outpatient Clinic Colorado Springs, CO*, (February 4, 2016), Report 15-02472-46, available at: <https://www.va.gov/oig/pubs/VAOIG-15-02472-46.pdf> (last visited April 4, 2019).

²⁷ U.S. Department of Veterans Affairs, VA Office of Inspector General Office of Audits and Evaluation, *Veterans Health Administration Review of the Implementation of the Veterans Choice Program*, (January 30, 2017), Report 15-04673-333, available at: <https://www.va.gov/oig/pubs/VAOIG-15-04673-333.pdf> (last visited April 4, 2019).

²⁸ *Id.* at ii and iii.

²⁹ *Id.* at 25-26.

³⁰ *Id.* at 26.

Alternative Treatment Options for Veterans

Complementary and integrative health (CIH) consists of products and practices that are not currently part of mainstream, conventional medical practice. CIH emphasizes patient empowerment, self-activation, preventive self-care, and wellness, often in conjunction with traditional medical treatment or in other alternative treatment settings. These approaches may be considered complementary (i.e., used in place of or used along with standard medical care). Integrative medicine refers to care that blends both mainstream and alternative practices. The boundaries between CIH and conventional medicine are not absolute, although most CIH approaches fall into one of two subgroups: natural products (e.g., herbs, vitamins and minerals, and probiotics) and mind and body practices (e.g., yoga, meditation, massage therapy, acupuncture, and relaxation techniques).³¹

In the United States, CIH approaches have gained popularity in recent years, and, as a result, more research is focusing on how CIH may improve various patient outcomes. According to the National Center for Complementary and Integrative Health (NCCIH) of the National Institutes of Health, more than 30 percent of American adults and about 12 percent of children use health care approaches developed outside of mainstream conventional medicine.³²

In the VA, CIH approaches are most commonly used to improve veterans' mental health, manage pain, and promote general wellness. More specifically, these approaches are often used to treat posttraumatic stress disorder (PTSD), depression, back pain, headache, arthritis, fibromyalgia, and substance abuse. One of the greatest challenges in CIH is critically examining the effectiveness of approaches that have not been rigorously tested through formal research. VA researchers remain committed to addressing these scientific gaps. They are conducting studies to determine which approaches are truly safe and effective, and for which conditions and populations they work best.³³

Through its Center for Compassionate Care Innovation (CCI)³⁴ and as part of its mission to better meet the needs of veterans on an ongoing basis, the VA provides a wide array of state-of-the-art treatments and evidence-based therapies, and is a leader in research and innovation. The VA is committed to providing the best health care available to veterans and is interested in learning about new treatment modalities used in the private sector that result in positive health outcomes. The mission of CCI is to explore emerging therapies that are safe and ethical to enhance veteran physical and mental well-being when other treatments have not been successful. CCI focuses on the conditions that may be resistant to standard treatments, including: chronic pain, PTSD, suicidality, and traumatic brain injury (TBI).

Given that there may be numerous innovative treatment approaches for each of the above conditions, the CCI is tasked with prioritizing proposals that have a current or emerging evidence-base documenting their efficacy, are cleared by the federal Food and Drug

³¹ U.S. Department of Veterans Affairs, Office of Research and Development, (updated September 19, 2018) available at: <https://www.research.va.gov/topics/cih.cfm> (last visited April 4, 2019).

³² *Id.*

³³ *Id.*

³⁴ U.S. Department of Veterans Affairs, Office of Community Engagement. Center of Compassionate Care Innovation, (updated March 22, 2019) available at <https://www.va.gov/HEALTHPARTNERSHIPS/CCIMission.asp> (last visited Mar. 26, 2019).

Administration for their intended purpose and are designed to offer sustained benefits to the target population. The CCI has a review process in order to identify proposals that are appropriate for implementation. Proposals shared with the CCI should be aligned with the CCI's mission, not already available within the VHA network, feasible to implement, and developed in accordance with the CCI's guidelines.³⁵

To accomplish its mission, the CCI:

- Maintains integrity of the fundamental principle to “Do No Harm.”
- Evaluates emerging modalities, devices, and interventions that are safe and ethical in order to augment and support current the evidence-based program.
- Advocates for shared decision-making where veterans are active participants in choosing treatments, interventions, or therapies.
- Examines innovative proposals that may provide help and hope to veterans who have not responded to standard treatments.
- Collaborates with experts across health care disciplines to consider noteworthy, safe, and ethical emerging therapies that are not currently in widespread clinical use in VA.³⁶

A sampling of alternative treatments being provided by the federal VA at present include things such as light emitting diode (LED) therapy for mild TBI, stellate ganglion block (SGB) for treatment of PTSD, various services delivered via telehealth, yoga and meditation, acupuncture, the training and use of service dogs, equine therapy, music therapy, accelerated resolution therapy, and various outdoor therapies including horseback riding, hiking, and rafting.^{37,38}

Florida Department of Veterans' Affairs

In 1988, Florida citizens voted to create the Department of Veterans' Affairs (FDVA) by constitutional amendment.³⁹ The FDVA is responsible for advocating on behalf of Florida's veterans to improve their quality of life and to facilitate access to federally funded medical care for eligible veterans.

The department also manages one assisted living facility and six state veterans' nursing homes with nursing homes seven and eight in construction stages in St. Lucie County and Orange County. To be eligible for admission to these state facilities, a veteran must have had an honorable discharge, be a state resident prior to admission, and have received a certification of need of assisted living or skilled nursing care as determined by a VA physician.

Other services are available to veterans in county services offices which may be co-located in VA Regional Offices in Bay Pines, each federal VA Medical Center and many of the federal VA Outpatient Clinics.

³⁵ *Id.*

³⁶ *Id.*

³⁷ News Release, U.S. Department of Veterans Affairs, *VA Exploring Alternative Treatments for TBI and PTSD* (Dec. 7, 2017) available at <https://www.va.gov/opa/pressrel/pressrelease.cfm?id=3986> (last visited Mar. 26, 2019).

³⁸ Florida Department of Veterans' Affairs, *Senate Bill 1518 Analysis*, (Mar. 20, 2019) (on file with the Senate Committee on Health Policy).

³⁹ See FLA. CONST. art IV, s. 11.

Currently, the FDVA offers primary care for residents at each of the state veterans' nursing homes and at the domiciliary for the residents. At present, the department does not offer secondary, specialized, or alternative care.⁴⁰

III. Effect of Proposed Changes:

Section 1 creates s. 295.156, F.S., to authorize the FDVA, subject to a legislative appropriation, to contract with a state university or a Florida College System institution furnish alternative treatment options for veterans. The university or institution must manage, monitor, and ensure compliance of contracted providers.

To qualify, a veteran must have been diagnosed with service-connected PTSD or a TBI by a health care practitioner, demonstrate having previously sought services for TBI or PTSD through the federal VA service delivery system or through private health insurance, and be certified by the VA or by any branch of the United States Armed Forces as having a TBI or PTSD.

The alternative treatment options specified in the bill are: accelerated resolution therapy, equine therapy, hyperbaric oxygen therapy, music therapy, and service animal training therapy.

The bill defines, "posttraumatic stress disorder," as a mental health disorder that is developed after having experienced or witnessed a life-threatening event, including but not limited to, military sexual trauma; and "traumatic brain injury," as an acquired injury to the brain,

The provision of the alternative treatment services must be under the direction and supervision of an individual licensed as: an allopathic physician under ch. 458, F.S., an osteopathic physician under ch. 459, F.S., a chiropractor under ch. 460, F.S., a psychologist under ch. 490, F.S., or a clinical social worker, a marriage and family therapist, a nurse under ch. 464, F.S., or a mental health counselor under ch. 491, F.S. The licensed provider supervising the provision of alternative treatment must agree to cooperate with the FDVA to provide data sufficient for an assessment of the efficacy of alternative treatment modalities.

The bill requires that by January 1 of each year, beginning January 1, 2020, the FDVA shall compile a report documenting each alternative treatment provided under this act, the provider type, the number of veterans served, and the treatment outcomes. The department must submit the report to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

The FDVA is given rulemaking authority for purposes of implementing the bill.

Section 2 specifies that the bill takes effect July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

⁴⁰ *Supra* note 38.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

PCS/CS/SB 1518 provides that implementation is subject to an appropriation.⁴¹ However, the provision of alternative medical services to Florida's veteran population could have a significant fiscal impact on state expenditures.

In addition to funding for services, the FDVA also indicates the need for one full-time equivalent position to implement the bill.⁴²

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

⁴¹ As of this writing, SB 2500, the Senate's proposed General Appropriations Bill for fiscal year 2019-2020, includes a \$50,000 nonrecurring appropriation from the General Revenue Fund to the University of South Florida for "Alternative Treatment for Veterans" under Specific Appropriation 575A, at page 111.

⁴² *Supra* note 38.

VIII. Statutes Affected:

This bill creates the following section of the Florida Statutes: 295.156

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

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

Recommended CS/CS by Appropriations Subcommittee on Health and Human Services on April 9, 2019:

The committee substitute adds the definition of posttraumatic stress disorder and traumatic brain injury and removes the following definitions from the bill: accelerated resolution therapy, alternative treatment, equine therapy, facility, hyperbaric oxygen therapy, music therapy, physician, service animal training therapy, traumatic brain injury, and veteran. The CS also authorizes the provision of alternative treatment services to be provided under the direction and supervision a nurse licensed under ch. 464, F.S.

CS by Health Policy on April 1, 2019:

The CS added provisions to the bill which:

- Requires a veteran seeking participation in the program to demonstrate having previously sought services for traumatic brain injury or posttraumatic stress disorder through the federal Veterans Affairs service delivery system or through private health insurance, if such coverage is available to the individual.
- Limits the FDVA to contracting with either one state university or one state college system institution for the purposes of entering into and managing multiple provider contracts, and the chosen contracting entity must manage, monitor, and ensure compliance of the contracted providers.
- Requires the licensed provider supervising the provision of alternative treatment to agree to cooperate with the FDVA to provide data sufficient for an assessment of the efficacy of alternative treatment modalities.
- Requires that by January 1 of each year, beginning January 1, 2020, the FDVA must compile a report documenting each alternative treatment provided under the bill, the provider type, the number of veterans served, and the treatment outcomes. The FDVA must submit the report to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

B. Amendments:

None.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Military and Veterans Affairs and Space, *Chair*
Children, Families, and Elder Affairs
Commerce and Tourism
Environment and Natural Resources

JOINT COMMITTEE:

Joint Administrative Procedures Committee

SENATOR TOM A. WRIGHT

14th District

April 1, 2019

The Honorable Aaron Bean
405, Senate Office Building
404 S. Monroe Street
Tallahassee, FL 32399

Re: Senate Bill 1518 – Alternative Treatment Options for Veterans

Dear Chairman Bean:

Senate Bill 1518, relating to Alternative Treatment Options for Veterans has been referred to the Appropriations Subcommittee on Health and Human Services. I am requesting your consideration on placing SB 1518 on your next agenda. Should you need any additional information please do not hesitate to contact my office.

Thank you for your consideration.

Sincerely,

A handwritten signature in cursive script that reads "Tom A. Wright".

Tom A. Wright, District 14

cc: Tonya Kidd, Staff Director of the Appropriations Subcommittee on Health and Human Services
Robin Jackson, Administrative Assistant of the Appropriations Subcommittee on Health and Human Services

REPLY TO:

- 4606 Clyde Morris Blvd., Suite 2-J, Port Orange, Florida 32129 (386) 304-7630
- 312 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5014

Senate's Website: www.flsenate.gov

BILL GALVANO
President of the Senate

DAVID SIMMONS
President Pro Tempore

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

5B-1578
Bill Number (if applicable)

Meeting Date _____

Topic ALTERNATIVE TREATMENT

Amendment Barcode (if applicable) _____

Name JOHN HAYNES

Job Title CHAIRMAN AMERITUS FL. VETERANS FOUNDATION

Address 424 HIAWATHA FARMS SO.
Street

Phone 850-443-3451

MONTICELLO, FL. 32344
City State Zip

Email john2045@earthlink.net
.com

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing _____

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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THE FLORIDA SENATE
APPEARANCE RECORD

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4-8-2019

Meeting Date

JB 1518

Bill Number (if applicable)

Topic ALT. TREATMENT FOR VETS

Amendment Barcode (if applicable)

Name JACK HEBERT

Job Title _____

Address _____

Phone 727-560-3323

Street Clearwater Fl

Email _____

City _____ State _____ Zip _____

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing FLORIDA CHIROPRACTIC ASSN

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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THE FLORIDA SENATE
APPEARANCE RECORD

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04/09/2019
Meeting Date

501518
Bill Number (if applicable)

Topic Alternative Treatment Options for Veterans

Amendment Barcode (if applicable)

Name Washington Sanchez, Col. US Army

Job Title VP, Tallahassee Veterans Legal Collaborative

Address 2229 GATES DRIVE
Street

Phone 850-322-8455

Tallahassee FL 32312
City State Zip

Email WJSAN4@GMAIL.COM

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Tallahassee Veterans Legal Collaborative

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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THE FLORIDA SENATE

APPEARANCE RECORD

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4/4/19
Meeting Date

1518
Bill Number (if applicable)

Topic Veterans

Amendment Barcode (if applicable)

Name Bill Helmich

Job Title

Address 303 Johns Dr
Street

Phone 850 251 3126

Tally FL 32301
City State Zip

Email

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing VFW / American Legion

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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THE FLORIDA SENATE
APPEARANCE RECORD

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4/9/19

Meeting Date

1518

Bill Number (if applicable)

Topic Alternative Treatment Options for Veterans

Amendment Barcode (if applicable)

Name Sharon Graham

Job Title Music Therapist - Board Certified

Address 8629 Alexandra Arbor Ln

Phone 813-625-3213

Street

Temple Terrace

City

FL

State

33637

Zip

Email FLmusictherapyTF@gmail.com

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing FL Music Therapy Task Force

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4-9-19

Meeting Date

1518

Bill Number (if applicable)

Topic ALT. TREATMENT OPTIONS VETS

Amendment Barcode (if applicable)

Name JESSE DIAZ

Job Title OUTREACH COORD.

Address 8360 PHILADELPHIA AVE

Phone 352-585-0626

Street

SPRING HILL

City

State

Zip

Email JESSE.RESPONDERS.FIRST@G.MAZ

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing _____

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

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APPEARANCE RECORD

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4/9/19

Meeting Date

1518

Bill Number (if applicable)

Topic Alternative Treatment Options for Veterans

Amendment Barcode (if applicable)

Name Corinne (core-n) Mixon

Job Title Lobbyist

Address 511 N. Adams St.

Phone 8507665495

Street

Tallahassee

FL

32301

Email corinnemixon@gmail.com

City

State

Zip

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Florida Music Therapy Taskforce

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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4/9/2019

Meeting Date

1518

Bill Number (if applicable)

Topic Alternative Treatment Options

Amendment Barcode (if applicable)

Name Allison Sitte ("city")

Job Title Legislative Affairs Director

Address 400 S. Monroe, Ste. 2105 Cap.

Phone 850-487-1533

Street

Tallahassee

FL

32399

City

State

Zip

Email sitteq@FDMA.state.fl.us

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Florida Department of Veterans' Affairs

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19

Meeting Date

1518

Bill Number (if applicable)

Topic Alternative Treatment Options

Amendment Barcode (if applicable)

Name Natalie King

Job Title VP/CEO

Address 235 W Brandon Blvd 640

Phone 839248278

Street
Brandon FL FL 33511

Email

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing United Way Suncoast

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4-9-19

Meeting Date

1578

Bill Number (if applicable)

Topic ALT. TREATMENTS

Amendment Barcode (if applicable)

Name BRIAN ANDERSON

Job Title VETERANS ALTERNATIVE CEO

Address 5041 CIRCUS LN

Phone 901-364-5960

Street

NEW PORT RICHEY FL

Email BRIAN@VETERANSALTERNATIVE@GMAIL

City

State

Zip

Speaking: [X] For [] Against [] Information

Waive Speaking: [X] In Support [] Against (The Chair will read this information into the record.)

Representing VETERANS ALTERNATIVE

Appearing at request of Chair: [] Yes [X] No

Lobbyist registered with Legislature: [] Yes [X] No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19

1518

Meeting DateBill Number (if applicable)Topic Alternative Treatment for VeteransAmendment Barcode (if applicable)Name Dan HendricksonJob Title president, TVLCAddress 319 E Park AvePhone 850/570-1967*Street*TallahasseeFL32301Email danbhendrickson@comcast.net*City**State**Zip*Speaking: For Against InformationWaive Speaking: In Support Against
*(The Chair will read this information into the record.)*Representing TALLAHASSEE VETERANS LEGAL COLLABORATIVEAppearing at request of Chair: Yes NoLobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

By the Committee on Health Policy; and Senators Wright, Book,
and Cruz

588-03686-19

20191518c1

A bill to be entitled

An act relating to alternative treatment options for veterans; creating s. 295.156, F.S.; providing definitions; specifying eligibility to receive alternative treatment; authorizing the Department of Veterans' Affairs, subject to appropriation, to contract with a state university or Florida College System institution to enter into and manage contracts for the provision of alternative treatment options for certain veterans; providing requirements as to the provision of alternative treatment options and related assessment data; requiring the department to annually prepare a report for submission to the Governor and Legislature; prescribing report requirements; authorizing the department to adopt rules; providing an effective date.

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

Section 1. Section 295.156, Florida Statutes, is created to read:

295.156 Alternative treatment options for veterans.-

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

(a) "Accelerated resolution therapy" means a process that replaces negative images and sensations with positive ones, uses specific eye movements in conjunction with controlled verbalization about details of the prior traumatic experience, and uses metaphors and other interventions to assist the patient in recalling less distressing images while retaining the facts

Page 1 of 5

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

588-03686-19

20191518c1

of the original experience.

(b) "Alternative treatment" means a treatment that is not part of the standard of medical care established by the United States Department of Veterans Affairs for treating traumatic brain injury or posttraumatic stress disorder but has been shown by at least one scientific or medical peer-reviewed study to have some positive effect for the treatment of traumatic brain injury or posttraumatic stress disorder.

(c) "Equine therapy" means the use of interaction with horses under the supervision of a trained equine instructor to improve the patient's sense of trust and self-efficiency; increase communication, socialization, and emotional management skills; and decrease isolation.

(d) "Facility" includes a hospital, a public health clinic, an outpatient health clinic, a community health center, and any other facility authorized under Department of Veterans' Affairs rule to provide hyperbaric oxygen therapy under this section.

(e) "Health care practitioner" means a person who is licensed to provide medical care or other health care in this state and who has prescriptive authority, including a physician.

(f) "Hyperbaric oxygen therapy" means a medical treatment, provided at a facility in compliance with applicable state fire codes, which is used in the prevention, treatment, or cure of a disease or a condition in human beings by delivering a saturation of 100 percent oxygen in a mono-place or multi-place hyperbaric chamber or a total body chamber approved by the United States Food and Drug Administration (FDA), or in a device that has an appropriate FDA-approved investigational device exemption, in which atmospheric pressure is increased and

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CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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59 controlled.

60 (g) "Music therapy" means the use of music listening or
 61 performance to address the patient's physical, emotional,
 62 cognitive, and social needs and to facilitate communication and
 63 expression.

64 (h) "Physician" means a person licensed to practice
 65 medicine under chapter 458 or chapter 459.

66 (i) "Service animal training therapy" means a technique
 67 that allows the patient to work directly with an animal trainer
 68 to train animals as therapy or service animals.

69 (j) "Traumatic brain injury" means an acquired injury to
 70 the brain. The term does not include brain dysfunction caused by
 71 congenital or degenerative disorders or birth trauma.

72 (k) "Veteran" means an individual who has served in any of
 73 the following:

74 1. The United States Armed Forces, including the United
 75 States Army, Navy, Air Force, Coast Guard, or Marine Corps.

76 2. The Florida National Guard.

77 3. A reserve component of the United States Armed Forces.

78 (2) A veteran qualifies to receive alternative treatment
 79 under this section if he or she:

80 (a) Has been diagnosed by a health care practitioner with
 81 service-connected posttraumatic stress disorder or a traumatic
 82 brain injury;

83 (b) Voluntarily agrees to such alternative treatment; and

84 (c) Can demonstrate that he or she has previously sought
 85 services for a posttraumatic stress disorder or a traumatic
 86 brain injury through the federal Veterans Affairs service
 87 delivery system or through private health insurance, if such

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88 coverage is available to the veteran.

89 (3) Subject to legislative appropriation, the Department of
 90 Veterans' Affairs may contract with one state university or
 91 Florida College System institution to enter into and to manage
 92 multiple licensed provider contracts to provide the alternative
 93 treatment options specified in paragraphs (a) through (e) to
 94 veterans who have been certified by the United States Department
 95 of Veterans Affairs or by any branch of the United States Armed
 96 Forces as having a traumatic brain injury or posttraumatic
 97 stress disorder. The university or institution shall manage,
 98 monitor, and ensure the compliance of contracted providers who
 99 provide any of the following alternative treatment options:

100 (a) Accelerated resolution therapy.

101 (b) Equine therapy.

102 (c) Hyperbaric oxygen therapy, which must be provided at a
 103 registered hyperbaric oxygen facility.

104 (d) Music therapy.

105 (e) Service animal training therapy.

106 (4) (a) The provision of alternative treatment must be under
 107 the direction and supervision of an individual licensed under
 108 chapter 458, chapter 459, chapter 460, chapter 490, or chapter
 109 491.

110 (b) The supervising licensed provider must agree to
 111 cooperate with the Department of Veterans' Affairs to provide
 112 data sufficient to assess the efficacy of alternative treatment
 113 modalities.

114 (5) By January 1 of each year, beginning in 2020, the
 115 Department of Veterans' Affairs shall prepare a report detailing
 116 each alternative treatment provided pursuant to this section,

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117 the provider type, the number of veterans served, and the
118 treatment outcomes, which it shall submit to the Governor, the
119 President of the Senate, and the Speaker of the House of
120 Representatives.

121 (6) The Department of Veterans' Affairs may adopt rules to
122 implement this section.

123 Section 2. This act shall take effect July 1, 2019.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/10/2019	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services
(Wright) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Section 295.156, Florida Statutes, is created to
read:

295.156 Alternative treatment options for veterans.-

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

(a) "Posttraumatic stress disorder" means a mental health
disorder that is developed after having experienced or witnessed



11 a life-threatening event, including but not limited to, military
12 sexual trauma.

13 (b) "Traumatic brain injury" means an acquired injury to
14 the brain. This term does not include brain dysfunction caused
15 by congenital or degenerative disorders or by birth trauma.

16 (2) Subject to legislative appropriation, the Department of
17 Veterans' Affairs may contract with a state university or
18 Florida College System institution to furnish alternative
19 treatment options for veterans who have been certified by the
20 United States Department of Veterans Affairs or any branch of
21 the United States Armed Forces as having a traumatic brain
22 injury or posttraumatic stress disorder. The university or
23 institution shall manage, monitor, and ensure the compliance of
24 contracted providers who provide any of the following
25 alternative treatment options:

26 (a) Accelerated resolution therapy.

27 (b) Equine therapy.

28 (c) Hyperbaric oxygen therapy, which must be provided at a
29 registered hyperbaric oxygen facility.

30 (d) Music therapy.

31 (e) Service animal training therapy.

32 (3) A veteran qualifies to receive alternative treatment
33 under this section if he or she:

34 (a) Has been diagnosed by a health care practitioner with
35 service-connected posttraumatic stress disorder or a traumatic
36 brain injury;

37 (b) Voluntarily agrees to such alternative treatment; and

38 (c) Can demonstrate that he or she has previously sought
39 services for a posttraumatic stress disorder or a traumatic



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40 brain injury through the federal Veterans Affairs service
41 delivery system or through private health insurance, if such
42 coverage is available to the veteran.

43 (4) (a) The provision of alternative treatment must be under
44 the direction and supervision of an individual licensed under
45 chapter 458, chapter 459, chapter 460, chapter 464, chapter 490,
46 or chapter 491.

47 (b) The supervising licensed provider must agree to
48 cooperate with the Department of Veterans' Affairs to provide
49 data sufficient to assess the efficacy of alternative treatment
50 modalities.

51 (5) By January 1 of each year, beginning in 2020, the
52 Department of Veterans' Affairs shall prepare a report detailing
53 each alternative treatment provided pursuant to this section,
54 the provider type, the number of veterans served, and the
55 treatment outcomes. The department shall submit the report to
56 the Governor, the President of the Senate, and the Speaker of
57 the House of Representatives.

58 (6) The Department of Veterans' Affairs may adopt rules to
59 implement this section.

60 Section 2. This act shall take effect July 1, 2019.

61
62 ===== T I T L E A M E N D M E N T =====

63 And the title is amended as follows:

64 Delete everything before the enacting clause
65 and insert:

66 A bill to be entitled
67 An act relating to alternative treatment options for
68 veterans; creating s. 295.156, F.S.; providing



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69 definitions; authorizing the Department of Veterans'
70 Affairs, subject to appropriation, to contract with a
71 state university or Florida College System institution
72 to furnish specified alternative treatment options for
73 certain veterans; providing requirements as to the
74 provision of alternative treatment options and related
75 assessment data; specifying eligibility to receive
76 alternative treatment; requiring direction and
77 supervision by certain licensed providers; requiring
78 the department to annually prepare a report for
79 submission to the Governor and Legislature;
80 authorizing the department to adopt rules; providing
81 an effective date.

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL: PCS/CS/SB 1528 (712656)

INTRODUCER: Appropriations Subcommittee on Health and Human Services; Health Policy Committee; and Senator Bean and others

SUBJECT: Canadian Prescription Drug Importation Program

DATE: April 11, 2019 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Lloyd</u>	<u>Brown</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>McKnight</u>	<u>Kidd</u>	<u>AHS</u>	<u>Recommend: Fav/CS</u>
3.	_____	_____	<u>AP</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 1528 creates the Canadian Prescription Drug Importation Program (Program). The Agency for Health Care Administration (AHCA) is directed to establish the Program for the safe and effective importation of prescription drugs from Canada which will have the highest potential for cost savings to the state.

The bill requires the AHCA to competitively procure and contract with a vendor to administer the Program by December 1, 2019, develop a plan for federal approval of the Program, and submit the plan to the U.S. Department of Health and Human Services (HHS) by July 1, 2020, Once federal approval is granted, the AHCA is required to return to the Legislature and receive final approval before implementation. As part of that final approval process, the bill requires the Legislature to consider the estimated cost savings to the state and whether the Program has met the required safety standards.

The bill contains numerous requirements for the vendor and for Program participants, designed to ensure the Program is safe and effective and results in cost-savings. The vendor, any participating supplier, and any participating importer must post two surety bonds of at least \$1 million each; one bond is for administrative and performance-related actions and the other is to ensure participation in and payment of any civil and criminal causes of action.

The bill also provides that the administrative fees borne by the state and the profit margins for any participating wholesaler, pharmacy, or pharmacist relating to drugs imported through the Program will be limited to a maximum amount as specified each year in the General Appropriations Act.

The AHCA is annually required to submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives providing required information by December 1. The AHCA is authorized to adopt rules to implement the Program.

The bill has an overall indeterminate fiscal impact at this time with an expectation that there will be start-up costs associated with the implementation prior to any achievement of potential savings under the Program, including costs associated with competitively soliciting a qualified vendor and hiring additional personnel to manage the contract and conduct appropriate oversight and monitoring activities. The AHCA anticipates requiring six additional full-time equivalent positions for Fiscal Year 2019-2020, estimating a total cost of \$572,495, and an estimated total recurring cost of \$545,837 for Fiscal Year 2020-2021 and beyond. The AHCA will need to determine the level of federal financial participation in the Program. See Section V. Fiscal Impact Statement.

The bill takes effect on July 1, 2019.

II. Present Situation:

U.S. Healthcare Marketplace

Health care spending represents over 17 percent of the nation's Gross Domestic Product.¹ In comparison to other countries, the United States' per capita health care costs nearly double other countries of comparable size and wealth.² In 2017, health care spending in the United States increased 3.9 percent over the prior year to \$3.5 trillion, or average health care spending of \$10,739 per person.³

Spending on prescription drugs in 2017 was \$333.4 billion.⁴ Of that amount, the vast majority, \$285 billion, was paid through health insurance coverage which includes private health insurance, Medicare, Medicaid, and other health insurance coverage.⁵

In a study sponsored by the federal Centers for Disease Control and Prevention (CDC), a majority of adults aged 18-64, nearly 60 percent, reported being prescribed a medication in the

¹ Centers for Medicare and Medicaid Services, *National Health Expenditures 2017 Highlights*, p. 1, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf> (last visited March 28, 2019).

² Peter J. Peterson Foundation, *Per Capita Healthcare Costs-International Comparison* (August 10, 2018), https://www.pgpf.org/chart-archive/0006_health-care-oced (last visited March 28, 2019).

³ *Supra* note 1.

⁴ *Id.*

⁵ Centers for Medicare and Medicaid Services, *National Health Expenditures, Table 16 – Retail Prescription Drugs Expenditure; Levels, Percent Change, and Percent Distribution by Source of Funds: Selected Calendar Year 1970-2017*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> (last visited March 21, 2019).

past 12 months.⁶ Further, approximately 70 percent of prescription medications carry out-of-pocket costs, such as requirements for co-insurance, co-payments, or a deductible, with generics costing an average of \$6 per prescription and brand names an average cost of \$30 per prescription.⁷

Many adults who are prescribed drugs with higher out-of-pocket costs will forego their prescriptions or will take other measures, including considering other non-medication therapies, to avoid the out-of-pocket costs. The CDC study found that while the number of adults who asked their health care provider for an alternative medical treatment option with a lower out-of-pocket cost had dropped from a prior study, the percentage remained relatively constant from 2015 through 2017 at 19.5 percent.⁸ Other strategies that adults used included not taking the medication as prescribed, which could mean skipping doses, taking less than the prescribed dose, delaying a refill, or using alternative therapies instead of the prescribed medication.⁹

As with the comparison of general health care costs, the United States' prescription drug spending on its own also stands in stark contrast to other industrialized nations. By 2015, the United States' spending on prescription drugs had exceeded \$1,000 per person per year and was 30 to 190 percent higher than nine other western countries.¹⁰

Role of Price Controls

Reasons given for the price differentials among the countries primarily are related to the fact that most of these nations have some type of price control over drug pricing. In the United States, only two federal entities, the U.S. Department of Defense (DoD) and the U.S. Department of Veterans Affairs (VA), negotiate directly with drug manufacturers for drug prices, and they pay approximately 50 percent of what is paid at a retail pharmacy.¹¹ The discount is equal to 24 percent off of a drug's average price or the lowest price paid by other non-federal buyers, as well as other discounts if a drug's price outstrips inflation.¹²

The United States typically uses drug price controls in one of two ways. First, in the manner described above with the DoD and the VA in the form of a required discount of the average price paid by other purchasers of the same product. The other manner is through negotiated pricing when the government wields its market power as a large purchaser of health care services to bargain for more favorable rates from pharmaceutical suppliers.¹³

⁶ Robin A. Cohen, et al, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Strategies Used by Adults Aged 18-64 to Reduce Their Prescription Drug Costs, 2017, NCHS Data Brief* (March 2019), p. 1, <https://www.cdc.gov/nchs/data/databriefs/db333-h.pdf> (last visited March 28, 2019).

⁷ *Id.*

⁸ *Id.*

⁹ Robin A. Cohen, *supra* note 6, at 2 - 4.

¹⁰ Dana O. Sarnak, et al, *Paying for Prescription Drugs Around the World: Why is the U.S. an Outlier?*, The Commonwealth Fund, <https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier> (last visited March 28, 2019). The nine western countries used in comparison are Switzerland, Germany, Canada, France, United Kingdom, Australia, Netherlands, Norway, and Sweden.

¹¹ Dana O. Sarnak, et al, *supra* note 10.

¹² David Blumenthal, M.D. and David Squires, *Drug Price Control: How Some Government Programs Do It*, The Commonwealth Fund, (May 10, 2016) [www.commonwealthfund.org, https://www.commonwealthfund.org/blog/2016/drug-price-control-how-some-government-programs-do-it?redirect_source=~/media/2aca550e3b1446fd91b0f5d0b16eb87c.ashx](https://www.commonwealthfund.org/blog/2016/drug-price-control-how-some-government-programs-do-it?redirect_source=~/media/2aca550e3b1446fd91b0f5d0b16eb87c.ashx) (last visited March 28, 2019).

¹³ David Blumenthal, M.D. and David Squires, *supra* note 12.

Medicaid is also the recipient of manufacturer discounts and rebates, receiving whichever is lower: typically 23.1 percent less than the average price paid for the drug by other buyers, or the lowest price at which the drug is sold to other buyers.¹⁴ Medicaid can also negotiate additional rebates and will receive additional discounts if the price of the drug rises faster than inflation.¹⁵

Medicare Part D, the prescription drug benefit for Medicare, differs from Medicaid in the prices paid for prescription drugs and in the measures used to control prescription drug spending. These differences are often a function of the varying options statutorily available relating to copayment restrictions, rebate levels, and the fact that the two programs do not serve the same constituencies, and therefore, the drug usage between the programs do not match up.¹⁶

Programmatic Differences – Prescription Drugs¹⁷		
	Medicare Part D	Medicaid Fee for Service
Average Rebate	17 percent	56 percent
Use of Generic Drugs	75 percent	70 percent
Average Price of Drugs in 53 Therapeutic Classes	\$49	\$36

Out of Pocket Costs

From a cost perspective, 58 percent of respondents to a recent Kaiser Family Foundation survey reported spending \$100 or more a month on prescriptions, 49 percent reported being in fair or poor health, 35 percent said they were taking four or more prescriptions a month, and 35 percent reported an annual income of less than \$40,000. Further, three in ten of all adults (29 percent) reported not taking their medicines as prescribed at some point in the past year because of the cost and one in ten (8 percent) said their condition got worse as a result of not taking their prescription as recommended.¹⁸

The survey also demonstrated that the public views profits made by pharmaceutical companies as the largest contributor to prescription drug prices (80 percent), followed by the cost of research and development (69 percent), profits made by pharmacy benefit managers or PBMs (63 percent), and the cost of marketing and advertising (52 percent).¹⁹

When the survey asked the public how prescription drug costs could be kept down, the top five answers were:

- Requiring drug companies to include list prices in ads (88 percent).
- Making it easier for generic drugs to come to market (88 percent).

¹⁴ David Blumenthal, M.D. and David Squires, *supra* note 12.

¹⁵ *Id.*

¹⁶ Congressional Budget Office, Competition and the Cost of Medicare's Prescription Drug Program (July 2014), p. 30, <https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/45552-PartD.pdf> (last visited March 28, 2019).

¹⁷ Congressional Budget Office, *supra* note 16, at 31-32.

¹⁸ KAISER FAMILY FOUNDATION, *Kaiser Health Tracking Poll – February 2019: Prescription Drugs*, <https://www.kff.org/report-section/kff-health-tracking-poll-february-2019-prescription-drugs-findings/> (last visited March 28, 2019).

¹⁹ *Id.*

- Allowing the government to negotiate with drug companies to get a lower price for people with Medicare (86 percent).
- Allowing Americans to buy drugs imported from Canada. (80 percent)
- Planning an annual limit on out-of-pocket drug costs for people with Medicare (76 percent).²⁰

Blame for prescription costs in the U.S. can likely be attributed to a number of different causes if the number of newspaper articles, blog posts, and magazine stories about the issue are anything to go by in the past several years. Representatives from the PBMs will argue that the country cannot be responsible for subsidizing the research and development costs for the world.²¹ Drug makers often insist that comparing prices country to country or even payor to payor is not a true comparison of prices since comparisons do not include all of the discounts drug makers may provide.²² In remarks to stakeholders and the news media, the current Secretary of the U.S. Department of Health and Human Services (HHS), Alex Azar, remarked that “the problem has multiple parts: high list prices, overpaying in government programs, high out-of-pocket costs, foreign government free-loading. They are connected in a way that attempting to squeeze one end of the balloon won’t lead to lasting change.”²³

Federal Regulation of Prescription Drugs

The U.S. Food and Drug Administration (FDA) is the federal agency responsible for ensuring that food, drugs, biological products, and medical devices are effective and safe for public consumption. The FDA regulates these areas under the authority of the Food, Drug, and Cosmetic Act (FDCA).²⁴ Generally, the state boards of pharmacy have primary responsibility for oversight and regulation of pharmacy; however, the FDA regulates, and in some cases preempts state action, through the FDCA and the Drug Quality and Security Act (DQSA). The DQSA created a national uniform standard and an electronic system for the tracing of drugs at the package level, preempting pedigree laws that previously existed in Florida and 28 other states. During the 2016 Legislative Session, Florida conformed its statutes to the revised federal standards.²⁵

The FDCA prohibits any drug from being introduced or delivered for introduction or delivered for introduction into interstate commerce unless approved by the FDA. The FDCA further

²⁰ KAISER FAMILY FOUNDATION, *Kaiser Health Tracking Poll – February 2019: Prescription Drugs*, <https://www.kff.org/report-section/kff-health-tracking-poll-february-2019-prescription-drugs-findings/> (last visited March 28, 2019).

²¹ Robert Langreth, et al, *The U.S. Pays a Lot More for Top Drugs Than Other Countries*, Bloomberg News (December 18, 2015), <https://www.bloomberg.com/graphics/2015-drug-prices/> (last visited March 28, 2019). “We can no longer sustain a system where 300 million Americans subsidize drug development for the entire world,” said Steve Miller, chief medical officer for Express Scripts Holding Co.

²² Robert Langreth, et al, Bloomberg News. “The difference in prices here in the U.S. compared to other countries is often vastly overstated,” said Robert Zirkelbach, spokesman for the Pharmaceutical Research Manufacturers of America trade group.

²³ Alex M. Azar, II, *Remarks on Drug Pricing Blueprint (May 14, 2018) as prepared for delivery*, delivered in Washington, D.C., <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html> (last visited March 28, 2019).

²⁴ Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq. 52 Stat. 1040 et. seq. as amended by the Drug Quality and Security Act, 21 U.S.C. 351 et seq.

²⁵ See ch. 2016-212 Laws of Florida (CS/CS/HB 1211)

prohibits adulterated²⁶ or misbranded drugs²⁷ and devices from being introduced, delivered for introduction, or received in interstate commerce.²⁸ In a warning letter dated February 26, 2019, to CanaRx, the FDA cited this statutory reference and at least five others it believed had been violated by a foreign pharmacy and its business associates in the delivery of prescription drugs from Canada to recipients in the United States.²⁹ CanaRx serves as a broker between foreign pharmacies and public and private employer sponsored health plans to provide employees with prescription drugs, according to the FDA. The letter identified issues with dispensing unapproved new drugs, substitution of FDA approved drugs with recalled or unapproved drugs, misbranded drugs, and drugs subject to the Risk Evaluation and Mitigation Strategy program.³⁰ More than 150 websites were included in the letter as affiliated with CanaRx. The FDA gave CanaRx 10 days to respond to the warning letter.

Drug Approval Process

The FDA process for new and innovative drugs is rigorous and requires an exhaustive and extensive series of clinical trials, first on animals and then on humans, before a new drug application (NDA) can even be formally filed with the FDA.³¹ The NDA process has three goals:

- Whether the drug is safe and effective in its proposed uses(s), and whether the benefits of the drug outweigh the risks.
- Whether the drugs proposed labeling (package insert) is appropriate and what it should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.³²

²⁶ An “adulterated drug or device” is defined, in part, under 21 U.S.C. 351, as a drug or device that consists “in whole or in part of any filthy, putrid, or decomposed substance; or if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or if it is a drug and the methods used in or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess...”

²⁷ A “misbranded drug or device” is defined, in part, under 21 U.S.C. 352, as a drug or device whose “labeling is false or misleading in any particular. Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement, shall not be considered to be false or misleading under this paragraph if the health care economic information related to an indication approved under section 505 or under section 351 of the Public Health Service Act for such drug, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 505 or under section 351 of the Public Health Service Act...”

²⁸ See 21 U.S.C. 331 (as amendment through P.L. 115-271, enacted October 24, 2018).

²⁹ Letter to Gregory Anthony Howard, CanaRx Services, Inc. (Feb. 26, 2019), U.S. Food and Drug Administration Warning Letter, <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm632061.htm> (last visited March 28, 2019).

³⁰ The FDA’s Risk Evaluation and Mitigation Strategy (REMS) program is a drug safety program for drugs that have a narrow therapeutic index, and/or is the drug is indicated to treat a serious condition such as HIV, cancer, or hepatitis. A strategy is designed specific to a particular drug to address the safety and risk concerns unique to that drug, such as requiring that a drug only be administered in a health care facility or by a provider. Another strategy may be a special patient information pamphlet insert included with the prescription. All of the strategies are aimed at reducing the frequency or severity of an adverse event.

³¹ U.S. Food and Drug Administration, *New Drug Application*, <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm> (last visited March 28, 2019).

³² U.S. Food and Drug Administration, *supra* note 31.

Drug Manufacturer Compliance

The FDA ensures the quality of the United States' drug products by carefully monitoring drug manufacturer's compliance with its Current Good Manufacturer's Practice Regulations. (CGMP), which are the main regulatory standard for ensuring pharmaceutical quality for human pharmaceuticals.³³ The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, packaging, and labeling pharmaceuticals. The regulations are found in 21 Code of Federal Regulations (CFR) Part 211 and specify the responsibilities of the quality control unit, personnel qualifications and responsibilities, the design and construction of facilities, the equipment requirements, production and process controls, packaging and labelling control, including tamper-evident package requirements, laboratory controls, requirements for records and reports, and returned and salvaged drug products.

Drug Distribution

The Drug Supply Chain Security Act³⁴ (DSCSA) establishes procedures to ensure the integrity of prescription drugs as they are distributed along the supply chain. Effective July 1, 2015, the DSCSA requires manufacturers, re-packagers, wholesale distributors, and dispensers to exchange product tracing information when transferring a product along the distribution chain. As noted earlier, this national product tracing process replaces Florida's previous pedigree paper system.

This product tracing information includes the following:

- Name of the drug.
- Strength and dosage form of the drug.
- National Drug Code number of the drug.
- Container size and number of containers.
- Lot number of the drug.
- Date of the transaction.
- Date of the shipment, if more than 24 hours after the date of transaction.
- Business name and address of the person from whom ownership is being transferred.
- Business name and address of the person to whom ownership is being transferred.

These entities must maintain these records for 6 years and provide them to the FDA upon request.

Drug Supply Chain Security

The path a drug takes from unfinished product to when it is handed to a patient, either at a hospital bedside or to a customer at a community pharmacy, is called the supply or distribution chain. Along that path, there are several opportunities for the product to become mishandled or adulterated, whether it is in the United States or abroad.

The first legislation that dealt with such issues was the 1906 Food and Drugs Act, which addressed the labeling of drugs; then the 1938 Food, Drug, and Cosmetics Act (FDCA), which

³³ U.S. Food and Drug Administration, *Questions and Answers on Current Good Manufacturing Practices (CGMPs)*, <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm124740.htm> (last visited March 28, 2019).

³⁴ See Title II of DQSA, the Drug Supply Chain Security Act, Pub. Law 113-54 (2015).

introduced the concepts of adulteration, misbranding, registration, and inspection of manufacturing establishments; and the Prescription Drug Marketing Act (PDMA, P.L. 100-293), which required that wholesale distributors be licensed by the states and that a wholesale distributor, except in certain circumstances, must issue a pedigree, which has since been superseded by the tracing requirements in the DQSA in 2015.³⁵

Supply security issues can include contamination of products, diversion, counterfeiting, and other adulteration, according to statements made by the Director of the Center for Drug Evaluation and Research (CDER) at the FDA, Dr. Janet Woodcock, in testimony to Congress in 2013.³⁶ In her testimony, she referenced cases involving counterfeit and fraudulent versions of Botox sold in the United States, Lipitor sold in the United Kingdom, and Avastin in the United States.³⁷

Interaction with the Foreign Market

As globalization has increased, the FDA has established foreign offices to work closely with foreign governments, industry, and other stakeholders to enable the FDA to more effectively protect American consumers, including inspections and investigations in those countries. The FDA indicates that about 35 percent of the medical devices used in the United States are imported.³⁸

Foreign companies that manufacture, prepare, propagate, compound, or process drugs that are offered for import in the United States must register with the FDA.³⁹ Today, there are 136,400 foreign facilities in more than 150 countries that export FDA-regulated products to the United States.⁴⁰ The FDA estimates that 80 percent of the active pharmaceutical ingredients and 40 percent of the finished drugs in the U.S. market are actually manufactured in FDA-registered facilities in other countries, primarily India and China.⁴¹

The FDA does not regularly inspect every foreign facility and instead relies on a risk-based assessment to determine which facilities to inspect and how often.⁴² In federal fiscal year 2017-18, the FDA conducted 94 on-site inspections of foreign drug manufacturing facilities, and

³⁵ Susan Thaul, Congressional Research Service, *Pharmaceutical Supply Chain Security* (October 31, 2013), Summary, <http://www.ncsl.org/documents/statefed/health/CRS-PharmSupChSec2013.pdf> (last visited March 28, 2019).

³⁶ Susan Thaul, Congressional Research Service, *supra* note 35, at 1.

³⁷ Susan Thaul, Congressional Research Service, *supra* note 35, at 2.

³⁸ U.S. Food and Drug Administration, *FDA Globalization*, <https://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/default.htm> (last visited March 28, 2019).

³⁹ Section 510 of the federal Food, Drug, and Cosmetic Act.

⁴⁰ U.S. Food and Drug Administration, *FDA Globalization*, *supra* note at 38.

⁴¹ FDA Commissioner Margaret Hamburg, *The Safety of Prescription Drugs Made Outside the U.S.*, The Diane Rehm Show (February 20, 2014), transcript available at <https://dianerehm.org/shows/2014-02-20/safety-prescription-drugs-made-outside-us> (last visited March 28, 2019).

⁴² Section 705 of the FDA Safety and Innovation Act, 2012. Factors considered include the establishment's compliance history or history and nature of recalls, the inherent risk of the drug being manufactured, whether the establishment has been inspected in the last 4 years, whether a foreign government has inspected the establishment, and anything else the FDA determines is important in determining where inspection resources should be spent.

historically, 381 since 2014-2015.⁴³ This means that less than 1 percent of foreign FDA-registered drug manufacturing facilities are inspected by the FDA each year.

Since the FDA does not have the resources to effectively enforce drug manufacturing regulations in every facility overseas, it must instead rely on cooperation with the governments of each country to ensure the safety of drugs or pharmaceutical products imported into the United States. The FDA may memorialize these partnerships in an international arrangement, which is a written understanding between two or more countries recognizing one another's conformity with certain processes or procedural standards and describing the willingness and good-faith intentions of the countries to engage in cooperative activities.⁴⁴ International arrangements can have a variety of titles, including "cooperation agreement," "memorandum of understanding," or "mutual recognition agreement." The FDA currently has at least 60 such international arrangements with foreign governments.⁴⁵

In instances where the U.S. determines that another country adheres to current good manufacturing practices for pharmaceutical products, it may enter into an international arrangement and authorize the foreign government to conduct facility inspections on the FDA's behalf. The FDA has such international arrangements with Australia, Austria, Belgium, Canada, China, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Malta, Romania, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

Drug Importation

The FDCA generally prohibits the importation of foreign drugs into the U.S. unless the drug was manufactured by a foreign facility registered with the FDA and the foreign drug is specifically FDA-approved, or the drug was manufactured in the U.S., is FDA-approved, and is being reintroduced into the U.S. by the original manufacturer.

The FDA approval requires the manufacturer to submit documentation establishing the drug's safety and efficacy, which includes information as to the method, facilities, and manner of manufacture.⁴⁶ Without this FDA-approval, these drugs are considered misbranded and illegal for importation. The FDCA prohibits interstate shipment, including importation, of 'unapproved new drugs,'⁴⁷ which includes any drugs, including foreign-made versions of U.S.-approved drugs, which have not been manufactured in accordance with and pursuant to FDA approval (i.e.

⁴³ U.S. Food and Drug Administration, *Total Number of Inspections Completed in the Month*, <https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=oip&id=OIP-Number-of-inspections-completed-in-country-by-commodity> (last visited March 28, 2019).

⁴⁴ U.S. Food and Drug Administration, *International Agreements*, <https://www.fda.gov/InternationalPrograms/Agreements/default.htm> (last visited March 28, 2019); *See also, FAQs: The Mutual Recognition Agreement*, <https://www.fda.gov/downloads/InternationalPrograms/Agreements/UCM544394.pdf> (last visited March 28, 2019).

⁴⁵ U.S. Food and Drug Administration, *Cooperative Arrangements*, <https://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm2016755.htm> (last visited March 28, 2019).

⁴⁶ 21 U.S.C. s. 355(b)(1).

⁴⁷ 21 U.S.C. s. 355(a).

not in an FDA-registered facility or by an FDA-approved manufacturer).⁴⁸ The FDCA further prohibits importation of an FDA-approved drug by anyone other than the original manufacturer of the drug.⁴⁹

Additionally, the DSCSA requires all health care entities that distribute, dispense, and administer prescription drugs to patients to purchase their prescription drug products only from authorized “trading partners” (wholesale distributors, manufacturers, re-packagers, and dispensers) that are licensed or registered with the state or federal government.⁵⁰

Therefore, any importation, by any person or entity other than the original manufacturer, of drugs not FDA-approved in the manner described above, would be a violation of federal law.

However, federal law does authorize the HHS to grant individual persons waivers to import drugs, exercise discretion in enforcing the law against individuals importing for personal use, and focus enforcement efforts on cases that pose a significant threat to public health.⁵¹ The FDA has stated in guidance documents that enforcing such prohibitions against individual persons was not considered a priority.⁵²

The Medicare Modernization Act of 2003⁵³

The federal Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) included a provision on the importation of pharmaceutical drugs. It authorizes a wholesaler or pharmacist to import prescription drugs from Canada under certain conditions with the approval of the HHS. Specifically, after consulting with relevant federal agencies and determining that such importation would produce costs savings and would not pose an additional risk to public health and safety, the HHS is required to adopt regulations to allow licensed pharmacists and wholesalers to import prescription drugs⁵⁴ from Canada into the United States. These regulations must:

- Require compliance with safeguard requirements of 21 U.S. sections 355 (regarding new drugs) and 351 (regarding adulteration) and 352 (regarding misbranding);
- Require an importer of a prescription drug to comply with the documentation and sample-testing requirements of the MMA; and
- Contain any additional provisions the HHS Secretary deems appropriate to safeguard public health or to facilitate the importation of prescription drugs.

⁴⁸ Marvin Blumberg, *Information on Importation of Drugs Prepared by the Division of Import Operations and Policy*, FDA, U.S. Food & Drug Admin., (September 25, 2015), <https://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm> (last visited March 28, 2019).

⁴⁹ 21 U.S.C. s. 381(d)(1). This prohibition also applies to wholesalers, 21 U.S.C. sec. 384(a)(5)(B). The FDA justifies this by saying that the safety and integrity of the drugs cannot be ensured by any other entity but the manufacturer, *Imported Drugs Raise Safety Concerns*, U.S. Food & Drug Admin. (May 4, 2016), <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143561.htm> (last visited March 28, 2019).

⁵⁰ [Pub.L. 113-54](#)

⁵¹ 21 U.S.C. s. 384(j).

⁵² U.S. Food and Drug Administration, *Importations of Drugs*, Information on the Importation of Drugs, <https://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm> (last visited March 28, 2019).

⁵³ Pub. L. No. 108-173 s. 1121.

⁵⁴ Excluding controlled substances, biological products, infused drugs, IV-injected drugs, drugs inhaled during surgery, or a parenteral drug the HHS Secretary deems to pose a threat to public health.

This would allow licensed or permitted entities to import FDA-approved drugs from Canada, whereas currently only the original manufacturer may do so.

However, this section of the MMA provides that it becomes effective only if the HHS Secretary certifies to the U.S. Congress that the implementation will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer. To date, no HHS Secretary has done so or has otherwise authorized an importation program under this provision.⁵⁵ Shortly after the MMA passed, states and local governments requested waivers from the FDA in an attempt to import prescription drugs within their jurisdictions, but states that sought prior approval have all been denied on the basis that they did not ensure the safety of drugs that would be imported.⁵⁶

In 2004, Illinois announced a plan to allow residents to order medications through a pharmacy-benefits manager network based in Canada that would access pharmacies located in Canada, Ireland, or the United Kingdom.⁵⁷ Only prescriptions that were refills, did not require refrigeration, were not controlled substances, and were for chronic conditions, would be allowed under the program.⁵⁸ Pharmacies that participated would also have to agree to allow state inspectors on-site.⁵⁹ News reports indicated that the program incurred \$1 million in start-up costs and enrolled fewer than 4,000 before it was terminated at the end of 2008.⁶⁰

Maine passed legislation in 2013 to facilitate personal importation of prescription drugs through the mail from Canada, the United Kingdom, Australia, and New Zealand via retail pharmacies shortly after the passage of the MMA.⁶¹ The law was introduced after the City of Portland, Maine, was banned in August 2012 by the state's then-Attorney General from purchasing pharmaceuticals from Canada.⁶² Before implementation could begin, a lawsuit was filed by the Maine Pharmacy Association, Maine Society of Health-System Pharmacists, and the Retail Association of Maine alleging that the federal FDCA preempted the new state importation law and the changes to the Maine Pharmacy Act; jeopardized the safety of the nation's prescription

⁵⁵ Additionally, in March 2017, the four most recent FDA commissioners sent a letter to Congress attesting that drug importation would "harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation's medical products." *letter available at* http://www.safemedicines.org/wp-content/uploads/2017_03_16_commissioners_letter_final.pdf (last visited March 28, 2019).

⁵⁶ Peral, Eloy A. *FDA Regulation on the Importation of Prescription Drugs: Opportunities and Barriers to Legal Importation*. HEALTH LAW & POLICY Brief 3, no. 1 (2009), 48 - 55, available at <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1094&context=hlp> (last visited March 28, 2019).

⁵⁷ Donna Young, *Illinois Initiates Importation Plan*, https://www.ashp.org/news/2004/08/17/illinois_initiates_importation_plan (last visited March 28, 2019).

⁵⁸ Donna Young, *supra* note at 57.

⁵⁹ *Id.*

⁶⁰ Sally C. Pipes, *Blagojevich's failed drug importation plan a cautionary tale*, <https://www.pacificresearch.org/blagojevichs-failed-drug-importation-plan-a-cautionary-tale/> (last visited March 28, 2019).

⁶¹ 2013 Me. Laws 373. See <http://legislature.maine.gov/ros/LawsOfMaine/breeze/Law/getDocById/?docId=20663> (last visited March 28, 2019).

⁶² Thomas Hemphill, *Prescription Drug Imports: Maine Leads, the Nation Follows?* <https://www.americanactionforum.org/insight/prescription-drug-imports-maine-leads-the-nation-follows/> (last visited March 28, 2019).

drug supply; and opened the door to counterfeit and tainted medications.⁶³ The Seventh District Court in Maine agreed, citing the basics of federalism in its opinion:

Federalism, central to the constitutional design, adopts the principal that both the National and State Government have elements of sovereignty the other is bound to respect. From the existence of two sovereigns follows the possibility that laws can be in conflict or at cross-purposes. The Supremacy Clause provides a clear rule that federal law shall be the supreme Law of the Land and the Judges in every State shall be bound thereby, any Thing in the Constitution or Law of any State to the contrary notwithstanding.” U.S. Const. art. VI, cl. 2. Under this principle, Congress has the power to preempt state law.

Arizona v. United States, 132 S. Ct. 2492, 2500 (2012) (citations omitted).

Since 2015, there has been renewed interest in drug importation. Over a dozen states each year have considered drug importation legislation in different formats, and in 2018, Vermont was the first state to pass wholesale prescription drug importation program legislation.⁶⁴ Vermont’s program is not a waiver of existing law, but is an importation program that seeks to satisfy both the safety and security assurances. Drugs may be imported only from Canada under provision, 21 U.S.C. section 384, with the inclusion of the required laboratory testing. Controlled substances, biological products, infused drugs, intravenously injected drugs, and drugs inhaled during surgery are excluded.⁶⁵ The initial program design focused on providing savings to the Vermont Medicaid program; however, the benefit to Medicaid was minimal because Vermont’s Medicaid program was already yielding substantial savings through existing rebates, and implementation of the drug importation program for that population would not result in any net savings.⁶⁶

Vermont found that a small number of drugs imported through Canada may be more cost-effective for a limited period of time; however, the state’s stakeholders decided to see if greater savings could be found for the state’s commercial health insurers.⁶⁷ Using conservative estimates, participating plans estimated savings in the range of \$2.61- \$2.82 per member per month, or \$1-\$5 million per year, without taking into account the state’s operating costs.⁶⁸

As part of the proposed regulatory process, Vermont plans to create two new licenses: Rx Drug Importer Wholesaler and Canadian Rx Drug Supplier. Vermont will extend the DCSA requirements to the licensees and has also established other participation requirements for both

⁶³ *Ouellette et al v. Mills et al*, 13-347 - Order on Parties Competing Motions on Facial Preemption (Docket No: 1:13-cv-00347-NT)(U.S. D.Ct. Maine)(February 23, 2015).

⁶⁴ NATIONAL ACADEMY FOR STATE HEALTH POLICY, *State Legislative Action to Lower Pharmaceutical Costs* (updated March 1, 2019), <https://nashp.org/rx-legislative-tracker-2019/> (last visited March 28, 2019).

⁶⁵ Vermont Agency of Human Services, *Wholesale Importation Program for Prescription Drugs Legislative Report* (December 31, 2018), https://nashp.org/wp-content/uploads/2019/01/Report-to-VT-Legislature-on-Rx-Wholesale-Importation-1_3_2019.pdf (last visited March 28, 2019).

⁶⁶ Vermont Agency of Human Services, *supra* note 65, at 3.

⁶⁷ Vermont Agency of Human Services, *supra* note 65, at 3.

⁶⁸ Vermont Agency of Human Services, *supra* note 65, at 4.

licenses.⁶⁹ Licensure will provide a potential revenue sources for the program through application, registration, and audit fees.⁷⁰

Vermont has not yet sent a plan to the federal government for approval. The state still has a list of tasks and options that need to be worked through before a plan is submitted.

The Trump Administration has also shown interest in lowering the costs of prescription drugs for American consumers, including the possibility of drug importation.

In May 2018, American Patients First, the Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs was released.⁷¹ The Blueprint includes four challenges in the American drug market:

- High list prices for drugs.
- Seniors and government programs overpaying for drugs due to lack of the latest negotiation tools.
- High and rising out-of-pocket costs for consumers.
- Foreign governments taking advantage of American investments in innovation.

Some of the opportunities listed in the *Blueprint* for lower costs include restricting the use of rebates, calling for Medicaid demonstration projects to test coverage and financing reforms that build on private sector best practices with drug formularies, creating incentives to lower list prices, addressing transparency in pricing in Medicare and Medicaid, and seeking public comment on further ideas and opportunities.

In July 2018, the HHS directed the FDA to establish a work group on drug importation.⁷² The work group is examining the potential for importation to promote competition for drugs that are off-patent or off-exclusivity and produced by one manufacturer. The work group has not yet issued any recommendations or reports.

Personal Importation

The MMA also authorized the HHS to allow individuals to import drugs from Canadian-licensed pharmacies for personal use without penalty in certain circumstances, either on a case-by-case waiver basis or by regulation.⁷³ The HHS has not yet implemented this provision, however, the FDA uses its enforcement discretion and does not generally enforce violations of drug importation for personal use.

The FDA generally does not object to a person importing a drug from any country so long as it is for personal use, even though such importation would violate the FDCA.⁷⁴ The FDA recognizes

⁶⁹ Vermont Agency of Human Services, *supra* note 65, at 5-6.

⁷⁰ Vermont Agency of Human Services, *supra* note 65, at 10.

⁷¹ U.S. Department of Health and Human Services, *American Patients First*, <https://www.hhs.gov/about/leadership/secretary/priorities/drug-prices/index.html> (last visited March 28, 2019).

⁷² U.S. Department of Health and Human Services, *Press Release* (July 19, 2018) <https://www.hhs.gov/about/news/2018/07/19/hhs-secretary-azar-directs-fda-establish-working-group-drug-importation-address-price-spikes.html> (last visited March 28, 2019).

⁷³ 21 U.S.C. s. 384(j).

⁷⁴ U.S. Food and Drug Administration, *Personal Importation*, <https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/ucm432661.htm> (last visited March 28, 2019).

there are situations where foreign medications may be appropriate for a particular individual consumer and that the FDA's resources are better served enforcing regulations against commercial shipments of foreign medication into the United States.⁷⁵

The FDA does not examine personal baggage or mail, leaving that to the U.S. Customs and Border Protection (CBP). The CBP is instructed to only notify the FDA when it appears that there is an FDA-regulated drug intended for commercial distribution, the FDA has specifically requested that drug be detained, or the drug appears to represent a health fraud or an unknown risk to health.⁷⁶

This FDA policy is not intended to cover importation of foreign-made chemical versions of drugs available in the U.S. (i.e., cheaper, foreign versions of U.S. drugs). However, since there is a permissive attitude towards drugs for personal use shipped or brought into the U.S., it is likely that people are importing such drugs undetected. A 2016 poll showed that eight percent of U.S. households have bought prescription drugs from Canada or other countries in order to pay a lower price.⁷⁷

A limited exception applies to individuals with terminal illnesses, who can legally import non-FDA approved drugs.⁷⁸ They must have exhausted all other treatment options in the United States and be unable to participate in a clinical trial for an investigational drug. The particular drug imported must be actively pursuing FDA-approval and have completed the first phase of clinical trials.

State Regulation of Prescription Drugs

The Department of Business and Professional Regulation's (DBPR) Division of Drugs, Devices, and Cosmetics and the Department of Health's (DOH) Board of Pharmacy together regulate prescription drugs in the state from manufacture to distribution and dispensing. All entities engaged in any process along this continuum must be either licensed or permitted to engage in such activity, subject to relevant laws and rules and enforcement authority of the DBPR or the DOH, as applicable. Due to the overlap in these two industries, the law requires entities permitted or licensed under either the DBPR or the DOH to comply with the laws and rules of both.⁷⁹

The DBPR's Division of Drugs Devices and Cosmetics

The DBPR's Division of Drugs, Devices, and Cosmetics protects the health, safety, and welfare of Floridians from adulterated, contaminated, and misbranded drugs, drug ingredients, and

⁷⁵ U.S. Food and Drug Administration, *Regulatory Procedures Manual, Chapter 9: Import Operations and Actions*, (December 2017) at 9-2, available at <https://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf> (last visited March, 28, 2019).

⁷⁶ U.S. Food and Drug Admin., *supra* note 72.

⁷⁷ KAISER FAMILY FOUNDATION, *Kaiser Health Tracking Poll: November 2016*, <http://files.kff.org/attachment/Kaiser-Health-Tracking-Poll-November-2016-Topline> (last visited March 28, 2019).

⁷⁸ Right to Try Act of 2017, Pub. Law No 115-176.

⁷⁹ Sections 499.067 and 465.023, F.S.

cosmetics by enforcing Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act.⁸⁰ The Florida Drug and Cosmetic Act conforms to the FDA drug laws and regulations and authorizes the DBPR to issue permits to Florida drug manufacturers and wholesale distributors and register drugs manufactured, packaged, repackaged, labeled, or relabeled in Florida.⁸¹

Florida has 18 distinct permits based on the type of entity and intended activity and includes permits for entities within the state, out of state, or even outside of the United States.⁸² The DBPR has broad authority to inspect and discipline permittees for violations of state or federal laws and regulations, which can include seizure and condemnation of adulterated or misbranded drugs or suspension or revocation of a permit.⁸³

Prescription Drug Manufacturer Permit

Drug manufacturing includes the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug.⁸⁴ A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.⁸⁵ Such manufacturer must comply with all state and federal good manufacturing practices. A permitted prescription drug manufacturer may engage in distribution of its own manufactured drug without requiring a separate permit.⁸⁶ The distribution of drugs includes the selling, purchasing, trading, delivering, handling, storing, and receiving of drugs, but does not include the administration or dispensing of drugs.⁸⁷

Prescription Drug Wholesale Distributor Permit

Wholesale distribution is the distribution of a prescription drug to a person other than a consumer or patient, or the receipt of a prescription drug by a person other than the consumer or patient, with various exceptions for activities related to healthcare entities, governmentally-contracted public health services, and charitable organizations.⁸⁸ A prescription drug wholesale distributor permit is required for any person who is a wholesale distributor of prescription drugs and that wholesale distributes such prescription drugs in this state.⁸⁹

Out-of-State Prescription Drug Wholesale Distributor Permit

An out-of-state prescription drug wholesale distributor permit is required for any person that is a wholesale distributor located outside this state, but within the United States or its territories,

⁸⁰ Department of Business and Professional Regulation, *Division of Drugs, Devices, and Cosmetics*, <http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/> (last visited March 28, 2019).

⁸¹ Section 499.01, F.S.

⁸² 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. Section 499.01(1), F.S.

⁸³ Section 499.051, 499.062, 499.065, 499.066, 499.0661, and 499.067, F.S.

⁸⁴ Section 499.003(28), F.S.

⁸⁵ Section 499.01(2), F.S.

⁸⁶ Section 499.01(2), F.S.

⁸⁷ Section 499.003(16), F.S.

⁸⁸ Section 499.003(48), F.S.

⁸⁹ Section 499.01(2), F.S.

which engages in the wholesale distribution of prescription drugs into this state.⁹⁰ The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident. If the state from which the wholesale distributor distributes prescription drugs does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor by the FDA.⁹¹

Board of Pharmacy

The Board of Pharmacy (Board) within the DOH regulates the practice of pharmacy by enforcing the Florida Pharmacy Act (Act), adopting rules that set the standards of practice in the state, and licensing and monitoring pharmacists and pharmacies to ensure safe practice.⁹² To operate a pharmacy, an entity must first obtain a pharmacy permit with the Board.⁹³ Any person or entity licensed, permitted, or registered pursuant to ch. 465, F.S., must practice pharmacy in accordance with the provisions of the Act and the Board rules.

The practice of pharmacy is also subject to the requirements of ch. 499, F.S., the Florida Drug and Cosmetic Act, ch. 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act, the FDCA, and the Federal Comprehensive Drug Abuse Prevention and Control Act. The DOH has broad authority to inspect pharmacies for violations and the Board can discipline a person or entity's license, permit, or registration for violation of any of these provisions, including suspension or revocation of the ability to practice pharmacy in the state.⁹⁴

III. Effect of Proposed Changes:

Section 1 creates the Canadian Prescription Drug Importation Program (Program) under newly created s. 381.02035, F.S. The Agency for Health Care Administration (AHCA) is directed to establish the Program for the safe and effective importation of prescription drugs from Canada which will have the highest potential cost savings to the state.

Definitions for the Program are specifically created:

- *Agency* means the Agency for Health Care Administration (AHCA).
- *Canadian supplier* means a manufacturer, wholesale distributor, or pharmacy appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs.
- *Drug or Prescription drug* has the same meaning as “prescription drug” in s. 499.003, F.S.
- *Federal Act* means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; Stat. 1040 et seq. as amended by the Drug Quality and Security Act, 21 U.S.C. 351 et seq.
- *Importer* means a wholesale distributor, pharmacy, or pharmacist importing prescription drugs into this state under this Program.
- *Pharmacist* means a person who holds an active and unencumbered license to practice pharmacy pursuant to chapter 465.

⁹⁰ Section 499.01(2), F.S.

⁹¹ Section 499.01(2), F.S.

⁹² Chapter 465, F.S.; Florida Board of Pharmacy, <https://floridaspharmacy.gov/> (last visited March 28, 2019).

⁹³ Section 465.022, F.S.

⁹⁴ Section 465.0465(1), F.S.

- *Program* means the Canadian Prescription Drug Importation Program.
- *Track and Trace* means the product-tracing process for the components of the pharmaceutical distribution supply chain as described in Title II of the Drug Quality and Security Act, Drug Supply Chain Security Act, 21 U.S.C. 351 et seq.
- *Vendor* means the entity contracted by the Agency to manage specified functions of the Program.

An importation process for the Program is established which includes the selection of a vendor by the AHCA, the identification of importers and suppliers, and establishment of eligibility for these entities. Criteria is also established for eligible prescription drugs as well as requirements for distribution and prescription drug supply chain documentation.

Steps in the implementation process delegated to the vendor or other entities to perform are reflected in the chart below.

The AHCA is also:

- Provided the authority to immediately suspend importation of a specific drug by an importer upon learning that any drug activity is in violation of the Program or any federal or state law or regulation.
- Required to request approval of the Program from the HHS Secretary by July 1, 2020, and upon federal approval, notify the President of the Senate, the Speaker of the House of Representatives, and the relevant legislative committees. Prior to implementation, the Legislature must approve the Program as authorized by the HHS.
- Submit an annual report to the Governor, President of the Senate, and Speaker of the House of Representatives by December 1, entailing specific information about the operation of the Program during the previous year.
- Authorized to adopt rules necessary to implement the Program.

Canadian Prescription Drug Importation Program Responsibilities of the Parties	
AHCA	
<i>Vendor Contract</i>	Contract with a vendor to provide services.
<i>Safety Concerns</i>	Authorized to immediately suspend the importation of a specific drug or the importation of specific drugs by a specific importer if there are safety concerns or there is any activity in violation of Canadian, federal, or state law. The suspension may be revoked if, after conducting an investigation, the AHCA determines that no threat to public safety exists from unsafe drugs.
<i>Program Plan</i>	Submit plan for federal approval to the HHS by January 1, 2020, and include, at a minimum, the following elements: <ul style="list-style-type: none"> • The AHCA’s plan for operating the Program. • A demonstration of how the prescription drugs will be imported into the state and meet the applicable federal and state standards for safety and cost effectiveness.

Canadian Prescription Drug Importation Program Responsibilities of the Parties	
	<ul style="list-style-type: none"> • A demonstration of how the drugs imported into the state under the Program will comply with federal tracing procedures. • A list of prescription drugs that have the highest potential for cost savings to the state through importation at the time the request is submitted. • Inclusion of an estimate of the total cost savings attributable to the Program. • Inclusion of an estimate of the total costs of Program implementation to the state. • Inclusion of a list of potential Canadian suppliers from which the state would import drugs and a demonstration that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations.
<i>Federal Approval</i>	<p>Once approved by the HHS, the AHCA will notify the President of the Senate, the Speaker of the House of Representatives, and the relevant committees of the Senate and the House. The Program may not be implemented until reviewed and approved by the Legislature.</p> <p>The bill requires that the estimated cost savings to the state and whether the proposed Program meets the safety standards must be considered as part of the final review process.</p>
<i>Annual Report</i>	<p>Submit an annual report by December 1, to the Governor, President of the Senate, and Speaker of the House of Representatives containing required information about the operation of the Program during the previous year, including documentation demonstrating how the Program ensures that:</p> <ul style="list-style-type: none"> • Canadian suppliers participating in the Program are of high quality, of high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations; • Prescription drugs imported under the Program are not shipped, sold, or dispensed outside of the state once in the possession of the importer; • Prescription drugs imported under the Program are pure, unadulterated, potent, and safe; • The Program does not put consumers at a higher health and safety risk than if the Program did not exist; and • The Program provides cost savings to the state on imported prescription drugs.
<i>Rulemaking</i>	Adopt rules necessary to implement the Program.
Vendor	
<i>Vendor Eligibility</i>	Submit evidence of two surety bonds or comparable security arrangements each in the minimum amount of \$1 million to ensure payment of penalties for non-performance and payment of any civil and criminal causes of action.
<i>List of Prescription Drugs</i>	Develop a list of prescription drugs every 3 months, and revise as necessary, that have the highest potential for cost savings to the state. At a minimum, the vendor is required to consider which drugs will provide the greatest cost savings to the state, including which drugs have shortages, specialty prescriptions, and high volume prescription drugs. The AHCA may direct the vendor to revise the list, as necessary.

Canadian Prescription Drug Importation Program Responsibilities of the Parties	
<i>Relationship with Suppliers, Importers, and the AHCA</i>	<ul style="list-style-type: none"> • Identify Canadian suppliers that are in full compliance with Canadian federal and provincial laws and regulations and the Federal Act who have agreed to export drugs on the list. Suppliers must also agree to meet all, or exceed, federal track and trace requirements and applicable federal and state laws and regulations. • Verify that all Canadian suppliers on the list meet all of the requirements and will export drugs at prices that will provide the state with cost savings. • Contract with or facilitate contracts between eligible Canadian suppliers and eligible importers to import drugs under the Program. • Maintain a list of all registered importers that participate in the program. • Ensure compliance with Title II of the DQSA by all suppliers, importers, and other distributors and participants in the Program. • Assist the AHCA in the presentation of the annual report and timely provide any requested information.
<i>Sample and Test</i>	<p>For an imported shipment, the vendor is required to statistically sample and test for authenticity and degradation in a manner consistent with the Federal Act:</p> <ul style="list-style-type: none"> • For the initial shipment: Each batch of the drug in the shipment. • For each subsequent shipment: A statistically valid sample of the shipment.
<i>Lab Testing</i>	<ul style="list-style-type: none"> • Maintain qualified laboratory records, including data derived from all tests necessary to ensure drug comply with these requirements. • Maintain information and documentation which demonstrates required testing was done in compliance with the Federal Act and any required federal and state testing guidelines. • Require all testing to be performed in a qualified lab which meets federal standards under the Federal Act, applicable federal laws and regulations, and state laws and regulations.
<i>Certification & Record Retention</i>	<ul style="list-style-type: none"> • Certify that any imported drug is approved for marketing in the U.S., is not adulterated or misbranded, and meets all of the required U.S. labeling standards. • Maintain records, information, and documentation under this section for at least seven years. • Maintain a list of all registered importers participating in the Program.
Importers and Eligible Drugs for Importation	
<i>Importer Eligibility</i>	<ul style="list-style-type: none"> • The following entities or persons may be eligible to import prescription drugs from a Canadian supplier under the Program after registering with the vendor, submitting evidence of two surety bonds or comparable security arrangements each in the minimum amount of \$1 million to ensure payment of penalties for non-performance and payment of any civil and criminal causes of action, and deemed in compliance with all other requirements: <ol style="list-style-type: none"> 1. A wholesale distributor 2. A pharmacy 3. A pharmacist

Canadian Prescription Drug Importation Program Responsibilities of the Parties	
	<ul style="list-style-type: none"> • Establish that the profit margin and administrative fees of any participating wholesaler, pharmacy, or pharmacies on imported drug products is limited to a maximum amount as annually specified in the GAA. • Comply with the tracking and tracing requirements under federal law. • May not distribute, dispense, or sell prescription drugs under the Program outside of the state.
<i>Eligible Drugs</i>	<p>Eligible importers may import a drug from an eligible Canadian supplier, if the importer:</p> <ul style="list-style-type: none"> • Meets the FDA’s standards related to safety, effectiveness, misbranding, and adulteration; • Importation would not violate U.S. patent laws; • Importation is expected to generate cost savings; and • The drug is not: <ul style="list-style-type: none"> ○ A controlled substance as defined in 21 U.S.C. section 802; ○ A biological product as defined in 42 U.S.C. section 262; ○ An infused drug; ○ An intravenously injected drug; ○ A drug that is inhaled during surgery; or ○ A drug that is a parenteral drug, a drug which is determined by the HHS Secretary to pose a threat.
<i>Information provided to vendor</i>	<p>Participating importers must provide the following information to the vendor:</p> <ol style="list-style-type: none"> 1. The name and quantity of the active ingredient of the drug. 2. A description of the dosage form of the drug. 3. The date on which the drug is received. 4. The quantity of the drug that is received. 5. The point of origin and destination of the drug. 6. The price paid by the importer of the drug.
Canadian Suppliers	
<i>Supplier Eligibility</i>	<ul style="list-style-type: none"> • A supplier may export prescription drugs into this state under the Program if the supplier is: <ul style="list-style-type: none"> ○ In full compliance with relevant Canadian federal and provincial laws and regulations; ○ Complies with track and trace at the package level. ○ Identified by the vendor as eligible to participate in the Program. ○ Submits evidence of two surety bonds or comparable security arrangements each in the minimum amount of \$1 million to ensure payment of penalties for non-performance and payment of any civil and criminal causes of action. • May not distribute, dispense, or sell prescription drugs under the Program outside of the state.
<i>Information and Documentation</i>	<ul style="list-style-type: none"> • A participating Canadian supplier must submit the following information and documentation for each imported drug specifying all of the following, in addition to any other information deemed necessary by the AHCA to ensure the protection of the public health:

Canadian Prescription Drug Importation Program Responsibilities of the Parties	
	<ol style="list-style-type: none"> 1. The original source of the drug, including: <ol style="list-style-type: none"> a. The name of the manufacturer of the drug. b. The date the drug was manufactured. c. The location (country, state/province, and city) where the drug was manufactured. 2. The date the drug was shipped. 3. The quantity of each lot of the drug originally received and from which source. 4. The quantity of each lot of the drug originally received and from which source. 5. The lot or control number and the batch number assigned to the drug by the manufacturer. <ul style="list-style-type: none"> • The AHCA may require that the vendor collect any other information necessary to ensure the protection of the public health.

Section 2 provides an effective date of July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

Supremacy Clause

As noted earlier in the analysis, in Maine, several pharmacy groups sued the state under a variety of theories, including the Supremacy Clause of the United States Constitution, Art. VI, cl. 2, arguing that federal law preempted state law and that federal law had, for now, created a “closed regulatory scheme which strictly limited the introduction of prescription drugs into interstate commerce. The plaintiffs also pointed out that Congress contemplated the potential importation of prescription drugs from Canada in the MMA,

but that this section had not taken effect because the HHS Secretary has not granted the necessary certification.”⁹⁵

The opinion further discusses those situations where state law can still rebut the presumption regarding preemption. The Court must begin with the “presumption that the state statute is valid,⁹⁶ particularly if the state law is a matter involving issues regulating public health.⁹⁷ There is also a presumption for the state if the area and subject matter is “in any field in which there is a history of state law regulation, even if there is also a history of federal law regulation.”⁹⁸ To preempt state law, Congress must clearly preempt state law when it is regulating in an area where the state traditionally regulates.⁹⁹ In *Ouellette*, the Plaintiffs’ argument was that preemption should apply because the amendments passed by the state of Maine to allow for the drug importation program touch on foreign affairs and that subject matter is reserved traditionally for the federal government.¹⁰⁰

The Court noted in *Ouellette* that Congress had legislated explicitly with respect to the importation of drugs from Canada and the MMA has provided a specific path to legally permissible importation.¹⁰¹ The Eighth Circuit had also weighed in on this issue and the *Ouellette* court repeated those findings:

That Congress created a special procedure for authorizing importation of prescription drugs from Canada supports our conclusion that the pre-existing system established by the FDCA does not permit such importation. While it is true that no federal statute by its express terms bans importation of prescription drugs from Canada, such an explicit country-by-country prohibition is unnecessary to accomplish the task. By creating the comprehensive regulatory system described above, Congress has effectively precluded importation of these drugs absent the sort of special authorization contemplated by 21 U.S.C. section 384.¹⁰²

Foreign Dormant Commerce Clause

A state’s drug importation program must also be carefully reviewed to ensure that it can meet the constitutionality tests of the foreign dormant commerce clause and does not place an undue burden on foreign commerce and the role that the federal government plays in the implementation of foreign policy. The possibility of potential conflicts,

⁹⁵ *Ouellette et al v. Mills et al*, *supra* note 63, at 9.

⁹⁶ *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 661 (2003); quoted in *Ouellette v. Mills*, at 10.

⁹⁷ See *Hillsborough County, Fla. v. Automated Med. Lab., Inc.*, 471 U.S. 707, 718 (1985); quoted in *Ouellette et al v. Mills et al*, at 10.

⁹⁸ *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156., 176 (1st Cir. 2009) (citing *Wyeth*, 555 U.S. at 565, n. 3).

⁹⁹ *Nat’l Foreign Trade Council v. Natsios*, 181 F.3d 38, 73 (1st Cir. 1999)(citing *Rice*, 331 U.S. at 230). The *Natsios* case dealt with a claim by Massachusetts’ that its law restricting trade with Burma was an exercise of its procurement authority, a traditional area of state power.

¹⁰⁰ *Supra* note 63, at 11.

¹⁰¹ *Ouellette v. Mills*, *supra* note 63, at 15.

¹⁰² *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790 (8th Cir. 2006) (cited in *Ouellette v. Mills*).

therefore, are less likely since a federal statute sets forward a path for federal approval of a program. Concerns regarding intersections with other pharmaceutical programs and arguments, such as those about multiple regulatory schemes, may be issues to be aware of, but they should not have an impact on international relations.¹⁰³

Recently in a case from Maryland, the U.S. Supreme Court declined to review a decision from the U.S. Circuit Court of Appeals for the Fourth Circuit finding that Maryland’s state-based price-gouging statute was a violation of the dormant commerce clause because it interfered with interstate commerce as it regulated transactions outside of the state.¹⁰⁴ “The principle against extraterritoriality as it relates to the dormant commerce clause is derived from the notion that ‘a state may not regulate commerce occurring wholly outside of its borders.’”¹⁰⁵

The Fourth Circuit held that Maryland illegally regulated wholesale pricing by drug companies through a provision enacted in 2017, which prohibited what the state termed as “unconscionable” price increases for essential drugs no longer covered by patents or generics that were sold in the state.¹⁰⁶ The conduct targeted by the law was the upstream pricing and sale of prescription drugs, all of which occurred outside of Maryland which as the court noted then requires the manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland.¹⁰⁷

From its “cases concerning extraterritorial effects of state economic regulation,” the Supreme Court outlined the principle against extraterritoriality in a Connecticut case where residents were prohibited from crossing state lines to purchase cheaper beer:

- 1) A state statute may not regulate “commerce that takes place wholly outside of the State’s borders, whether or not the comer has effects within the State.¹⁰⁸ Specifically, a state law may not have the practical effect of establishing a scale of prices for use in other states.”¹⁰⁹
- 2) A statute that directly controls commerce occurring wholly outside the [legislating state’s] boundaries... is invalid regardless of whether the

¹⁰³ Anna Zaret and Darien Shanske, *The Dormant Commerce Clause: What Impact Does It Have on the Regulation of Pharmaceutical Costs?*(November 2017) National Academy for State Health Policy, <https://nashp.org/wp-content/uploads/2017/11/DCC-White-Paper.pdf> (last visited March 28, 2019).

¹⁰⁴ *Association for Accessible Medicines v. Frosh*, 887 F.3d 664 (U.S. App. 4th Cir. 2018).

¹⁰⁵ *Id.* (citing *Star Sci., Inc. v. Beales*, 278 F. 3d 339, 355 (4th Cir. 2002) (citing *Healy v. Beer Inst.*, 324, 335-36 (1989); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 582-83 (1986); *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982)(plurality opinion)).

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Healy at 336.*

¹⁰⁹ *Healy* (quoting *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 528 (1935)).

statute's extraterritorial reach was intended by the legislature."¹¹⁰ The statute's "practical effect" is the focus of the inquiry.¹¹¹

- 3) In evaluating a statute's "practical effect," the Court considers "not only... the consequences of the statute itself, but also ...how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation."¹¹² This is because "the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State."¹¹³

Because the Act targets wholesale rather than retail pricing, the court notes that it has the potential to subject the manufacturers to conflicting state requirements.¹¹⁴

"The manufacturer's compliance would require more than modification of their distribution systems; it would force them to enter into a separate transaction for each state in order to tailor their conduct so as not to violate any state's price restrictions...The potential for 'the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude'¹¹⁵ is therefore both real and significant. We are thus pressed to invalidate the Act."¹¹⁶

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Wholesalers, pharmacies, and pharmacists who are licensed entities would potentially be eligible under the bill to participate as importers under the Program which they are not currently able to do. To the extent that such entities participate in the Program to import less expensive FDA-approved drugs, they may experience cost savings which may be passed along to entities that purchase those drugs in Florida.

C. Government Sector Impact:

The bill has an indeterminate fiscal impact on the AHCA. The AHCA anticipates needing additional resources to implement the bill before any cost savings from the importation Program are implemented.¹¹⁷

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Healy* at 336.

¹¹³ *Healy* at 336-37.

¹¹⁴ *Supra* note 104, at 19-21.

¹¹⁵ *Healy* at 337.

¹¹⁶ *Supra* note 104, at 21.

¹¹⁷ Agency for Health Care Administration, *House Bill 19 Analysis* (March 1, 2019) (on file with the Senate Committee on Health Policy).

While the bill has the potential to bring savings to the Florida Medicaid program and to other state government programs through lowering the cost of prescription drugs to individuals served by those programs, the amount of those savings currently cannot be quantified. However, since the federal law requires the Program to generate significant savings in order to be approved, this impact should be offset by drug price savings.

The bill also provides that the administrative fees borne by the state and the profit margins for any participating wholesaler, pharmacy, or pharmacist relating to drugs imported through the Program will be limited to a maximum amount as specified each year in the General Appropriations Act.

The AHCA is required to contract with a vendor to provide services under the Canadian Prescription Drug Importation Program. The AHCA did not provide an estimate of the cost to procure a contract with a qualified third-party vendor to administer the Program.

The AHCA indicated the need for six additional personnel dedicated to the project who will be developing, procuring, and managing and conducting oversight and monitoring activities. The AHCA would begin recruitment activities immediately upon adoption of the bill as staff are needed to start Program design activities, development of the competitive solicitation, request for federal authority, etc. The AHCA will need to determine the level of federal financial participation in the Program.

AHCA Fiscal Impact		
<i>(Contingent Upon Federal Approval)</i>	First Year Implementation	2nd Year and Beyond: Recurring Expenditures
FTE:		
1.00 – AHCA Administrator – SES	\$98,345	\$98,345
5.00 – Government Analyst II	\$409,770	\$409,770
Operational Expenses:	\$64,380	\$37,722
Grand Total	\$575,495	\$545,837

The Board of Pharmacy, within the DOH, would be responsible for the licensing and permitting of business entities acting as importers, wholesalers, or suppliers.

VI. Technical Deficiencies:

The DBPR indicates that the bill applies to “prescription drugs” which, pursuant to s. 499.003(40), F.S., applies not only to finished dosage forms, but also to active pharmaceutical ingredients (API) that are routinely imported for further manufacturing and/or distribution by Florida companies.¹¹⁸

¹¹⁸ Department of Business and Professional Regulation, *Senate Bill 1528 Analysis*, at 11 (March 5, 2019) (on file with the Senate Committee on Health Policy).

VII. Related Issues:

Canadian Drug Supply

In 2015, Canada's population (35 million) was one-ninth the population of the United States (318 million).¹¹⁹ The number of prescriptions dispensed in the United States was almost seven times larger than in Canada and, taking into account the number of individuals and the number of prescriptions, one researcher in 2010, and again in 2015, calculated how long Canada's drug supply would last if 20 percent of Americans sought to have their prescriptions filled in Canada. In 2015, the number of days' supply without any additional manufacturing or imports was 150.83 days.¹²⁰ In 2010, the number of days' supply was 201 days before the then-existing Canadian drug supply was depleted.¹²¹

That researcher pointed out that Canada has options to meet a growing demand, such as increasing its drug manufacturing output, increasing pharmaceutical imports, continuing the practice of allowing internet pharmacies to fill medications from foreign sources while looking the other way from a regulatory standpoint, or calling a halt to foreign sales of prescriptions.¹²² That researcher also noted that Canada imported \$13.180 billion in pharmaceuticals with \$5.16 billion coming from the United States in 2015. In other words, the United States was Canada's largest supplier of pharmaceuticals in 2015, representing 33.1 percent of all drugs imported by Canada.¹²³

Another concern maybe that Canada has been experiencing its own access to drug issues and rising drug prices. Health Canada, Canada's national health ministry, recently released its own *Interim Report of the Advisory Council on the Implementation of National Pharmacare* on how to implement a national drug care program.¹²⁴ How Canada moves forward with this plan may impact how pharmacies and vendors in Canada operate in the future.

Canadian Law

The import and export of health products in Canada is regulated under Canada's *Food and Drugs Act* and its associated regulations. No drugs may be sold that are mislabeled, or adulterated.¹²⁵ Depending on how a product is labeled as it leaves Canada, for the Canadian market or the U.S. market, it may be considered "mislabeled" in one of the markets.

Additionally, under Canadian Federal Regulation A.01.045, all exports of food and drugs from Canada must have a certificate attached which is signed by the exporter attesting to the legality of the items and that the items being shipped are done so accordance with the laws of its

¹¹⁹ Marv Shepherd, *U.S. Drug Importation: Impact on Canada's Prescription Drug Supply*, Health Economics & Outcome Research: Open Access, Vol. 4, Iss.1 (February 5, 2018) <http://www.safemedicines.org/wp-content/uploads/2017/08/us-drug-importation-impact-on-canadas-prescription-drug-supply-2471-268X-1000146.pdf> (last visited March 28, 2019).

¹²⁰ Marv Shepherd, *supra* note 132, at 3.

¹²¹ Marv Shepherd, *supra* note 132, at 3.

¹²² Marv Shepherd, *supra* note 132, at 4.

¹²³ Marv Shepherd, *supra* note 132, at 4.

¹²⁴ Health Canada, *Advisory Council on the Implementation of National Pharmacare*, <https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare.html#a1> (last visited March 22, 2019).

¹²⁵ R.S., c. F-27, s. 8. (Can.)

destination.¹²⁶ An inspector is also authorized by law to take samples of an article at any reasonable time if the inspector believes that a package contains an item which is covered by the *Food and Drugs Act* and those items may also be subject to seizure.¹²⁷

Federal Approval

The bill directs the AHCA, by July 1, 2020, to submit a request to the HHS Secretary for approval of the Florida Program under 21 USC s. 384(l). That subsection of federal law provides that the federal drug importation program under 21 USC s. 384 becomes effective only if the Secretary certifies to the U.S. Congress that the implementation of the federal program will pose no additional risk to the public's health and safety and result in a significant reduction in the cost of covered products to the American consumer. No HHS Secretary has yet sent such a certification to the U.S. Congress. The cited subsection also provides for termination of the federal program. However, the subsection contains no authority for the HHS Secretary to approve any state-based drug importation program under any circumstances, nor to waive any aspects of the federal program regarding public health and safety or cost reduction, which other states have requested through the FDA for their own state-based program proposals.

VIII. Statutes Affected:

This bill creates section 381.02035 of the Florida Statutes.

IX. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

Recommended CS/CS by Appropriations Subcommittee on Health and Human Services on April 9, 2019:

The committee substitute:

- Makes several technical changes to the bill and clarifies requirements for eligible suppliers, importers, and the vendor related to surety bonds or other comparable security arrangements;
- Removes from the bill the provision that requires the vendor to export drugs at prices providing cost savings to the state. The bill, however, as part of the final approval process, maintains the requirement that the Legislature consider the estimated cost savings to the state and also contains numerous requirements for the vendor and for Program participants, designed to ensure the Program results in cost-savings; and
- Provides that the vendor will assist the AHCA in the presentation of the annual report.

CS by Health Policy on March 25, 2019:

The CS removes several provisions from the underlying bill, adds several safety and transparency components, clarifies existing components, and aligns the Program with updated tracing procedures under federal law. The CS:

¹²⁶ C.R.C., SOR/80-318, s-1(Can.)

¹²⁷ R.S.C., 1985, C. F-27, Part II(23)

- Removes from the underlying bill the provision that pharmacists or wholesalers may import Canadian prescription drugs under the Program only if they are employed by or under contract with:
 - The DOH's central pharmacy, for distribution to a county health department or free clinic for clients served in those settings;
 - A Medicaid pharmacy, for dispensing to the pharmacy's Medicaid recipients;
 - The Department of Corrections (DOC), for dispensing to inmates in DOC custody;
 - A developmental disabilities center, for dispensing to clients treated in those settings; or
 - A state-owned, state-operated, or state-supported treatment facility for persons with mental illness, or a private facility designated by the Department of Children and Families for that purpose, for dispensing to persons treated in those settings.
- Removes from the underlying bill the requirement for the AHCA to begin operating the Program within six months of receiving federal approval.
- Requires that any Canadian supplier must comply fully with U.S. law and any other federal and state laws and regulation relating to track and trace procedures. The definitions were updated to define what is meant by track and trace procedures.
- Requires the vendor, suppliers, and importers under the Program to post two surety bonds of at least \$1 million each at the time of contract execution to ensure contractual performance and non-payment of any administrative penalties over the contract term and to ensure participation in any civil or criminal litigation and payment of any claims or judgment that may arise from those actions. For suppliers and importers, the minimum amount of the bonds may escalate over time depending on Program volume.
- Requires the vendor under contract with the AHCA to maintain a list of all registered importers participating in the Program.
- Requires the vendor to ensure that all suppliers, importers, distributors, and other Program participants remain in compliance with all laws and regulations, U.S. and Canadian.
- Requires that a maximum administrative fee and profit margin amount or rate will be set by the state in the General Appropriations Act for any participating wholesaler, pharmacy, or pharmacist in the Program.
- Adds a limitation for participating suppliers and importers that drugs imported under this Program may not be sold outside of the Program.
- Sets a record retention requirement for laboratory testing records of seven years.
- Adds components to what should be included in the state's plan submission to the HHS to include information about the state's track and trace procedures, the state's estimated costs to implement the Program, and a list of Canadian suppliers willing to do business in Florida.
- Requires that the Program approved at the federal level to receive final approval from the Legislature before being implemented. Additional information about safety and cost effectiveness of the plan must accompany the approval request to the Legislature.
- Requires that the AHCA describe how it has complied with federal track and trace requirements in its Annual Report.

B. Amendments:

None.

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

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/2019
Meeting Date

CS/SB 1528
Bill Number (if applicable)

Topic Drugs from Canada

Amendment Barcode (if applicable)

Name Mark Delegal

Job Title Retained Counsel

Address 315 S. Calhoun St, 600

Phone 8502247000

Street TLH City FL State FL Zip

Email

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Pharmaceutical Researches & Manufactures of America

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19
Meeting Date

1528
Bill Number (if applicable)

Topic Impairation

Amendment Barcode (if applicable)

Name Michelle Flowers

Job Title President

Address PO Box 358440

Phone _____

Street

Gainesville, FL 32635

Email _____

City

State

Zip

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Oncology Managers of Florida

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/19/19

Meeting Date

CS/SB 1528

Bill Number (if applicable)

Topic Canadian Prescription Drug Importation

Amendment Barcode (if applicable)

Name Dorene Barker Program

Job Title Associate State Director

Address 200 W. College Ave, Ste 304 A

Phone 850-228-6387

Street

Tallahassee

FL

32301

City

State

Zip

Email dobarker@aarp.org

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing AARP Florida

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

By the Committee on Health Policy; and Senators Bean and Gruters

588-03459-19

20191528c1

1 A bill to be entitled
 2 An act relating to the Canadian Prescription Drug
 3 Importation Program; creating s. 381.02035, F.S.;
 4 requiring the Agency for Health Care Administration to
 5 establish the Canadian Prescription Drug Importation
 6 Program; defining terms; authorizing a Canadian
 7 supplier to export drugs into this state under the
 8 program under certain circumstances; providing
 9 eligibility criteria and requirements for drug
 10 importers; requiring the agency to contract with a
 11 vendor to facilitate wholesale prescription drug
 12 importation under the program; providing
 13 responsibilities for the vendor; providing eligibility
 14 criteria for prescription drugs, Canadian suppliers,
 15 and importers under the program; requiring
 16 participating Canadian suppliers and importers to
 17 comply with specified federal requirements for
 18 distributing prescription drugs imported under the
 19 program; prohibiting Canadian suppliers and importers
 20 from distributing, dispensing, or selling prescription
 21 drugs imported under the program outside the state;
 22 providing certain documentation requirements;
 23 requiring the agency to suspend the importation of
 24 drugs in violation of this section or any federal or
 25 state law or regulation; authorizing the agency to
 26 revoke the suspension under certain circumstances;
 27 requiring the agency to request federal approval of
 28 the program; requiring the request to include certain
 29 information; requiring the agency to begin operating

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CODING: Words ~~stricken~~ are deletions; words underlined are additions.

588-03459-19

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30 the program within a specified timeframe after
 31 receiving federal approval; requiring the agency, in
 32 consultation with the vendor, to submit an annual
 33 report to the Governor and the Legislature by a
 34 specified date; providing requirements for such
 35 report; authorizing the agency to adopt rules;
 36 providing an effective date.
 37

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

39
 40 Section 1. Section 381.02035, Florida Statutes, is created
 41 to read:
 42 381.02035 Canadian Prescription Drug Importation Program.—
 43 (1) PROGRAM ESTABLISHED.—The Agency for Health Care
 44 Administration shall establish a program for the importation of
 45 safe and effective prescription drugs from Canada which have the
 46 highest potential for cost savings to the state.
 47 (2) DEFINITIONS.—As used in this section, the term:
 48 (a) "Agency" means the Agency for Health Care
 49 Administration.
 50 (b) "Canadian supplier" means a manufacturer, wholesale
 51 distributor, or pharmacy appropriately licensed or permitted
 52 under Canadian law to manufacture, distribute, or dispense
 53 prescription drugs.
 54 (c) "Drug" or "prescription drug" has the same meaning as
 55 "prescription drug" in s. 499.003.
 56 (d) "Federal Act" means the Federal Food, Drug, and
 57 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.
 58 as amended by the Drug Quality and Security Act, 21 U.S.C. 351

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CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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59 et seq.

60 (e) "Importer" means a wholesale distributor, pharmacy, or
 61 pharmacist importing prescription drugs into this state under
 62 the program.

63 (f) "Pharmacist" means a person who holds an active and
 64 unencumbered license to practice pharmacy pursuant to chapter
 65 465.

66 (g) "Program" means the Canadian Prescription Drug
 67 Importation Program.

68 (h) "Track-and-trace" means the product-tracing process for
 69 the components of the pharmaceutical distribution supply chain
 70 as described in Title II of the Drug Quality and Security Act,
 71 Drug Supply Chain Security Act, 21 U.S.C. 351 et seq.

72 (i) "Vendor" means the entity contracted by the agency to
 73 manage specified functions of the program.

74 (3) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may
 75 export drugs into this state under the program if the supplier
 76 meets all of the following requirements:

77 (a) Complies fully with relevant Canadian federal and
 78 provincial laws and regulations.

79 (b) Complies fully with the Federal Act, including all
 80 other state and federal law and regulations relating to the
 81 track-and-trace requirements at the package level.

82 (c) Submits evidence at time of contract award and
 83 throughout the contract term of a surety bond or comparable
 84 security arrangement from this state or any other state in the
 85 United States in the minimum amount of \$1 million. The agency
 86 shall reevaluate and adjust the amount of the bond annually,
 87 based on program volume. The surety bond or comparable security

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88 arrangement must include the State of Florida as a beneficiary.

89 In lieu of the surety bond, the supplier may provide a
 90 comparable security arrangement such as an irrevocable letter of
 91 credit or a deposit into a trust account or financial
 92 institution which includes the State of Florida as a
 93 beneficiary. The purposes of the bond or other security
 94 arrangements for the program are to:

95 1. Ensure payment of any administrative penalties imposed
 96 by the agency or any other state agency under the contract when
 97 the supplier fails to pay within 30 days after assessment;

98 2. Ensure performance of contractual and statutory
 99 obligations by the supplier through use of a bond or other
 100 comparable security arrangements to receive payment of any other
 101 costs or fees incurred by the agency, the state, or other
 102 entities acting on behalf of the state if the supplier is non-
 103 compliant with its contractual and statutory obligations. If the
 104 supplier is assessed a penalty under the program and fails to
 105 pay within 30 days after that assessment, the agency, the state,
 106 or an entity acting on behalf of the state may file a claim for
 107 reimbursement against the bond or other comparable security
 108 arrangement; and

109 3. Allow for claims to be made against the bond or other
 110 comparable security arrangements for up to 1 year after the
 111 supplier's contract under the program has ended with the agency
 112 or the state, the supplier's license is no longer valid, or the
 113 program has ended, whichever occurs last.

114
 115 A surety bond or other comparable security arrangement is
 116 required regardless of the time of bid or negotiation process

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117 used by the agency or the type of final contract or agreement
 118 executed for services.

119 (d) Is identified by the vendor as eligible to participate
 120 in the program.

121 (e) Submits evidence at the time of contract award and
 122 throughout the contract term of a surety bond or comparable
 123 security arrangement from this state or any other state in the
 124 United States in the minimum amount of \$1 million. The agency
 125 shall reevaluate and adjust the amount of the bond annually,
 126 based on program volume. The surety bond or comparable security
 127 arrangement must include the State of Florida as a beneficiary.
 128 In lieu of the surety bond, the supplier may provide a
 129 comparable security arrangement such as an irrevocable letter of
 130 credit or a deposit into a trust account or financial
 131 institution which includes the State of Florida as a
 132 beneficiary. The purposes of the bond or other security
 133 arrangements for the program are to:

134 1. Indemnify the supplier in the event that any civil or
 135 criminal legal action is brought by the state, the agency, any
 136 other state agency, or private individuals or entities against
 137 the supplier because of the supplier's failure to perform under
 138 the contract, including, but not limited to, causes of actions
 139 for personal injury, negligence, and wrongful death;

140 2. Ensure payment by the supplier of legal judgements and
 141 claims that have been awarded to the state, the agency, other
 142 entities acting on behalf of the state, individuals, or
 143 organizations if the supplier is assessed a final judgement or
 144 other monetary penalty in a court of law for a civil or criminal
 145 action related to participation in the program. The bond or

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146 comparable security arrangement may be accessed if the supplier
 147 fails to pay any judgement or claim within 60 days after final
 148 judgement; and

149 3. Allow for civil and criminal litigation claims to be
 150 made against the bond or other comparable security arrangements
 151 for up to 1 year after the supplier's contract under the program
 152 has ended with the agency or the state, the supplier's license
 153 is no longer valid, or the program has ended, whichever occurs
 154 last.

155 (4) ELIGIBLE IMPORTERS.-

156 (a) The following entities or persons may import
 157 prescription drugs from a Canadian supplier under the program:

158 1. A wholesale distributor.

159 2. A pharmacy.

160 3. A pharmacist.

161 (b) An eligible importer must meet all of the following
 162 requirements at time of contract award and throughout the
 163 contract term:

164 1. Register with the vendor before importing drugs into the
 165 state under the program and be deemed in compliance with all
 166 requirements, including any relevant provisions of the Federal
 167 Act.

168 2. Submit evidence at time of contract award and throughout
 169 the contract term of a surety bond or other comparable security
 170 arrangement from this state or any other state in the United
 171 States in the amount of \$1 million. The surety bond or
 172 comparable security arrangement must include the State of
 173 Florida as a beneficiary. In lieu of the surety bond, the
 174 supplier may provide a comparable security agreement such as an

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175 irrevocable letter of credit or a deposit into a trust account
 176 or financial institution which includes the State of Florida as
 177 a beneficiary, payable to the State of Florida. The purposes of
 178 the bond or other security arrangements for the program are to:
 179 a. Ensure payment of any administrative penalties imposed
 180 by the agency or any other state agency under the contract when
 181 the importer fails to pay within 30 days after assessment;
 182 b. Ensure performance of contractual and statutory
 183 obligations by the importer through use of a bond or other
 184 comparable security arrangements to receive payment of any other
 185 costs or fees incurred by the agency, the state, or other
 186 entities acting on behalf of the state if the importer is non-
 187 compliant with its contractual and statutory obligations. If the
 188 importer is assessed a penalty under the program and fails to
 189 pay within 30 days after that assessment, the agency, the state,
 190 or an entity acting on behalf of the state may file a claim for
 191 reimbursement against the bond or other comparable security
 192 arrangement; and
 193 c. Allow for claims to be made against the bond or other
 194 comparable security arrangements for up to 1 year after the
 195 importer's contract under the program has ended with the agency
 196 or the state, the importer's license is no longer valid, or the
 197 program has ended, whichever occurs last.
 198
 199 A surety bond or comparable document is required regardless of
 200 the time of bid or negotiation process used by the agency or the
 201 type of final contract or agreement executed for services.
 202 (c) Submits evidence at the time of contract award and
 203 throughout the contract term of a surety bond or comparable

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204 security arrangement from this state or any other state in the
 205 United States in the minimum amount of \$1 million. The agency
 206 shall reevaluate and adjust the amount of the bond annually,
 207 based on program volume. The surety bond or comparable security
 208 arrangement must include the State of Florida as a beneficiary.
 209 In lieu of the surety bond, the supplier may provide a
 210 comparable security agreement such as an irrevocable letter of
 211 credit or a deposit into a trust account or financial
 212 institution which includes the State of Florida as a
 213 beneficiary, payable to the State of Florida. The purposes of
 214 the bond or other security arrangements for the program are to:
 215 1. Ensure participation of the supplier in any civil or
 216 criminal legal action by the state, the agency, any other state
 217 agency, or private individuals or entities against the supplier
 218 because of the supplier's failure to perform under the contract,
 219 including, but not limited to causes of actions for personal
 220 injury, negligence, and wrongful death;
 221 2. Ensure payment by the supplier through the use of a bond
 222 or other comparable security arrangements of legal judgements
 223 and claims that have been awarded to the agency, the state,
 224 other entities acting on behalf of the state, individuals, or
 225 organizations if the supplier is assessed a final judgement or
 226 other monetary penalty in a court of law for a civil or criminal
 227 action under the program. The bond or comparable security
 228 arrangement will be accessed if the supplier fails to pay any
 229 judgement or claim within 60 days after final judgement; and
 230 3. Allow for civil and criminal litigation claims to be
 231 made against the bond or other comparable security arrangements
 232 for up to 1 year after the supplier's contract under the program

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233 has ended with the agency or the state, the supplier's license
 234 is no longer valid, or the program has ended, whichever occurs
 235 last.

236 (5) IMPORTATION PROCESS.-

237 (a) The agency shall contract with a vendor to provide
 238 services under the program. The vendor must submit evidence of a
 239 surety bond with any bid or initial contract negotiation
 240 documents and maintain documentation of evidence of such a bond
 241 with the agency throughout the contract term of a surety bond
 242 from this state or any other state in the United States in the
 243 same amount of \$1 million. The surety bond or comparable
 244 security arrangement must include the State of Florida as a
 245 beneficiary. In lieu of the surety bond, the supplier may
 246 provide a comparable security agreement such as an irrevocable
 247 letter of credit or a deposit into a trust account or financial
 248 institution which includes the State of Florida as a
 249 beneficiary, payable to the State of Florida. The purposes of
 250 the bond or other security arrangements for the program are to:

251 1. Ensure payment of any administrative penalties imposed
 252 by the agency or any other state agency under the contract when
 253 the vendor fails to pay within 30 days after assessment;

254 2. Ensure performance of contractual and statutory
 255 obligations by the vendor through use of a surety bond or other
 256 comparable security arrangements to receive payment of any other
 257 costs or fees incurred by the agency, the state, or other
 258 entities acting on behalf of the state if the vendor is non-
 259 compliant with its contractual and statutory obligations. If the
 260 vendor is assessed a penalty under the program and fails to pay
 261 within 30 days after that assessment, the agency, the state, or

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262 an entity acting on behalf of the state may file a claim for
 263 reimbursement against the bond or other comparable security
 264 arrangement; and

265 3. Allow for claims to be made against the bond or other
 266 comparable security arrangements for up to 1 year after the
 267 vendor's contract under the program has ended with the agency or
 268 the state, the importer's license is no longer valid, or the
 269 program has ended, whichever occurs last.

270
 271 A surety bond or comparable document is required regardless of
 272 the time of bid or negotiation process used by the agency or the
 273 type of final contract or agreement executed for services.

274 (b) Submits evidence at the time of contract award and
 275 throughout the contract term of a surety bond or comparable
 276 security arrangement from this state or any other state in the
 277 United States in the minimum amount of \$1 million. The agency
 278 shall reevaluate and adjust the amount of the bond annually,
 279 based on program volume. The surety bond or comparable security
 280 arrangement must include the State of Florida as a beneficiary.
 281 In lieu of the surety bond, the supplier may provide a
 282 comparable security arrangement such as an irrevocable letter of
 283 credit or a deposit into a trust account or financial
 284 institution which names the State of Florida as a beneficiary.
 285 The purposes of the bond or other security arrangements for the
 286 program are to:

287 1. Ensure participation of the vendor in any civil or
 288 criminal legal action by the state, the agency, any other state
 289 agency, or private individuals or entities against the vendor
 290 because of the vendor's failure to perform under the contract,

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291 including, but not limited to causes of actions for personal
 292 injury, negligence, and wrongful death;

293 2. Ensure payment by the vendor through the use of a bond
 294 or other comparable security arrangements of legal judgements
 295 and claims that have been awarded to the agency, the state,
 296 other entities acting on behalf of the state, individuals, or
 297 organizations if the vendor is assessed a final judgement or
 298 other monetary penalty in a court of law for a civil or criminal
 299 action under the program. The bond or comparable security
 300 arrangement will be accessed if the vendor fails to pay any
 301 judgement or claim within 60 days after final judgement; and

302 3. Allow for civil and criminal litigation claims to be
 303 made against the bond or other comparable security arrangements
 304 for up to 1 year after the vendor's contract under the program
 305 has ended with the agency or the state, the vendor's license is
 306 no longer valid, or the program has ended, whichever occurs
 307 last.

308 (c) The vendor shall provide all of the following services
 309 at a minimum:

310 1. Develop a list every 3 month of drugs that have the
 311 highest potential for cost savings to the state if imported from
 312 Canada. In developing the list, the vendor shall consider, at a
 313 minimum, which drugs will provide the greatest cost savings to
 314 the state, including drugs for which there are shortages,
 315 specialty drugs, and high-volume drugs. The agency may direct
 316 the vendor to revise the list, as necessary.

317 2. Identify Canadian suppliers that are in full compliance
 318 with relevant Canadian federal and provincial laws and
 319 regulations and the Federal Act and who have agreed to export

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320 drugs identified on the list. The vendor must verify that such
 321 Canadian suppliers meet all of the requirements of the program
 322 and will export drugs at prices that will provide cost savings
 323 to the state while meeting or exceeding the track-and-trace
 324 federal and state laws and regulations.

325 3. Contract with such eligible Canadian suppliers, or
 326 facilitate contracts between eligible importers and Canadian
 327 suppliers, to import drugs under the program.

328 4. Maintain a listing of all registered importers that
 329 participate in the program.

330 5. Ensure compliance with Title II of the federal Drug
 331 Quality and Security Act P.L. 113-54 by all suppliers, importers
 332 and other distributors and participants in the program.

333 6. Assist the agency with the annual report as required in
 334 subsection (12) and provide any information requested by the
 335 agency for such report on a timely basis.

336 (d) The profit margin and administrative fees of any
 337 participating wholesaler, pharmacy, or pharmacist on imported
 338 drug products is limited to a maximum amount as specified
 339 annually in the General Appropriations Act.

340 (6) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers may
 341 import a drug from an eligible Canadian supplier if:

342 (a) The drug meets the United States Food and Drug
 343 Administration's standards related to safety, effectiveness,
 344 misbranding, and adulteration;

345 (b) Importing the drug would not violate the patent laws of
 346 the United States;

347 (c) Importing the drug is expected to generate cost
 348 savings; and

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349 (d) The drug is not:
 350 1. A controlled substance as defined in 21 U.S.C. s. 802;
 351 2. A biological product as defined in 42 U.S.C. s. 262;
 352 3. An infused drug;
 353 4. An intravenously injected drug;
 354 5. A drug that is inhaled during surgery; or
 355 6. A drug that is a parenteral drug, the importation of
 356 which is determined by the United States Secretary of Health and
 357 Human Services to pose a threat to the public health.
 358 (7) DISTRIBUTION REQUIREMENTS.—Eligible Canadian suppliers
 359 and importers participating under the program:
 360 (a) Must comply with the tracking and tracing requirements
 361 of 21 U.S.C. ss. 360eee et seq.
 362 (b) May not distribute, dispense, or sell drugs imported
 363 under the program outside of the program or outside of this
 364 state.
 365 (8) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—
 366 (a) The vendor shall ensure the safety and quality of drugs
 367 imported under the program. The vendor shall:
 368 1. For an initial imported shipment, ensure that each batch
 369 of the drug in the shipment is statistically sampled and tested
 370 for authenticity and degradation in a manner consistent with the
 371 Federal Act.
 372 2. For any subsequent imported shipment, ensure that a
 373 statistically valid sample of the shipment was tested for
 374 authenticity and degradation in a manner consistent with the
 375 Federal Act.
 376 3. Certify that the drug:
 377 a. Is approved for marketing in the United States and is

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378 not adulterated or misbranded; and
 379 b. Meets all of the labeling requirements under 21 U.S.C.
 380 s. 352.
 381 4. Maintain qualified laboratory records, including
 382 complete data derived from all tests necessary to ensure that
 383 the drug is in compliance with the requirements of this section.
 384 5. Maintain documentation demonstrating that the testing
 385 required by this section was conducted at a qualified laboratory
 386 in accordance with the Federal Act and any other applicable
 387 federal and state laws and regulations governing laboratory
 388 qualifications.
 389 (b) All testing required by this section must be conducted
 390 in a qualified laboratory that meets the standards under the
 391 Federal Act and any other applicable federal and state laws and
 392 regulations governing laboratory qualifications for drug
 393 testing.
 394 (c) The vendor shall maintain information and documentation
 395 submitted under this section for a period of at least 7 years.
 396 (d) A participating importer must submit the all of
 397 following information to the vendor:
 398 1. The name and quantity of the active ingredient of the
 399 drug.
 400 2. A description of the dosage form of the drug.
 401 3. The date on which the drug is received.
 402 4. The quantity of the drug that is received.
 403 5. The point of origin and destination of the drug.
 404 6. The price paid by the importer for the drug.
 405 (e) A participating Canadian supplier must submit the
 406 following information and documentation to the vendor specifying

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407 all of the following:408 1. The original source of the drug, including:409 a. The name of the manufacturer of the drug.410 b. The date on which the drug was manufactured.411 c. The location (country, state or province, and city)412 where the drug was manufactured.413 2. The date on which the drug is shipped.414 3. The quantity of the drug which is shipped.415 4. The quantity of each lot of the drug originally received416 and from which source.417 5. The lot or control number and the batch number assigned418 to the drug by the manufacturer.419 (f) The agency may require that the vendor collect any420 other information necessary to ensure the protection of the421 public health.

422 (9) IMMEDIATE SUSPENSION.—The agency shall immediately
 423 suspend the importation of a specific drug or the importation of
 424 drugs by a specific importer if it discovers that any drug or
 425 activity is in violation of this section or any federal or state
 426 law or regulation. The agency may revoke the suspension if,
 427 after conducting an investigation, it determines that the public
 428 is adequately protected from counterfeit or unsafe drugs being
 429 imported into the state.

430 (10) FEDERAL APPROVAL.—By July 1, 2020, the agency shall
 431 submit a request to the United States Secretary of Health and
 432 Human Services for approval of the program under 21 U.S.C. s.
 433 384(1). At a minimum, the request must do all of the following:

434 (a) Describe the agency's plan for operating the program.435 (b) Demonstrate how the drugs imported into the state under

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436 the program will meet the applicable federal and state standards
 437 for safety and effectiveness.

438 (c) Demonstrate how the drugs imported into the state under
 439 the program will comply with federal tracing procedures.

440 (d) Include a list of proposed drugs that have the highest
 441 potential for cost savings to the state through importation at
 442 the time that the request is submitted.

443 (e) Estimate the total cost savings attributable to the
 444 program.

445 (f) Provide the costs of program implementation to the
 446 state.

447 (g) Include a list of potential Canadian suppliers from
 448 which the state would import drugs and demonstrate that the
 449 suppliers are in full compliance with relevant Canadian federal
 450 and provincial laws and regulations as well as all applicable
 451 federal and state laws and regulations.

452 (11) NOTIFICATION OF FEDERAL APPROVAL.—Upon receipt of
 453 federal approval of the program, the agency shall notify the
 454 President of the Senate, the Speaker of the House of
 455 Representatives, and the relevant committees of the Senate and
 456 the House of Representatives. The program may not be implemented
 457 until the Legislature approves the program as authorized by the
 458 federal government. As part of its review process for
 459 implementation approval, the Legislature shall consider the
 460 estimated cost savings to the state and whether the program has
 461 met the required safety standards.

462 (12) ANNUAL REPORT.—By December 1 of each year, the agency
 463 shall submit a report to the Governor, the President of the
 464 Senate, and the Speaker of the House of Representatives on the

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465 operation of the program during the previous fiscal year. The
466 report must include, at a minimum:

467 (a) A list of the drugs that were imported under the
468 program;

469 (b) The number of participating entities;

470 (c) The number of prescriptions dispensed through the
471 program;

472 (d) The estimated cost savings during the previous fiscal
473 year and to date in the program;

474 (e) A description of the methodology used to determine
475 which drugs should be included; and

476 (f) Documentation of how the program ensures the following
477 criteria:

478 1. Canadian suppliers participating in the program are of
479 high quality, high performance, and in full compliance with
480 relevant Canadian federal and provincial laws and regulations as
481 well as all United States and Florida laws and regulations;

482 2. Drugs imported under the program are not shipped, sold,
483 or dispensed outside of the state or the program once in the
484 possession of the importer;

485 3. Drugs imported under the program are unadulterated,
486 potent, and safe;

487 4. The program does not put consumers at a higher health
488 and safety risk than if the consumer did not participate; and

489 5. The program provides cost savings to the state.

490 (13) RULEMAKING.—The agency may adopt rules necessary to
491 implement this section.

492 Section 2. This act shall take effect July 1, 2019.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/09/2019	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services (Bean)
recommended the following:

Senate Amendment

Delete lines 116 - 281
and insert:
required regardless of the type of bid or negotiation process
used by the agency or the type of final contract or agreement
executed for services.

(d) Is identified by the vendor as eligible to participate
in the program.

(e) Submits evidence at the time of contract award and



11 throughout the contract term of a surety bond or a comparable
12 security arrangement from this state or any other state in the
13 United States in the minimum amount of \$1 million. The agency
14 shall reevaluate and adjust the amount of the bond annually,
15 based on program volume. The surety bond or comparable security
16 arrangement must include the State of Florida as a beneficiary.
17 In lieu of the surety bond, the supplier may provide a
18 comparable security arrangement, such as an irrevocable letter
19 of credit or a deposit into a trust account or financial
20 institution which includes the State of Florida as a
21 beneficiary. The purposes of the bond or other security
22 arrangement for the program are to:

23 1. Indemnify the supplier in the event that any civil or
24 criminal legal action is brought by the state, the agency, any
25 other state agency, or private individuals or entities against
26 the supplier because of the supplier's failure to perform under
27 the contract, including, but not limited to, causes of action
28 for personal injury, negligence, and wrongful death;

29 2. Ensure payment by the supplier of legal judgments and
30 claims that have been awarded to the state, the agency, other
31 entities acting on behalf of the state, individuals, or
32 organizations if the supplier is assessed a final judgment or
33 other monetary penalty in a court of law for a civil or criminal
34 action related to participation in the program. The bond or
35 comparable security arrangement may be accessed if the supplier
36 fails to pay any judgment or claim within 60 days after final
37 judgment; and

38 3. Allow for civil and criminal litigation claims to be
39 made against the bond or other comparable security arrangement



40 for up to 1 year after the supplier's contract under the program
41 has ended with the agency or the state, the supplier's license
42 is no longer valid, or the program has ended, whichever occurs
43 last.

44 (4) ELIGIBLE IMPORTERS.—

45 (a) The following entities or persons may import
46 prescription drugs from a Canadian supplier under the program:

47 1. A wholesale distributor.

48 2. A pharmacy.

49 3. A pharmacist.

50 (b) An eligible importer must meet all of the following
51 requirements at the time of contract award and throughout the
52 contract term:

53 1. Register with the vendor before importing drugs into
54 this state under the program and be deemed in compliance with
55 all requirements, including any relevant provisions of the
56 Federal Act.

57 2. Submit evidence at the time of contract award and
58 throughout the contract term of a surety bond or other
59 comparable security arrangement from this state or any other
60 state in the United States in the minimum amount of \$1 million.
61 The surety bond or comparable security arrangement must include
62 the State of Florida as a beneficiary. In lieu of the surety
63 bond, the importer may provide a comparable security agreement,
64 such as an irrevocable letter of credit or a deposit into a
65 trust account or financial institution which includes the State
66 of Florida as a beneficiary, payable to the State of Florida.
67 The purposes of the bond or other security arrangement for the
68 program are to:



69 a. Ensure payment of any administrative penalties imposed
70 by the agency or any other state agency under the contract when
71 the importer fails to pay within 30 days after assessment;

72 b. Ensure that the importer meets contractual and statutory
73 obligations through use of a bond or other comparable security
74 arrangements to pay any other costs or fees incurred by the
75 agency, the state, or other entities acting on behalf of the
76 state if the importer fails to meet its contractual and
77 statutory obligations. If the importer is assessed a penalty
78 under the program and fails to pay within 30 days after that
79 assessment, the agency, the state, or an entity acting on behalf
80 of the state may file a claim for reimbursement against the bond
81 or other comparable security arrangement; and

82 c. Allow for claims to be made against the bond or other
83 comparable security arrangements for up to 1 year after the
84 importer's contract under the program has ended with the agency
85 or the state, the importer's license is no longer valid, or the
86 program has ended, whichever occurs last.

87
88 A surety bond or comparable document is required, regardless of
89 the type of bid or negotiation process the agency used or the
90 type of final contract or agreement executed for services.

91 (c) An eligible importer must submit evidence at the time
92 of contract award and throughout the contract term of a surety
93 bond or comparable security arrangement from this state or any
94 other state in the United States in the minimum amount of \$1
95 million. The agency shall reevaluate and adjust the amount of
96 the bond annually, based on program volume. The surety bond or
97 comparable security arrangement must include the State of



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98 Florida as a beneficiary. In lieu of the surety bond, the
99 importer may provide a comparable security agreement, such as an
100 irrevocable letter of credit or a deposit into a trust account
101 or financial institution which includes the State of Florida as
102 a beneficiary, payable to the State of Florida. The purposes of
103 the bond or other security arrangement for the program are to:

104 1. Ensure the importer's participation in any civil or
105 criminal legal action by the state, the agency, any other state
106 agency, or private individuals or entities against the importer
107 because of the importer's failure to perform under the contract,
108 including, but not limited to causes of action for personal
109 injury, negligence, and wrongful death;

110 2. Ensure payment by the importer through the use of a bond
111 or other comparable security arrangements of legal judgments and
112 claims that have been awarded to the agency, the state, other
113 entities acting on behalf of the state, individuals, or
114 organizations if the importer is assessed a final judgment or
115 other monetary penalty in a court of law for a civil or criminal
116 action under the program. The bond or comparable security
117 arrangement may be accessed if the importer fails to pay any
118 judgment or claim within 60 days after final judgment; and

119 3. Allow for civil and criminal litigation claims to be
120 made against the bond or other comparable security arrangements
121 for up to 1 year after the importer's contract under the program
122 has ended with the agency or the state, the importer's license
123 is no longer valid, or the program has ended, whichever occurs
124 last.

125 (5) IMPORTATION PROCESS.

126 (a) The agency shall contract with a vendor to provide



127 services under the program. The vendor shall submit evidence of
128 a surety bond with any bid or initial contract negotiation
129 documents and shall maintain documentation of evidence of such a
130 bond with the agency throughout the contract term. The surety
131 bond may be from this state or any other state in the United
132 States in the minimum amount of \$1 million. The surety bond or
133 comparable security arrangement must include the State of
134 Florida as a beneficiary. In lieu of the surety bond, the vendor
135 may provide a comparable security agreement, such as an
136 irrevocable letter of credit or a deposit into a trust account
137 or financial institution which includes the State of Florida as
138 a beneficiary, payable to the State of Florida. The purposes of
139 the bond or other security arrangement for the program are to:

140 1. Ensure payment of any administrative penalties imposed
141 by the agency or any other state agency under the contract when
142 the vendor fails to pay within 30 days after assessment;

143 2. Ensure that the vendor meets contractual and statutory
144 obligations through use of a surety bond or other comparable
145 security arrangements to pay any other costs or fees incurred by
146 the agency, the state, or other entities acting on behalf of the
147 state if the vendor fails to meet its contractual and statutory
148 obligations. If the vendor is assessed a penalty under the
149 program and fails to pay within 30 days after that assessment,
150 the agency, the state, or an entity acting on behalf of the
151 state may file a claim for reimbursement against the bond or
152 other comparable security arrangement; and

153 3. Allow for claims to be made against the bond or other
154 comparable security arrangements for up to 1 year after the
155 vendor's contract under the program has ended with the agency or



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156 the state or the program has ended, whichever occurs last.

157

158 A surety bond or comparable document is required, regardless of
159 the type of bid or negotiation process the agency used or the
160 type of final contract or agreement executed for services.

161 (b) The eligible vendor must submit evidence at the time of
162 contract award and throughout the contract term of a surety bond
163 or comparable security arrangement from this state or any other
164 state in the United States in the minimum amount of \$1 million.
165 The agency shall reevaluate and adjust the amount of the bond
166 annually, based on program volume. The surety bond or comparable
167 security arrangement must include the State of Florida as a
168 beneficiary. In lieu of the surety bond, the vendor may provide

169 a



104102

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/09/2019	.	
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	.	
	.	

Appropriations Subcommittee on Health and Human Services (Bean)
recommended the following:

Senate Amendment

Delete lines 321 - 339

and insert:

Canadian suppliers meet all of the requirements of the program,
while meeting or exceeding the federal and state track-and-trace
laws and regulations.

3. Contract with such eligible Canadian suppliers, or
facilitate contracts between eligible importers and Canadian
suppliers, to import drugs under the program.



104102

11 4. Maintain a list of all registered importers that
12 participate in the program.

13 5. Ensure compliance with Title II of the federal Drug
14 Quality and Security Act, Pub. L. No. 113-54, by all suppliers,
15 importers and other distributors, and participants in the
16 program.

17 6. Assist the agency in the preparation of the annual
18 report required by subsection (12) and timely provide any
19 information requested by the agency for the report.

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL: PCS/CS/SB 1712 (209464)

INTRODUCER: Appropriations Subcommittee on Health and Human Services; Health Policy Committee; and Senator Harrell

SUBJECT: Hospital Licensure

DATE: April 11, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Looke</u>	<u>Brown</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>McKnight</u>	<u>Kidd</u>	<u>AHS</u>	<u>Recommend: Fav/CS</u>
3.	_____	_____	<u>AP</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 1712 amends and repeals various sections of the Florida Statutes to eliminate the requirement that a new freestanding general hospital must obtain a certificate of need (CON) from the Agency for Health Care Administration (AHCA) prior to being licensed. The bill maintains the existing CON program for specialty hospitals and other facility types, such as nursing homes and hospice facilities, and for existing hospitals that wish to provide tertiary services, such as neonatal intensive care, comprehensive rehabilitation, and pediatric cardiac catheterization services.

The bill also establishes additional licensure requirements applicable to general hospitals licensed on or after July 1, 2019, without a CON, including that such hospitals must:

- Have at least 100 beds, and have intensive care, progressive care, and medical surgical beds;
- Have an onsite emergency department that operates 24 hours a day, seven days a week;¹
- Participate in the Medicaid and Medicare programs; and
- Provide certain amounts of charity care or equivalent donations to the AHCA's Grants and Donations Trust Fund. The bill establishes penalties for a general hospital that does not comply with charity care requirements.

¹ The bed requirements do not apply to long-term care hospitals, rural hospitals, and hospitals located in a medically underserved area. The requirement to have an emergency department does not apply to a long-term care hospital.

The bill requires a new general hospital licensure applicant to notify the AHCA prior to beginning construction and directs the AHCA to adopt rules to implement the new licensure requirements.

The bill increases penalties for existing hospitals that violate any conditions related to providing Medicaid services or charity care that were agreed to by the hospital when the hospital was issued a CON and requires that general hospitals comply with such conditions as part of licensure, regardless of the status of the hospital's CON.

Effective upon becoming law, the bill prohibits the AHCA from accepting any new applications for general hospital CONs. The AHCA is required to issue a CON to all current general hospital applicants whose CON has been approved by the AHCA, regardless of litigation, if the applicant will have intensive care beds, progressive care beds, medical/surgical beds, and an onsite emergency department that operates 24 hours a day, seven days a week. Also, the bill allows current general hospital CON applicants whose applications have been denied or whose status is pending to continue through the current CON process until a final outcome is reached.

The bill has an overall indeterminate fiscal impact. See Section V.

Except as otherwise specified, the bill takes effect on July 1, 2019.

II. Present Situation:

Hospital Licensure

Hospitals are licensed by the AHCA 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.² Hospitals must, at a minimum, make clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment, regularly available.³

A specialty hospital, in addition to providing the same services as general hospitals, provides other services, including:

- A range of medical services restricted to a defined age or gender group;
- A restricted range of services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical or psychiatric illnesses or disorders; or
- Intensive residential treatment programs for children and adolescents.⁴

Section 395.1041(2), F.S., requires the AHCA to maintain an inventory of hospitals with an emergency department. The inventory must list all services within the service capability of each

² Section 395.002(12), F.S.

³ Id.

⁴ Section 395.002(27), F.S.

hospital, and such services must appear on the face of the hospital's license. As of March 12, 2019, 217 of the 308 licensed hospitals in the state have an emergency department.⁵

Unless exempt, a hospital must obtain a CON prior to licensure. Facilities must meet initial licensing requirements by submitting a completed application and required documentation, and the satisfactory completion of a facility survey. The current license fee is \$1,565.13 or \$31.46 per bed, whichever is greater.⁶ The survey fee is \$400 or \$12 per bed, whichever is greater.⁷

Section 395.1055, F.S., requires the AHCA to adopt rules for hospitals. Separate standards may be provided for general and specialty hospitals.⁸ The rules for general and specialty hospitals 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.⁹

The minimum standards for hospital licensure are provided under Rule 59A-3, Florida Administrative Code (F.A.C.). The AHCA may perform inspections of hospitals, including:

- Inspections directed by the federal Centers for Medicare & Medicaid Services;
- Validation inspections;
- Life safety inspections;
- Licensure complaint investigations; and
- Emergency access complaint investigations.¹⁰

The AHCA must accept an inspection performed by an accrediting organization in lieu of its own periodic licensure inspection.¹¹

Florida's Certificate of Need Program

Overview

In Florida, a CON is a written statement issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service, including hospices. The Florida CON program has three levels of review: full,

⁵ Agency for Health Care Administration, Facility/Provider Search Results, Hospitals, *available at* <http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx> (reports generated on March 13, 2019).

⁶ Rule 59A-3.066(3), F.A.C.

⁷ Section 395.0161(3)(a), F.S.

⁸ Section 395.1055(2), F.S.

⁹ Section 395.1055(1), F.S.

¹⁰ Section 395.0161(1), F.S.

¹¹ Section 395.0161(2), F.S.

expedited, and exempt.¹² Unless a hospital project is exempt from the CON program, it must undergo a full comparative review. Expedited review is primarily targeted toward nursing home projects.

Florida's CON program has existed since July 1973. From 1974 through 1986, the specifics of the program were largely dictated by the federal National Health Planning and Resources Development Act of 1974 (Act), which established minimum requirements regarding the type of services subject to CON review, review procedures, and review criteria.¹³ Each state was required to have a CON program in compliance with the Act as a condition for obtaining federal funds for health programs. The Act was repealed in 1986.

Projects Subject to Full Review

Some hospital projects are required to undergo a full comparative CON review under the statute, including:

- New construction of general hospitals, long-term care hospitals, and freestanding specialty hospitals;
- Replacement of a hospital if the proposed project site is not located on the same site or within one mile of the existing health care facility;¹⁴
- Increasing the number of beds for comprehensive rehabilitation; and
- Establishing tertiary health services.¹⁵

Projects Subject to Expedited Review

Section 408.036(2), F.S., permits certain projects to undergo expedited CON review. Applicants for expedited review are not subject to the application deadlines associated with full comparative review and may submit an application at any time. Projects subject to an expedited review include the transfer of a CON and certain replacements, relocations, and new construction of nursing homes.¹⁶

Exemptions from Review

Section 408.036(3), F.S., provides many exemptions to CON review for certain hospital projects, including:

- Adding swing beds¹⁷ in a rural hospital, the total of which does not exceed one-half of its licensed beds.

¹² Section 408.036, F.S.

¹³ Pub. Law No. 93-641, 42 U.S.C. s. 300k et seq.

¹⁴ Section 395.6025, F.S., exempts rural hospitals from the requirement to obtain a CON for building a new hospital, or replacing a hospital, located in a county with a population between 15,000 and 18,000 and a population density of less than 30 persons per square mile as long as the new or replacement hospital is located within 10 miles of the current rural hospital.

¹⁵ Section 408.032(17), F.S., defines "tertiary health service" as a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service. Examples of such service include, but are not limited to, pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care units, comprehensive rehabilitation, and medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service. Pursuant to this section, the AHCA established a list of all tertiary health services in Rule 59C-1.002, F.A.C.

¹⁶ Section 408.036(2), F.S.

¹⁷ Section 395.602(2)(c), F.S., defines "swing bed" as a bed which can be used interchangeably as either a hospital, skilled nursing facility (SNF), or intermediate care facility (ICF) bed pursuant to 42 C.F.R. parts 405, 435, 440, 442, and 447.

- Converting licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital, as defined in s. 395.602, F.S., so long as the conversion of the beds does not involve the construction of new facilities.
- Adding hospital beds licensed under ch. 395, F.S., for comprehensive rehabilitation, the total of which may not exceed the greater of 10 total beds or 10 percent of the licensed capacity.
- Establishing a Level II neonatal intensive care unit (NICU) if the unit has at least 10 beds, and if the hospital had a minimum of 1,500 births during the previous 12 months.
- Establishing a Level III NICU if the unit has at least 15 beds, and if the hospital had a Level II NICU and a minimum of at least 3,500 births during the previous 12 months.
- Establishing a Level III NICU if the unit has at least five beds, and is a verified trauma center,¹⁸ and if the applicant has a Level II NICU.
- Establishing an adult open heart surgery program in a hospital located within the boundaries of a health service planning district, which:
 - Has experienced an annual net out-migration of at least 600 open heart surgery cases for three consecutive years; and
 - Has a population that exceeds the state average population per licensed and operational open-heart programs by at least 25 percent.
- For the addition of mental health services or beds if the applicant commits to providing services to Medicaid or charity care patients at a level equal to or greater than the district average.

Determination of Need, Application, and Review Processes

A CON is predicated on a determination of need. The future need for services and projects is known as the “fixed need pool,”¹⁹ which the AHCA publishes for each batching cycle. Rule 59C-1, F.A.C., provides need formulas to calculate the fixed need pool for certain services, including NICU services,²⁰ adult and child psychiatric services,²¹ adult substance abuse services,²² and comprehensive rehabilitation services.²³

Upon determining that a need exists, the AHCA accepts applications for CON based on batching cycles. A batching cycle is a means of grouping, for comparative review, of CON applications submitted for beds, services, or programs having a like CON need methodology or licensing category in the same planning horizon and the same applicable district or subdistrict.²⁴

The CON review process consists of four batching cycles each year, including two batching cycles each year for two project categories: hospital beds and facilities, and other beds and

¹⁸ Section 395.4001(15), F.S., defines “trauma center” as a hospital that has been verified by the Department of Health to be in substantial compliance with the requirements in s. 395.4025, F.S., and has been approved to operate as a Level I trauma center, Level II trauma center, or pediatric trauma center, or is designated as a Level II trauma center pursuant to s. 395.4025(15), F.S.

¹⁹ Rule 59C-1.002(19), F.A.C., defines “fixed need pool” as the identified numerical need, as published in the Florida Administrative Register, for new beds or services for the applicable planning horizon established by the AHCA in accordance with need methodologies which are in effect by rule at the time of publication of the fixed need pools for the applicable batching cycle.

²⁰ Rule 59C-1.042(3), F.A.C.

²¹ Rule 59C-1.040(4), F.A.C.

²² Rule 59C-1.041(4), F.A.C.

²³ Rule 59C-1.039(5), F.A.C.

²⁴ Rule 59C-1.002(5), F.A.C. Note: s. 408.032(5), F.S., establishes the 11 district service areas in Florida.

programs.²⁵ The “hospital beds and facilities” batching cycle includes applicants for new or expanded:

- Comprehensive medical rehabilitation beds;
- Adult psychiatric beds;
- Child and adolescent psychiatric beds;
- Adult substance abuse beds;
- NICU level II beds; and
- NICU level III beds.²⁶

The “other beds and programs” batching cycle includes:

- Nursing home beds;
- Hospice beds;
- Pediatric open heart surgery;
- Pediatric cardiac catheterization services; and
- Organ transplantation services.²⁷

Requests for an expedited review or exemption may be made at any time and are not subject to batching requirements.²⁸

At least 30 days prior to the application deadline for a batch cycle, an applicant must file a letter of intent with the AHCA.²⁹ A letter of intent must describe the proposal, specify the number of beds sought, and identify the services to be provided, and the location of the project.³⁰

Applications for CON review must be submitted by the specified deadline for the particular batch cycle.³¹ The AHCA must review the application within 15 days of the filing deadline and, if necessary, request additional information for an incomplete application.³² The applicant then has 21 days to complete the application or it is deemed withdrawn from consideration.³³

Within 60 days of receipt of the completed applications for that batch, the AHCA must issue a State Agency Action Report and Notice of Intent to grant a CON for a project in its entirety, to grant a CON for identifiable portions of a project, or to deny a CON for a project.³⁴ The AHCA must then publish the decision, within 14 days, in the Florida Administrative Register.³⁵ If no administrative hearing is requested within 21 days of the publication, the State Agency Action Report and the Notice of Intent become a final order of the AHCA.³⁶

²⁵ Rule 59C-1.008(1)(g), F.A.C.

²⁶ Rule 59C-1.008(1), F.A.C.

²⁷ Id.

²⁸ Section 408.036, F.S., and Rule 59C-1.004(1), F.A.C.

²⁹ Section 408.039(2)(a), F.S.

³⁰ Section 408.039(2)(c), F.S.

³¹ Rule 59C-1.008(1)(g), F.A.C.

³² Section 408.039(3)(a), F.S.

³³ Id.

³⁴ Section 408.039(4)(b), F.S.

³⁵ Section 408.039(4)(c), F.S.

³⁶ Section 408.039(4)(d), F.S.

In 2008, the Legislature significantly modified the application and review process for hospital CONs. The revisions included new and separate requirements for general hospital CONs, including:

- Revised contents for CON applications;
- Revised criteria which the AHCA must consider when reviewing a CON application;
- Prohibiting an applicant with a current CON application from submitting a letter of intent for to file another application;
- Requiring the AHCA to hold a public hearing upon the request of any applicant or substantially affected person;
- Limiting the period of a continuance for any CON related hearings to four months; and
- Requiring a party appealing a final order for a CON to post a \$1 million bond which is forfeited for attorney's fees and costs if the appellant loses.³⁷

Fees

An applicant for CON review must submit a fee to the AHCA at the time of application submission. The minimum CON application filing fee is \$10,000.³⁸ In addition to the base fee, an applicant must pay a fee of 1.5 percent of each dollar of the proposed expenditure; however, the total fee may not exceed \$50,000.³⁹ A request for a CON exemption must be accompanied by a \$250 fee payable to the AHCA.⁴⁰

Litigation

Florida law authorizes competitors to challenge CON decisions. A Notice of Intent to Award may be challenged by a competing applicant in the same review cycle or an existing provider in the same district by submitting evidence that they will be substantially affected if the CON is awarded. For general hospital CONs, only competing applicants and existing hospitals that submitted a written statement of opposition may initiate or intervene in an administrative hearing.⁴¹ A challenge to a CON decision is heard by an administrative law judge under the Division of Administrative Hearings.⁴² A recommended order must be issued by the administrative law judge within 30 days after the receipt of the proposed recommended order or the deadline for submission for a proposed recommended order, whichever occurs first. The AHCA must render a Final Order within 45 days of receiving the recommended order of the administrative law judge.⁴³ A party to an administrative hearing may challenge a Final Order to the District Court of Appeals for judicial review within 30 days of receipt of a Final Order. Parties challenging a general hospital CON must post a \$1 million bond which will be used to pay attorney fees and costs if the appeal is lost.⁴⁴

³⁷ Chapter 2008-29, L.O.F.

³⁸ Section 408.038, F.S.

³⁹ Id.

⁴⁰ Section 408.036(4), F.S., and Rule 59C-1.005(2)(g), F.A.C.

⁴¹ Section 408.039(5)(c), F.S.

⁴² Id.

⁴³ Section 408.039(5)(e), F.S.

⁴⁴ Section 408.039(6), F.S.

Nationwide

Thirty-five states have some form of CON program while 12 states do not have CON requirements for any type of health care facility or service.⁴⁵ The types of facilities covered and the requirements of each CON program vary from state to state.

Purpose and Effect of Certificate of Need

Cost Containment

Certificate of need programs are designed to restrain health care costs and provide for directed, measured planning for new services and facilities. Such programs were originally established to regulate the addition of new facilities, or new beds in hospitals and nursing homes, for example, and to prevent overbuying of expensive equipment, under the economic theory that excess capacity directly results in health care price inflation. When a hospital or health care service provider cannot meet its obligations, fixed costs must be met through higher charges for the beds that are used or for the number of patients using the service.⁴⁶

In addition to cost containment, CON regulation is intended to create a “quid pro quo” in which profitability of covered medical services is increased by restricting competition and, in return, medical providers cross-subsidize specified amounts of indigent care, or medical services to the poor that are unprofitable to the provider.⁴⁷ Some states address indigent care to underinsured or uninsured patients and the provision of care for the Medicaid program in their CON process.⁴⁸ In Florida applicants may apply conditions to increase their chances of being issued a CON, including by committing to providing services to Medicaid and charity patients at certain levels.

Some studies have found that CON programs do not meet the goal of limiting costs in health care. One study found that “at best, CON has had a modest cost-containing influence on hospital and other acute care services.”⁴⁹ Additionally, a literature review conducted in 2004 by the Federal Trade Commission and the Department of Justice concluded that “[O]n balance, CON programs are not successful in containing health care costs, and that they pose serious anticompetitive risks that usually outweigh their purported economic benefits. . . . [i]ndeed, there is considerable evidence that CON programs can actually increase prices by fostering

⁴⁵ National Conference of State Legislators, *Certificate of Need State Laws* (February 28, 2019), available at <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last viewed April 3, 2019).

⁴⁶ *Id.*

⁴⁷ Thomas Stratmann and Jacob Russ, *Do Certificate-of-Need Laws Increase Indigent Care?* Mercatus Center at George Mason University (July 2014) p. 2, available at <https://www.mercatus.org/publication/do-certificate-need-laws-increase-indigent-care> (last viewed April 3, 2019).

⁴⁸ For example, Delaware (Del. Code Ann. tit. 16 s. 9303), Georgia (Ga. Code Ann. §111-2-2.03) (providing an exemption from CON with a certain percentage of Medicaid and charity care), Rhode Island (216-RICR-40-10-22.14) (requiring findings of indigent and Medicaid care that will be offered), and Virginia (12 Va. Admin. Code §5-230-40 and §5-220-270) require CON applicants to comply with such provisions.

⁴⁹ Christopher J. Conover and Frank A. Sloan, *Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?* *Journal of Health Politics, Policy, and Law*: Vol. 23, No. 3, June 1998, p. 478, available at <https://read.dukeupress.edu/jhpl/article-abstract/23/3/455/82081/Does-Removing-Certificate-of-Need-Regulations-Lead> (last viewed April 3, 2019).

anticompetitive barriers to entry. Other means of cost control appear to be more effective and pose less significant competitive concerns.”⁵⁰

Indigent Care

Studies are split, however, on whether CON regulation has improved access to care for the underinsured and uninsured. Some studies have found that access to care for the underserved populations has increased in states with CON programs,⁵¹ while another has found only insignificant evidence to support such a conclusion.⁵² A study of the Illinois CON program, while not opposing the removal of CON in Illinois, was concerned about the effect of eliminating CON on the financial health of safety-net hospitals, stating that “for some of [those hospitals]...new pressures could lead to failures [which] could force the remaining providers to serve an ever-larger number of less profitable patients, which could lead to a cascade of failures.”⁵³

Medically Underserved Areas

A medically underserved area (MUA) is a geographic area with a lack of access to primary care services. MUAs have a shortage of primary care health services for residents within a geographic area such as:

- A whole county;
- A group of neighboring counties;
- A group of urban census tracts; or
- A group of county or civil divisions.⁵⁴

MUAs are designated by the Health Resources and Services Administration (HRSA) within the U.S. Department of Health and Human Services. Eligibility for MUA designation depends on the Index of Medical Underservice (IMU) calculated for the area proposed for designation. Under the established criteria, an area or population with an IMU of 62.0 or below qualifies for designation as an MUA.⁵⁵

The IMU scale is from 0 to 100, where 0 represents completely underserved and 100 represents best served or least underserved. The HRSA calculates the IMU by assigning a weighted value to an area or population’s performance on four demographic and health indicators, then adding the weighted values together. The HRSA uses the following indicators:

- Provider per 1,000 population ratio (28.7 points max);

⁵⁰ Improving Health Care: *A Dose of Competition*: A Report by the Federal Trade Commission and the U.S. Department of Justice (July 23, 2004) p. 22, available at <https://www.ftc.gov/reports/improving-health-care-dose-competition-report-federal-trade-commission-department-justice> (last viewed April 3, 2019). Note: this report is based on 27 days of joint hearings, an FTC-sponsored workshop, and independent research (see p. 1).

⁵¹ Tracy Yee, Lucy B. Stark, et al, *Health Care Certificate-of-Need Laws: Policy or Politics?*, Research Brief, National Institute for Health Care Reform, No. 4, (May 2011), available at <http://nihcr.org/analysis/improving-care-delivery/prevention-improving-health/con-laws/> (last viewed April 3, 2019).

⁵² *Supra* note 47.

⁵³ An Evaluation of Illinois’ Certificate of Need Program, The Lewin Group, p. 31 (February 22, 2007) available at <http://cgfa.ilga.gov/Upload/LewinGroupEvalCertOfNeedPresentation.pdf> (last viewed April 3, 2019).

⁵⁴ See <https://bhw.hrsa.gov/shortage-designation/muap> (last viewed April 3, 2019).

⁵⁵ See <https://bhw.hrsa.gov/shortage-designation/muap-process> (last viewed April 3, 2019).

- Percent of population at 100 percent of the Federal Poverty Level (25.1 points max);
- Percent of population age 65 and over (20.2 points max); and
- Infant Mortality Rate (26 points max).⁵⁶

Currently, there are 70 MUAs designated in Florida. Five of those MUAs have IMU scores of 0 while the other 65 have scores ranging from 43.3 to 61.5.⁵⁷

III. Effect of Proposed Changes:

The bill amends multiple statutes related to hospital licensure and CON.

Section 1 amends s. 395.003, F.S., to apply new licensure criteria to general hospitals that are licensed on or after July 1, 2019, without a CON issued by the AHCA and that are not replacing a currently operating general hospital located within one mile of the newly licensed hospital. Each such hospital must:

- Notify the AHCA of the intention to establish a new hospital prior to beginning construction. The notice must include the location, the number of beds and types of beds to be licensed, and the services the hospital will offer;
- Have at least 100 beds and have intensive care, progressive care, and medical/surgical beds. This requirement does not apply to long-term care hospitals, rural hospitals, or hospitals located in a MUA.
- Have an onsite emergency department that operates 24 hours a day, seven days a week. This requirement does not apply to long-term care hospitals.
- Participate in the Florida Medicaid and the Medicare programs;
- Provide charity care, as defined in s. 409.911(1), F.S., in an amount equal to or greater than the district average;
 - If a hospital is located in an MUA, the amount of charity care that the hospital must provide is reduced so that it is equal in percentage to that area's IMU;
 - In lieu of providing the required charity care, the hospital may donate to the AHCA's Grants and Donations Trust Fund an amount determined by the AHCA to be functionally equivalent to the amount of charity care required;
- Annually report compliance with these requirements to the AHCA. If a hospital does not report compliance or fails to comply with these requirements, the AHCA must assess a fine equal to one percent of the hospital's net revenue for each 0.5 percent of the required charity care the hospital did not provide or donate.

The section also grants the AHCA rulemaking authority to implement the new licensure provisions and strikes obsolete language related to off-site hospital emergency departments and makes cross-reference changes.

Section 2 repeals section 395.6025, F.S., relating to rural hospital replacement facilities.

Section 3 amends section 408.032, F.S., to update the definition of a health care facility and remove the definition of a long-term care facility.

⁵⁶ Id.

⁵⁷ See <https://data.hrsa.gov/tools/shortage-area/mua-find>. (last viewed April 3, 2019).

Section 4 amends section 408.034, F.S., to authorize the AHCA to issue a license to a general hospital that has not been issued a CON if the hospital meets the criteria established in s. 395.003, F.S.

Section 5 amends section 408.035, F.S., to remove provisions related to the AHCA's consideration and review of CONs for general hospitals.

Section 6 amends s. 408.036, F.S., to provide an exception for the construction or establishment of a general hospital and the conversion to a general hospital from CON review requirements.

Section 7 and 8 amend s. 408.037 and s. 408.039, F.S., to delete provisions relating to CON applications for general hospitals.

Section 9 amends s. 408.040, F.S., to require the AHCA to assess a fine of \$2,500 per day if a health care facility fails to comply with a condition of its CON related to providing charity care or providing care under the Florida Medicaid program. Currently, the AHCA is authorized to assess a fine of up to \$1,000 per day. The bill also requires general hospitals initially licensed with a CON to comply with such conditions as part of licensure, regardless of the status of the hospital's CON.

Section 10 amends s. 408.043, F.S., to remove provisions relating to a CON for osteopathic acute care hospitals.

Section 11 creates a new unnumbered section of law to prohibit the AHCA from accepting any new applications for general hospital CONS. The AHCA is required to issue a CON to all current general hospital applicants whose CON has been approved by the AHCA, regardless of litigation, if the applicant will have intensive care beds, progressive care beds, medical/surgical beds, and an onsite emergency department that operates 24 hours a day, seven days a week. Also, the bill allows current general hospital CON applicants whose applications have been denied or whose status is pending to continue through the current CON process until a final outcome is reached.

Section 12 provides an effective date of July 1, 2019, except as otherwise specified.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

PCS/CS/SB 1712 may have an indeterminate negative fiscal impact on existing hospitals if additional hospitals are licensed in the same area and if such hospital projects would not have been licensed under current law.

This bill may have an indeterminate positive fiscal impact on individuals who receive medical services in a hospital if the individual is paying for the services directly, or if there is an increase in the number of hospitals that are licensed under the provisions of the bill and such increase results in a decrease in the amount that hospital charge for such services.

The bill may have an indeterminate positive fiscal impact on individuals who receive the benefits of charity care that new general hospitals will be required to offer.

C. Government Sector Impact:

The bill establishes an administrative fine for newly licensed hospitals on or after July 1, 2019, without a CON, of one percent of the hospital's net revenue for each 0.5 percent of the required charity care the hospital did not provide or donate. The bill also increases the maximum administrative fine the AHCA may assess from \$1,000 to \$2,500 per day for each instance of noncompliance for facilities subject to CON that fail to comply with a condition.

This bill may have an indeterminate fiscal impact on the AHCA due to removing CON application fees (as much as \$50,000 per new hospital).⁵⁸

However, should there be an increase in new hospital licensures, there will also be an increase in hospital licensure fees. Further, revenues will increase for those facilities required to contribute to the Grants and Donations Trust Fund. Fine revenues may also increase due to the new fine authority established in the bill and the increase in fine amounts.

⁵⁸ Hospital CON application fees were \$703,120 in CY 2018. See AHCA, *Senate Bill 1712 Analysis* (March 5, 2019) (on file with Senate Committee on Health Policy).

The bill may also have an indeterminate fiscal impact on the AHCA by potentially increasing the number of hospitals the AHCA will be required to regulate. The workload in the Hospital and Outpatient Services Unit, responsible for licensing, registering, and regulating hospitals and various other outpatient and health care service facilities, could increase depending on licensure growth and other associated duties of the bill. The AHCA also anticipates an increase in workload for the Office of the General Counsel due to the increase in sanctioning ability on condition compliance. Another area that may also experience increased workload includes the Office of Plans and Construction, charged with reviewing and approving facilities' plans and specifications and surveying construction. The AHCA plans to shift CON staff to assist with the new tasks in the bill and help manage potential program growth.

The bill requires hospitals to submit financial data and all required attachments and certifications to the AHCA Financial Analysis Unit's web-based platform, the Florida Hospital Uniform Reporting System (FHURS). According to the AHCA, if utilizing the FHURS data is insufficient due to the time delay, a new reporting system will need to be developed. Options range from a manual form hospitals will be required to fill out and submit to the AHCA to a new online reporting system. The AHCA estimated cost ranges from \$2,000 to \$3,000 for updates to rules, forms, and basic data storage, to \$150,000 for an online reporting system.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.003, 408.032, 408.034, 408.035, 408.036, 408.037, 408.039, 408.040, and 408.043.

This bill repeals section 395.6025 of the Florida Statutes.

This bill creates one non-statutory section of Florida law.

IX. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

Recommended CS/CS by Appropriations Subcommittee on Health and Human Services on April 9, 2019:

The committee substitute provides an exception for conversion to a general hospital from CON review requirements if, once converted, the hospital meets the licensure

requirements established in s. 395.003(8), F.S. The exception previously applied only to conversions of a specialty hospital to a general hospital.

CS by Health Policy on April 1, 2019.

The CS:

- Narrows the repeal of CON to the construction of new general hospitals, rather than for all hospitals.
- Establishes additional licensure requirements applicable to new general hospitals licensed after July 1, 2019, without a CON, including that each such hospital:
 - Must have at least 100 beds and have intensive care, progressive care, and medical surgical beds. This requirement does not apply to rural hospitals, long-term care hospitals, and hospitals established in a MUA;
 - Must have an onsite emergency department that operates 24 hours a day, seven days a week. This requirement does not apply to long-term care hospitals; and
 - Must notify the AHCA before beginning construction.
- Requires each such new hospital to participate in the Medicaid and Medicare programs.
- Eliminates the definition of “charity care” established in the bill and instead refers to the definition of “charity care” as established for the disproportionate share program in s. 409.911(1), F.S.
- Grants the AHCA rulemaking authority to implement the new licensure requirements.
- Specifies that a currently licensed general hospital that was issued a CON with conditions related to providing charity care or providing care under the Florida Medicaid program must continue to meet those conditions as part of its licensure, regardless of the status of the hospital’s CON.
- Creates a new unnumbered section of Florida law to:
 - Prohibit the AHCA from accepting any new applications for general hospital CONs;
 - Require the AHCA to issue a CON to all current general hospital applicants whose CON has been approved by the AHCA, regardless of litigation, if the applicant will have intensive care beds, progressive care beds, medical/surgical beds, and an onsite emergency department that operates 24 hours a day, seven days a week; and
 - Allow current CON applicants whose applications have been denied or whose status is pending to continue through the current CON process until a final outcome is reached.

B. Amendments:

None.

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19

SB1712

Meeting Date

Bill Number (if applicable)

Topic Hospital Licensure

Amendment Barcode (if applicable)

Name Logan Padgett

Job Title Director of Communications and Public Affairs

Address 100 N Duval Street

Phone 850-386-3131

Street

Tallahassee

FL

32301

Email lpadgett@jamesmadison.org

City

State

Zip

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing The James Madison Institute

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

9 April 2019
Meeting Date

SB 1712
Bill Number (if applicable)

Topic Hospital Licensure Amendment Barcode (if applicable)

Name Diego Echeverri "Dee-yay-goh Eteh-uh-vay-ree"

Job Title Director of Coalitions

Address 200 West College Ave Phone 813-767-2084

Tallahassee FL Email decheverri@cv4a.org
City State Zip

Speaking: For Against Information Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Concerned Veterans For America

Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19

Meeting Date

1712

Bill Number (if applicable)

Topic Hospital Licensure by Harrell

Amendment Barcode (if applicable)

Name Monica Rodriguez

Job Title Director of Government Affairs

Address 201 E Park Ave 5th Floor Phone 850-577-0444

Street

Tallahassee

FL

32301

Email monica@ballardfl.com

City

State

Zip

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing UF Health Shands

Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19
Meeting Date

1712
Bill Number (if applicable)

Topic Hospital licensure

Amendment Barcode (if applicable)

Name Nathan Ray

Job Title Associate Vice President

Address 7125 Sleepy Hollow Circle

Phone 850 766-0793

Tallahassee FL 32312
Street City State Zip

Email _____

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Jackson Health Systems

Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/2019
Meeting Date

1712
Bill Number (if applicable)

Topic HOSPITAL LICENSURE

Amendment Barcode (if applicable)

Name CHRISTIAN CANARA

Job Title _____

Address 901 N. GLEBE RD #900
Street
ARLINGTON, VA 22203
City State Zip

Phone 305-721-1600

Email CHRISTIAN@CHAMBERCONSULTANTS.COM

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing INSTITUTE FOR JUSTICE

Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19
Meeting Date

SB 1712
Bill Number (if applicable)

Topic Hospital Licensure

Amendment Barcode (if applicable)

Name Dr. Rick Templin

Job Title _____

Address 135 S. Monroe
Street
Tallahassee FL 32301
City State Zip

Phone 850-224-0926

Email _____

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Florida AFL-CIO

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/9/19

Meeting Date

1712

Bill Number (if applicable)

Topic Hospital Licensure

Amendment Barcode (if applicable)

Name Phillip Suderman

Job Title Policy Director

Address _____
Street

Phone _____

City

State

Zip

Email _____

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Americans for Prosperity

Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

By the Committee on Health Policy; and Senator Harrell

588-03679-19

20191712c1

1 A bill to be entitled
 2 An act relating to hospital licensure; amending s.
 3 395.003, F.S.; deleting an obsolete provision;
 4 providing applicability; requiring certain hospitals
 5 licensed after a specified date to submit a notice to
 6 the Agency for Health Care Administration which
 7 contains specified information before filing for
 8 approval of plans and specifications to establish a
 9 new general hospital; prohibiting the agency from
 10 licensing a new general hospital unless certain
 11 criteria are met; requiring certain hospitals to
 12 participate in the Medicaid program and the Medicare
 13 program and to provide a certain amount of charity
 14 care; defining the terms "charity care" and
 15 "district"; providing a separate calculation of
 16 required charity care for such hospitals located in a
 17 medically underserved area; authorizing such hospitals
 18 to provide a certain donation the agency's Grants and
 19 Donations Trust Fund in lieu of providing the required
 20 charity care; requiring such hospitals to annually
 21 report compliance to the agency; requiring the agency
 22 to impose a specified administrative fine for
 23 noncompliance; requiring the agency to adopt rules;
 24 repealing s. 395.6025, F.S., relating to rural
 25 hospital replacement facilities; amending s. 408.032,
 26 F.S.; revising the definition of the term "health care
 27 facility" to eliminate a reference to long-term care
 28 hospitals; deleting the definition of the term "long-
 29 term care hospital"; amending s. 408.034; authoring

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CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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30 the agency to issue a license to a general hospital
 31 that has not been issued a certificate of need under
 32 certain circumstances; amending s. 408.035, F.S.;
 33 deleting provisions related to the agency's
 34 consideration and review of certificates of need for
 35 general hospitals; amending s. 408.036, F.S.;
 36 providing an exception for the construction or
 37 establishment of a general hospital and the conversion
 38 of a specialty hospital to a general hospital from
 39 certificate of need review requirements; amending ss.
 40 408.037 and 408.039, F.S.; deleting provisions
 41 relating to certificate of need applications for
 42 general hospitals; amending s. 408.040, F.S.;
 43 requiring the agency to assess a specified
 44 administrative fine against the holder of a
 45 certificate of need or the holder of an exemption
 46 which fails to comply with specified conditions;
 47 requiring a general hospital that was issued a
 48 certificate of need with certain conditions to
 49 continue to meet those conditions to maintain
 50 licensure; amending s. 408.043, F.S.; deleting
 51 provisions relating to certificates of need for
 52 osteopathic acute care hospitals; prohibiting the
 53 agency from initiating a review cycle or from
 54 accepting letters of intent or applications for the
 55 issuance of certificate of need for the new
 56 construction or the establishment of a freestanding
 57 hospital; requiring the agency to issue such a
 58 certificate of need to certain applicants, regardless

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59 of litigation status; providing applicability;
60 providing effective dates.

61
62 Be It Enacted by the Legislature of the State of Florida:

63
64 Section 1. Present subsections (8), (9), and (10) of
65 section 395.003, Florida Statutes, are redesignated as
66 subsections (9), (10), and (11), respectively, paragraph (c) of
67 subsection (1) and present subsections (9) and (10) of that
68 section are amended, and a new subsection (8) is added to that
69 section, to read:

70 395.003 Licensure; denial, suspension, and revocation.—

71 (1)

72 ~~(e) Until July 1, 2006, additional emergency departments~~
73 ~~located off the premises of licensed hospitals may not be~~
74 ~~authorized by the agency.~~

75 (8) Applicable only to a general hospital that is, or will
76 be, newly licensed on or after July 1, 2019; that does not hold
77 a certificate of need issued by the agency; and that is not
78 replacing a currently operating general hospital located within
79 1 mile of the newly licensed hospital:

80 (a) When proposing a new general hospital project subject
81 to this subsection and before filing for approval of plans and
82 specifications under s. 395.0163, each prospective applicant for
83 licensure must submit a notice to the agency of its intent to
84 establish a newly licensed hospital which includes the location
85 for the proposed hospital, the number and types of beds to be
86 licensed, and the services that the hospital will offer.

87 (b) Other than a long-term care hospital, the agency may

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88 not license a new general hospital subject to this subsection
89 unless:

90 1. The hospital has at least 100 beds and has intensive
91 care, progressive care, and medical-surgical beds. This
92 requirement does not apply if the hospital is a rural hospital,
93 as defined in s. 395.602, or is located in a medically
94 underserved area; and

95 2. The hospital has an onsite emergency department that
96 will operate 24 hours per day, 7 days per week.

97 (c) Each such hospital must participate in the state
98 Medicaid program and the Medicare program.

99 (d) Except as provided in paragraph (e), each such hospital
100 must provide charity care in an amount equal to or greater than
101 the district average for hospitals in the applicable district.
102 The agency shall adopt by rule a method for calculating the
103 district average for charity care for each district. For
104 purposes of this subsection, the term "charity care" has the
105 same meaning as in s. 409.911(1) and the term "district" has the
106 same meaning as in s. 408.032.

107 (e) If such a hospital is located in a medically
108 underserved area, the amount of charity care required to be
109 provided by the hospital under paragraph (d) is equivalent in
110 percentage to the medically underserved area's Index of Medical
111 Underservice score as calculated by the federal Health Resources
112 and Services Administration within the Department of Health and
113 Human Services.

114 (f) In lieu of providing charity care under paragraph (d)
115 or paragraph (e), each such hospital may donate an amount
116 determined by the agency to be functionally equivalent to the

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117 amounts required under those paragraphs to the agency's Grants
 118 and Donations Trust Fund.

119 (g) Each such hospital shall annually report to the agency
 120 its compliance with paragraphs (c)-(f). Failure to report
 121 compliance constitutes noncompliance. The agency shall assess an
 122 administrative fine on a hospital that fails to comply with this
 123 subsection in the amount of 1 percent of its net revenue for
 124 each 0.5 percent of the required amount of charity care not
 125 provided pursuant to paragraph (d) or paragraph (e) or the
 126 required amount as determined by the agency pursuant to
 127 paragraph (f).

128 (h) The agency shall adopt rules to implement this
 129 subsection.

130 (10)(9) A hospital licensed as of June 1, 2004, is shall be
 131 exempt from subsection (9) (8) as long as the hospital maintains
 132 the same ownership, facility street address, and range of
 133 services that were in existence on June 1, 2004. Any transfer of
 134 beds, or other agreements that result in the establishment of a
 135 hospital or hospital services within the intent of this section,
 136 shall be subject to subsection (9) (8). Unless the hospital is
 137 otherwise exempt under subsection (9) (8), the agency shall deny
 138 or revoke the license of a hospital that violates any of the
 139 criteria set forth in that subsection.

140 (11)(10) The agency may adopt rules implementing the
 141 licensure requirements set forth in subsection (9) (8). Within
 142 14 days after rendering its decision on a license application or
 143 revocation, the agency shall publish its proposed decision in
 144 the Florida Administrative Register. Within 21 days after
 145 publication of the agency's decision, any authorized person may

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146 file a request for an administrative hearing. In administrative
 147 proceedings challenging the approval, denial, or revocation of a
 148 license pursuant to subsection (9) ~~(8)~~, the hearing must be
 149 based on the facts and law existing at the time of the agency's
 150 proposed agency action. Existing hospitals may initiate or
 151 intervene in an administrative hearing to approve, deny, or
 152 revoke licensure under subsection (9) ~~(8)~~ based upon a showing
 153 that an established program will be substantially affected by
 154 the issuance or renewal of a license to a hospital within the
 155 same district or service area.

156 Section 2. Section 395.6025, Florida Statutes, is repealed.

157 Section 3. Subsections (8) and (13) of section 408.032,
 158 Florida Statutes, are amended to read:

159 408.032 Definitions relating to Health Facility and
 160 Services Development Act.—As used in ss. 408.031-408.045, the
 161 term:

162 (8) "Health care facility" means a hospital, ~~long-term care~~
 163 ~~hospital~~, skilled nursing facility, hospice, or intermediate
 164 care facility for the developmentally disabled. A facility
 165 relying solely on spiritual means through prayer for healing is
 166 not included as a health care facility.

167 ~~(13) "Long-term care hospital" means a hospital licensed~~
 168 ~~under chapter 395 which meets the requirements of 42 C.F.R. s.~~
 169 ~~412.23(e) and seeks exclusion from the acute care Medicare~~
 170 ~~prospective payment system for inpatient hospital services.~~

171 Section 4. Subsection (2) of section 408.034, Florida
 172 Statutes, is amended to read:

173 408.034 Duties and responsibilities of agency; rules.—

174 (2) In the exercise of its authority to issue licenses to

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 175 health care facilities and health service providers, as provided
 176 under chapters 393 and 395 and parts II, IV, and VIII of chapter
 177 400, the agency may not issue a license to any health care
 178 facility or health service provider that fails to receive a
 179 certificate of need or an exemption for the licensed facility or
 180 service, except that the agency may issue a license to a general
 181 hospital that has not been issued a certificate of need if that
 182 hospital meets the criteria established in s. 395.003(8).

183 Section 5. Section 408.035, Florida Statutes, is amended to
 184 read:

185 408.035 Review criteria.—

186 ~~(1)~~ The agency shall determine the reviewability of
 187 applications and shall review applications for certificate-of-
 188 need determinations for health care facilities and health
 189 services in context with the following criteria, ~~except for~~
 190 ~~general hospitals as defined in s. 395.002:~~

191 (1)(a) The need for the health care facilities and health
 192 services being proposed.

193 (2)(b) The availability, quality of care, accessibility,
 194 and extent of utilization of existing health care facilities and
 195 health services in the service district of the applicant.

196 (3)(e) The ability of the applicant to provide quality of
 197 care and the applicant's record of providing quality of care.

198 (4)(d) The availability of resources, including health
 199 personnel, management personnel, and funds for capital and
 200 operating expenditures, for project accomplishment and
 201 operation.

202 (5)(e) The extent to which the proposed services will
 203 enhance access to health care for residents of the service

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 204 district.

205 ~~(6)(f)~~ The immediate and long-term financial feasibility of
 206 the proposal.

207 ~~(7)(g)~~ The extent to which the proposal will foster
 208 competition that promotes quality and cost-effectiveness.

209 ~~(8)(h)~~ The costs and methods of the proposed construction,
 210 including the costs and methods of energy provision and the
 211 availability of alternative, less costly, or more effective
 212 methods of construction.

213 ~~(9)(i)~~ The applicant's past and proposed provision of
 214 health care services to Medicaid patients and the medically
 215 indigent.

216 (10)(j) The applicant's designation as a Gold Seal Program
 217 nursing facility pursuant to s. 400.235, when the applicant is
 218 requesting additional nursing home beds at that facility.

219 ~~(2) For a general hospital, the agency shall consider only~~
 220 ~~the criteria specified in paragraph (1)(a), paragraph (1)(b),~~
 221 ~~except for quality of care in paragraph (1)(b), and paragraphs~~
 222 ~~(1)(e), (g), and (i).~~

223 Section 6. Paragraphs (b) and (c) of subsection (1) of
 224 section 408.036, Florida Statutes, are amended to read:

225 408.036 Projects subject to review; exemptions.—

226 (1) APPLICABILITY.—Unless exempt under subsection (3), all
 227 health-care-related projects, as described in paragraphs (a)-
 228 (f), are subject to review and must file an application for a
 229 certificate of need with the agency. The agency is exclusively
 230 responsible for determining whether a health-care-related
 231 project is subject to review under ss. 408.031-408.045.

232 (b) The new construction or establishment of additional

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233 health care facilities, except for the construction of or
 234 establishment of a general hospital or including a replacement
 235 health care facility when the proposed project site is ~~not~~
 236 located on the same site as or within 1 mile of the existing
 237 health care facility~~;~~ if the number of beds in each licensed bed
 238 category will not increase.

239 (c) The conversion from one type of health care facility to
 240 another, including the conversion from a general hospital or a
 241 specialty hospital, ~~or a long-term care hospital~~ except that the
 242 conversion of a specialty hospital to a general hospital is not
 243 subject to review if, once converted, the hospital meets the
 244 licensure criteria in s. 395.003(8).

245 Section 7. Section 408.037, Florida Statutes, is amended to
 246 read:

247 408.037 Application content.—

248 (1) ~~Except as provided in subsection (2) for a general~~
 249 ~~hospital,~~ An application for a certificate of need must contain:

250 (a) A detailed description of the proposed project and
 251 statement of its purpose and need in relation to the district
 252 health plan.

253 (b) A statement of the financial resources needed by and
 254 available to the applicant to accomplish the proposed project.
 255 This statement must include:

256 1. A complete listing of all capital projects, including
 257 new health facility development projects and health facility
 258 acquisitions applied for, pending, approved, or underway in any
 259 state at the time of application, regardless of whether or not
 260 that state has a certificate-of-need program or a capital
 261 expenditure review program pursuant to s. 1122 of the Social

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262 Security Act. The agency may, by rule, require less-detailed
 263 information from major health care providers. This listing must
 264 include the applicant's actual or proposed financial commitment
 265 to those projects and an assessment of their impact on the
 266 applicant's ability to provide the proposed project.

267 2. A detailed listing of the needed capital expenditures,
 268 including sources of funds.

269 3. A detailed financial projection, including a statement
 270 of the projected revenue and expenses for the first 2 years of
 271 operation after completion of the proposed project. This
 272 statement must include a detailed evaluation of the impact of
 273 the proposed project on the cost of other services provided by
 274 the applicant.

275 (c) An audited financial statement of the applicant or the
 276 applicant's parent corporation if audited financial statements
 277 of the applicant do not exist. In an application submitted by an
 278 existing health care facility, health maintenance organization,
 279 or hospice, financial condition documentation must include, but
 280 need not be limited to, a balance sheet and a profit-and-loss
 281 statement of the 2 previous fiscal years' operation.

282 ~~(2) An application for a certificate of need for a general~~
 283 ~~hospital must contain a detailed description of the proposed~~
 284 ~~general hospital project and a statement of its purpose and the~~
 285 ~~needs it will meet. The proposed project's location, as well as~~
 286 ~~its primary and secondary service areas, must be identified by~~
 287 ~~zip code. Primary service area is defined as the zip codes from~~
 288 ~~which the applicant projects that it will draw 75 percent of its~~
 289 ~~discharges. Secondary service area is defined as the zip codes~~
 290 ~~from which the applicant projects that it will draw its~~

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291 remaining discharges. If, subsequent to issuance of a final
 292 order approving the certificate of need, the proposed location
 293 of the general hospital changes or the primary service area
 294 materially changes, the agency shall revoke the certificate of
 295 need. However, if the agency determines that such changes are
 296 deemed to enhance access to hospital services in the service
 297 district, the agency may permit such changes to occur. A party
 298 participating in the administrative hearing regarding the
 299 issuance of the certificate of need for a general hospital has
 300 standing to participate in any subsequent proceeding regarding
 301 the revocation of the certificate of need for a hospital for
 302 which the location has changed or for which the primary service
 303 area has materially changed. In addition, the application for
 304 the certificate of need for a general hospital must include a
 305 statement of intent that, if approved by final order of the
 306 agency, the applicant shall within 120 days after issuance of
 307 the final order or, if there is an appeal of the final order,
 308 within 120 days after the issuance of the court's mandate on
 309 appeal, furnish satisfactory proof of the applicant's financial
 310 ability to operate. The agency shall establish documentation
 311 requirements, to be completed by each applicant, which show
 312 anticipated provider revenues and expenditures, the basis for
 313 financing the anticipated cash-flow requirements of the
 314 provider, and an applicant's access to contingency financing. A
 315 party participating in the administrative hearing regarding the
 316 issuance of the certificate of need for a general hospital may
 317 provide written comments concerning the adequacy of the
 318 financial information provided, but such party does not have
 319 standing to participate in an administrative proceeding

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320 regarding proof of the applicant's financial ability to operate.
 321 The agency may require a licensee to provide proof of financial
 322 ability to operate at any time if there is evidence of financial
 323 instability, including, but not limited to, unpaid expenses
 324 necessary for the basic operations of the provider.

325 (2)(3) The applicant must certify that it will license and
 326 operate the health care facility. For an existing health care
 327 facility, the applicant must be the licenseholder of the
 328 facility.

329 Section 8. Paragraphs (c) and (d) of subsection (3),
 330 paragraphs (b) and (c) of subsection (5), and paragraph (d) of
 331 subsection (6) of section 408.039, Florida Statutes, are amended
 332 to read:

333 408.039 Review process.—The review process for certificates
 334 of need shall be as follows:

335 (3) APPLICATION PROCESSING.—

336 ~~(c)~~ Except for competing applicants, in order to be
 337 eligible to challenge the agency decision on a general hospital
 338 application under review pursuant to paragraph (5)(c), existing
 339 hospitals must submit a detailed written statement of opposition
 340 to the agency and to the applicant. The detailed written
 341 statement must be received by the agency and the applicant
 342 within 21 days after the general hospital application is deemed
 343 complete and made available to the public.

344 ~~(d)~~ In those cases where a written statement of opposition
 345 has been timely filed regarding a certificate of need
 346 application for a general hospital, the applicant for the
 347 general hospital may submit a written response to the agency.
 348 Such response must be received by the agency within 10 days of

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349 ~~the written statement due date.~~

350 (5) ADMINISTRATIVE HEARINGS.—

351 (b) Hearings shall be held in Tallahassee unless the
 352 administrative law judge determines that changing the location
 353 will facilitate the proceedings. The agency shall assign
 354 proceedings requiring hearings to the Division of Administrative
 355 Hearings of the Department of Management Services within 10 days
 356 after the time has expired for requesting a hearing. Except upon
 357 unanimous consent of the parties or upon the granting by the
 358 administrative law judge of a motion of continuance, hearings
 359 shall commence within 60 days after the administrative law judge
 360 has been assigned. ~~For an application for a general hospital,~~
 361 ~~administrative hearings shall commence within 6 months after the~~
 362 ~~administrative law judge has been assigned, and a continuance~~
 363 ~~may not be granted absent a finding of extraordinary~~
 364 ~~circumstances by the administrative law judge.~~ All parties,
 365 except the agency, shall bear their own expense of preparing a
 366 transcript. In any application for a certificate of need which
 367 is referred to the Division of Administrative Hearings for
 368 hearing, the administrative law judge shall complete and submit
 369 to the parties a recommended order as provided in ss. 120.569
 370 and 120.57. The recommended order shall be issued within 30 days
 371 after the receipt of the proposed recommended orders or the
 372 deadline for submission of such proposed recommended orders,
 373 whichever is earlier. The division shall adopt procedures for
 374 administrative hearings which shall maximize the use of
 375 stipulated facts and shall provide for the admission of prepared
 376 testimony.

377 (c) In administrative proceedings challenging the issuance

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378 or denial of a certificate of need, only applicants considered
 379 by the agency in the same batching cycle are entitled to a
 380 comparative hearing on their applications. Existing health care
 381 facilities may initiate or intervene in an administrative
 382 hearing upon a showing that an established program will be
 383 substantially affected by the issuance of any certificate of
 384 need, whether reviewed under s. 408.036(1) or (2), to a
 385 competing proposed facility or program within the same district.
 386 ~~With respect to an application for a general hospital, competing~~
 387 ~~applicants and only those existing hospitals that submitted a~~
 388 ~~detailed written statement of opposition to an application as~~
 389 ~~provided in this paragraph may initiate or intervene in an~~
 390 ~~administrative hearing. Such challenges to a general hospital~~
 391 ~~application shall be limited in scope to the issues raised in~~
 392 ~~the detailed written statement of opposition that was provided~~
 393 ~~to the agency. The administrative law judge may, upon a motion~~
 394 ~~showing good cause, expand the scope of the issues to be heard~~
 395 ~~at the hearing. Such motion shall include substantial and~~
 396 ~~detailed facts and reasons for failure to include such issues in~~
 397 ~~the original written statement of opposition.~~

398 (6) JUDICIAL REVIEW.—

399 ~~(d) The party appealing a final order that grants a general~~
 400 ~~hospital certificate of need shall pay the appellee's attorney's~~
 401 ~~fees and costs, in an amount up to \$1 million, from the~~
 402 ~~beginning of the original administrative action if the appealing~~
 403 ~~party loses the appeal, subject to the following limitations and~~
 404 ~~requirements:~~

405 ~~1. The party appealing a final order must post a bond in~~
 406 ~~the amount of \$1 million in order to maintain the appeal.~~

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407 ~~2. Except as provided under s. 120.595(5), in no event~~
 408 ~~shall the agency be held liable for any other party's attorney's~~
 409 ~~fees or costs.~~

410 Section 9. Subsection (1) of section 408.040, Florida
 411 Statutes, is amended, to read:

412 408.040 Conditions and monitoring.—

413 (1) (a) The agency may issue a certificate of need, or an
 414 exemption, predicated upon statements of intent expressed by an
 415 applicant in the application for a certificate of need or an
 416 exemption. Any conditions imposed on a certificate of need or an
 417 exemption based on such statements of intent shall be stated on
 418 the face of the certificate of need or in the exemption
 419 approval.

420 (b) The agency may consider, in addition to the other
 421 criteria specified in s. 408.035, a statement of intent by the
 422 applicant that a specified percentage of the annual patient days
 423 at the facility will be utilized by patients eligible for care
 424 under Title XIX of the Social Security Act. Any certificate of
 425 need issued to a nursing home in reliance upon an applicant's
 426 statements that a specified percentage of annual patient days
 427 will be utilized by residents eligible for care under Title XIX
 428 of the Social Security Act must include a statement that such
 429 certification is a condition of issuance of the certificate of
 430 need. The certificate-of-need program shall notify the Medicaid
 431 program office and the Department of Elderly Affairs when it
 432 imposes conditions as authorized in this paragraph in an area in
 433 which a community diversion pilot project is implemented.
 434 Effective July 1, 2012, the agency may not impose sanctions
 435 related to patient day utilization by patients eligible for care

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436 under Title XIX of the Social Security Act for nursing homes.

437 (c) A certificateholder or an exemption holder may apply to
 438 the agency for a modification of conditions imposed under
 439 paragraph (a) or paragraph (b). If the holder of a certificate
 440 of need or an exemption demonstrates good cause why the
 441 certificate or exemption should be modified, the agency shall
 442 reissue the certificate of need or exemption with such
 443 modifications as may be appropriate. The agency shall by rule
 444 define the factors constituting good cause for modification.

445 (d) If the holder of a certificate of need or the holder of
 446 an exemption fails to comply with a condition that is unrelated
 447 to the provision of charity care or the provision of care under
 448 the Florida Medicaid program upon which the issuance of the
 449 certificate or exemption was predicated, the agency may assess
 450 an administrative fine against the certificateholder or
 451 exemption holder in an amount not to exceed \$1,000 per failure
 452 per day. If the holder of a certificate of need or the holder of
 453 an exemption fails to comply with a condition related to the
 454 provision of charity care or the provision of care under the
 455 Florida Medicaid program upon which the issuance of the
 456 certificate or exemption was predicated, the agency must assess
 457 an administrative fine against the certificateholder or
 458 exemption holder in the amount of \$2,500 per day for each
 459 instance of noncompliance. Failure to annually report compliance
 460 with any condition upon which the issuance of the certificate or
 461 exemption was predicated constitutes noncompliance. In assessing
 462 the penalty, the agency shall take into account as mitigation
 463 the degree of noncompliance. Proceeds of such penalties shall be
 464 deposited in the Public Medical Assistance Trust Fund.

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465 (e) A general hospital that was issued a certificate of
 466 need with conditions imposed as described in paragraph (a) or
 467 paragraph (b), relating to the provision of charity care or the
 468 provision of care under the Florida Medicaid program, must
 469 continue to meet those conditions to maintain licensure
 470 regardless of the status of that hospital's certificate of need
 471 unless such conditions are modified by the agency pursuant to
 472 paragraph (c).

473 Section 10. Subsection (1) of section 408.043, Florida
 474 Statutes, is amended to read:

475 408.043 Special provisions.—

476 ~~(1) OSTEOPATHIC ACUTE CARE HOSPITALS. When an application~~
 477 ~~is made for a certificate of need to construct or to expand an~~
 478 ~~osteopathic acute care hospital, the need for such hospital~~
 479 ~~shall be determined on the basis of the need for and~~
 480 ~~availability of osteopathic services and osteopathic acute care~~
 481 ~~hospitals in the district. When a prior certificate of need to~~
 482 ~~establish an osteopathic acute care hospital has been issued in~~
 483 ~~a district, and the facility is no longer used for that purpose,~~
 484 ~~the agency may continue to count such facility and beds as an~~
 485 ~~existing osteopathic facility in any subsequent application for~~
 486 ~~construction of an osteopathic acute care hospital.~~

487 Section 11. Effective upon this act becoming a law:

488 (1) The Agency for Health Care Administration may not
 489 initiate a review cycle or accept letters of intent or
 490 applications for the issuance of a certificate of need for the
 491 new construction or establishment of a freestanding general
 492 hospital.

493 (2) The agency shall issue a certificate of need to any

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494 pending applicant for a certificate of need for the new
 495 construction of or establishment of a freestanding general
 496 hospital:

497 (a) With intensive care, progressive care, and medical-
 498 surgical beds;

499 (b) With an onsite emergency department that will be
 500 operational 24 hours per day, 7 days per week; and

501 (c) Whose application for a certificate of need has been
 502 approved by the agency, regardless of the litigation status of
 503 the application.

504 (3) For an applicant seeking a certificate of need for the
 505 new construction or establishment of a freestanding general
 506 hospital that does not meet the criteria in subsection (2),
 507 including an applicant whose application is pending approval or
 508 denial by the agency and an applicant whose application was
 509 initially denied by the agency but such denial is under appeal,
 510 ss. 395.6025, 408.032, 408.034, 408.035, 408.036, 408.037,
 511 408.039, and 408.043, Florida Statutes (2018), and any rules
 512 adopted thereunder remain in effect until such time as the
 513 agency has either issued the applicant a certificate of need,
 514 the agency has denied the application and all appeals of the
 515 denial have been exhausted, or the application has been
 516 withdrawn.

517 Section 12. Except as otherwise expressly provided in this
 518 act and except for this section, which shall take effect upon
 519 this act becoming a law, this act shall take effect July 1,
 520 2019.



834398

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/09/2019	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services
(Harrell) recommended the following:

Senate Amendment (with title amendment)

Delete lines 240 - 242
and insert:
another, including the conversion from a general hospital, a
specialty hospital, or a long-term care hospital, except that a
conversion to a general hospital is not

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

And the title is amended as follows:



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11 Delete line 38
12 and insert:
13 to a general hospital from

CourtSmart Tag Report

Room: KN 412

Case No.:

Type:

Caption: Senate Appropriations Subcommittee on Health and Human Services

Judge:

Started: 4/9/2019 4:02:47 PM

Ends: 4/9/2019 5:59:44 PM Length: 01:56:58

4:02:53 PM Sen. Bean (Chair)
4:04:55 PM Sen. Wright
4:05:05 PM S 1518
4:06:03 PM Am. 132100
4:06:10 PM Sen. Bean (Chair)
4:08:01 PM Washington Sanchez, VP of Tallahassee Veterans Legal Collaborative (waives in support)
4:08:13 PM Bill Helmich, VFW American Legion (waives in support)
4:08:24 PM Sharon Graham, Music Therapist Board Certified, Florida Music Therapy Task Force (waives in support)
4:08:39 PM Jesse Diaz, Outreach Coors (waives in support)
4:09:05 PM Corinne Mixon, Lobbyist, Florida Music Therapy Taskforce (waives in support)
4:09:15 PM Allison Sitte, Legislative Affairs Director, Florida Department of Veterans Affairs (waives in support)
4:09:25 PM Natalie King, VP, United Way Suncoast (waives in support)
4:09:33 PM Brian Anderson, Veterans Alternative (waives in support)
4:09:44 PM Dan Hendrickson, President of TVLC, Tallahassee Veterans Legal Collaborative (waives in support)
4:09:52 PM Jack Herbert, Florida Chiropractic Association (waives in support)
4:10:13 PM Sen. Harrell
4:10:51 PM Sen. Diaz
4:11:12 PM Sen. Wright
4:12:12 PM S 1712
4:12:19 PM Sen. Harrell
4:17:25 PM Sen. Bean (Chair)
4:17:34 PM Am. 834398
4:17:41 PM Sen. Harrell
4:18:24 PM Sen. Rouson
4:18:37 PM Sen. Harrell
4:19:43 PM Sen. Bean (Chair)
4:20:10 PM Logan Padgett, Director of Communications and Public Affairs, The James Madison Institute (waives in support)
4:21:37 PM Diego Echeverri, Director of Coalitions, Concerned Veterans For America
4:22:48 PM Monica Rodriguez, Director Of Government Affairs, UF Health Shands (waives in support)
4:22:58 PM Nathan Ray, Associate Vice President, Jackson Health Systems (waives in support)
4:23:03 PM Christian Camara, Institute For Justice (waives in support)
4:23:24 PM Rich Templin, Florida AFL C10
4:25:28 PM Phillip Suderman, Americans For Prosperity
4:26:57 PM Sen. Bean (Chair)
4:27:12 PM Sen. Flores
4:28:52 PM Sen. Farmer
4:30:12 PM Sen. Bean (Chair)
4:30:36 PM Sen. Harrell
4:32:52 PM Sen. Bean (Chair)
4:33:38 PM Sen. Harrell (Chair)
4:33:55 PM S 1528
4:34:00 PM Sen. Bean
4:38:41 PM Sen. Harrell (Chair)
4:39:00 PM AM. 872890
4:39:33 PM Sen. Bean
4:39:43 PM Sen. Harrell (Chair)
4:40:05 PM Am. 104102
4:40:19 PM Sen. Bean
4:41:24 PM Sen. Rader
4:42:32 PM Sen. Bean
4:43:39 PM Sen. Rader

4:44:11 PM Sen. Bean
4:44:20 PM Sen. Passidomo
4:45:41 PM Sen. Bean
4:46:01 PM Sen. Harrell (Chair)
4:46:41 PM Sen. Passidomo
4:47:20 PM Sen. Harrell (Chair)
4:48:29 PM Sen. Passidomo
4:48:56 PM Sen. Rader
4:50:18 PM Sen. Harrell (Chair)
4:50:24 PM Sen. Bean
4:51:05 PM Sen. Harrell (Chair)
4:51:28 PM Sen. Farmer
4:52:09 PM Sen. Bean
4:53:17 PM Mark Delegal, Retained Counsel, Pharmaceutical Researchers and Manufactures of America
5:02:31 PM Michelle Flowers, President, Oncology Managers of Florida
5:05:26 PM Dorene Barker, Associate State Director, AARP Florida (waives in support)
5:05:34 PM Sen. Harrell (Chair)
5:05:41 PM Sen. Hooper
5:07:13 PM Sen. Passidomo
5:09:48 PM Sen. Farmer
5:11:19 PM Sen. Harrell (Chair)
5:12:54 PM Sen. Bean
5:14:33 PM Sen. Bean (Chair)
5:14:46 PM S 732
5:14:50 PM Sen. Flores
5:14:54 PM Sen. Flores
5:14:54 PM Sen. Flores
5:16:30 PM Am. 359744
5:16:33 PM Am. 978476
5:16:47 PM Am. 868332
5:16:57 PM Sen. Flores
5:23:07 PM Sen. Bean (Chair)
5:23:40 PM Am 978476
5:23:46 PM Chris Nuland, Florida Society of Plastic Surgeons
5:24:49 PM Sen. Book
5:25:22 PM Sen. Harrell
5:26:16 PM Sen. Flores
5:30:08 PM S 732 (cont.)
5:30:33 PM Sen. Bean (Chair)
5:30:54 PM Sen. Book
5:30:58 PM S 1460
5:32:03 PM Am. 538518
5:32:30 PM Am 835638
5:33:05 PM Mark Landrets, GRD, American Heart Association (waives in support)
5:33:21 PM Kelly Mallette, Society for Neuro International Surgery (waives in support)
5:33:36 PM Sen. Book
5:34:17 PM Sen. Bean (Chair)
5:34:42 PM Sen. Hooper
5:35:10 PM Am. 740542
5:35:56 PM Sen. Rader
5:36:44 PM Sen. Hooper
5:37:41 PM Joe Anne Hart, Chief Legislative Officer, Florida Dental Association (waives in support)
5:38:04 PM Sen. Flores
5:39:05 PM Sen. Bean (Chair)
5:39:10 PM Sen. Rader
5:40:30 PM Sen. Farmer
5:43:19 PM Sen. Hooper
5:43:34 PM Sen. Bean (Chair)
5:44:15 PM Sen. Book
5:44:21 PM S 1218
5:46:31 PM Am. 235940
5:47:13 PM Devon West, (Legislative Policy Advisor, Broward County (waives in support))

5:47:20 PM Robert Beck, Partner at Pinpoint Results, Florida Coalition for the Homeless (waives in support)
5:47:29 PM Lauren Jackson, Florida Association of Counties (waives in support)
5:47:48 PM Sen. Book
5:48:32 PM Sen. Bean (Chair)
5:48:47 PM S 900
5:49:11 PM Sen. Harrell
5:52:42 PM Am. 312576 withdrawn
5:53:25 PM Am. 839894
5:53:28 PM Am. 122872
5:53:43 PM Sen. Harrell
5:54:03 PM Austin Stowers, Deputy Director of Legislative Affairs, Department of Financial Services (waives in support)
5:55:02 PM Sen. Bean (Chair)
5:55:27 PM Sen. Harrell
5:56:04 PM David Bernhardt, FOP (waives in support)
5:56:15 PM Rebecca Dela Rosa, Legislative Affairs Director, Palm Beach County (waives in support)
5:56:23 PM Devon West, Legislative Policy Advisor, Broward County (waives in support)
5:56:29 PM Gemma Sunnergren, Student, League of Women Voters of Florida (waives in support)
5:56:41 PM Neal McGarry, CEO, Florida Certification Board (waives in support)
5:56:43 PM Alisa Lapolt, Lobbyist, National Alliance on Mental Illness Palm Beach (waives in support)
5:56:52 PM Mark Fontaine, Director, Florida Alcohol and Drug Abuse Association (waives in support)
5:57:00 PM Natalie Kelly, CEO, Florida Association of Managing Entities (waives in support)
5:57:26 PM Sen. Rouson
5:58:34 PM Sen. Bean (Chair)
5:58:39 PM Sen. Harrell
5:59:24 PM Sen. Book