The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Harrell, Chair
Senator Berman, Vice Chair

MEETING DATE: Tuesday, January 28, 2020
TIME: 1:30—3:30 p.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Harrell, Chair; Senator Berman, Vice Chair; Senators Baxley, Bean, Book, Cruz, Diaz, Hooper, Mayfield, and Rouson

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**SB 120** Pizzo (Identical H 331)	Naloxone in Schools; Authorizing a public school to purchase a supply or enter into an arrangement to receive a supply of the opioid antagonist naloxone for a certain purpose; requiring the school district to adopt a protocol for the administration of naloxone; providing that a school district and its employees and agents and the physician who provides the protocol are not liable for any injury arising from the administration of the naloxone pursuant to the protocol, etc. ED 11/12/2019 Favorable HP 01/21/2020 Not Considered HP 01/28/2020 Favorable RC	Favorable Yeas 9 Nays 0
2	**SB 916** Baxley (Similar H 833)	Program of All-Inclusive Care for the Elderly; Authorizing the Agency for Health Care Administration, in consultation with the Department of Elderly Affairs, to approve certain applicants to provide benefits pursuant to the Program of All-Inclusive Care for the Elderly (PACE); specifying requirements and procedures for the submission, publication, review, and initial approval of applications; requiring prospective PACE organizations that are granted initial approval to apply within a certain timeframe for federal approval, etc. HP 01/21/2020 Not Considered HP 01/28/2020 Favorable AHS AP	Favorable Yeas 10 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
3	**SB 1374** Harrell (Compare H 665)	Regional Perinatal Intensive Care Centers; Authorizing the Department of Health to designate regional perinatal intensive care centers; providing that designation by the department is required for participation in the regional perinatal intensive care centers program; specifying standards that must be included in department rules relating to the designation, development, and operation of a regional perinatal intensive care center; specifying reimbursement parameters for certain services provided in a regional perinatal intensive care center setting, etc. HP 01/21/2020 Not Considered HP 01/28/2020 Favorable AHS AP	Favorable Yeas 10 Nays 0
4	Review of Florida's Organ Donation and Transplantation System by OPPAGA		Presented
5	**SB 1516** Harrell (Compare H 1187)	Organ Transplant Technical Advisory Council; Requiring the Agency for Health Care Administration to establish the Organ Transplant Technical Advisory Council for a specified purpose; requiring the council to submit a report to the Governor, the Legislature, the Secretary of Health Care Administration, and the State Surgeon General by a specified date; extending sovereign immunity to council members under certain circumstances; requiring the agency to amend or adopt specified rules based on the council's recommendations, etc. HP 01/28/2020 Fav/CS JU RC	Fav/CS Yeas 9 Nays 0
6	**SB 798** Rouson (Identical H 563)	Procurement of Human Organs and Tissue; Prohibiting for-profit entities from procuring certain human organs and tissue, with certain exceptions; prohibiting for-profit entities from procuring certain human organs and tissue, with certain exceptions, etc. HP 01/28/2020 Favorable CJ RC	Favorable Yeas 10 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
7	**SB 1556** Bean (Identical H 1179)	Nondiscrimination in Organ Transplants; Prohibiting certain entities from making certain determinations or engaging in certain actions related to organ transplants solely on the basis of an individual's disability; specifying an instance where certain entities may consider an individual's disability, with an exception; requiring certain entities to take certain necessary steps to ensure an individual with a disability is not denied services, with exceptions; prohibiting insurers, nonprofit health care service plans, and health maintenance organizations that provide coverage for organ transplants from denying coverage solely on the basis of an individual's disability under certain circumstances, etc. HP 01/28/2020 Favorable BI AP	Favorable Yeas 10 Nays 0
8	**SB 1726** Bean (Compare H 731)	Agency for Health Care Administration; Requiring birth centers to report certain deaths and stillbirths to the agency; revising provisions requiring the agency to conduct licensure inspections of nursing homes; removing the requirement that the agency annually report to the Governor and the Legislature by a specified date on the progress of implementation of electronic prescribing, etc. HP 01/28/2020 Fav/CS AHS AP	Fav/CS Yeas 9 Nays 0
9	**SB 1742** Mayfield (Similar H 1183, Compare H 1143)	Home Medical Equipment Providers; Exempting allopathic, osteopathic, and chiropractic physicians who sell or rent electrostimulation medical equipment and supplies in the course of their practice from certain licensure requirements, etc. HP 01/28/2020 Favorable AHS AP	Favorable Yeas 8 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
10	**SB 926** Harrell (Compare H 77, CS/CS/CS/H 115, CS/H 713, H 1143, H 1269, CS/S 66, CS/S 356, CS/S 474, Linked S 928)	Health Care Practitioner Licensure; Establishing that a physician licensed under the Interstate Medical Licensure Compact is deemed to be licensed under chapter 458; establishing that an osteopathic physician licensed under the Interstate Medical Licensure Compact is deemed to be licensed under chapter 459; deleting a provision classifying the failure to repay a student loan issued or guaranteed by the state or federal government in accordance with the terms of the loan as a failure to perform a statutory or legal obligation; implementing the Interstate Medical Licensure Compact in this state, etc. HP 01/28/2020 Favorable AHS AP	Favorable Yeas 8 Nays 0
11	**SB 928** Harrell (Similar H 1269, Linked S 926)	Public Records and Meetings/Interstate Medical Licensure Compact; Providing an exemption from public records requirements for certain information held by the Department of Health, the Board of Medicine, or the Board of Osteopathic Medicine, pursuant to the Interstate Medical Licensure Compact; providing an exemption from public meeting requirements for certain meetings or portions of certain meetings of the Interstate Medical Licensure Compact Commission; providing for future legislative review and repeal of the exemptions; providing a statement of public necessity, etc. HP 01/28/2020 Fav/CS GO RC	Fav/CS Yeas 8 Nays 0
12	**SB 1676** Albritton	Direct Care Workers; Requiring a nursing home facility that authorizes a registered nurse to delegate tasks to a certified nursing assistant to ensure that certain requirements are met; authorizing a certified nursing assistant to perform tasks delegated by a registered nurse; authorizing an unlicensed person to assist with self-administration of certain treatments; authorizing a home health aide to administer certain prescription medications under certain conditions, etc. HP 01/28/2020 Temporarily Postponed AHS AP	Temporarily Postponed

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
13	**SB 1344** Harrell (Similar H 1163)	Intermediate Care Facilities; Requiring certain facilities that have been granted a certificate-of-need exemption to demonstrate and maintain compliance with specified criteria; providing an exemption from a certificate-of-need requirement for certain intermediate care facilities; prohibiting the Agency for Health Care Administration from granting an additional exemption to a facility unless a certain condition is met, etc. HP 01/28/2020 Favorable AHS AP	Favorable Yeas 9 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 Committee on Health Policy

BILL:	SB 120
INTRODUCER:	Senators Pizzo and Book
SUBJECT:	Naloxone in Schools
DATE:	January 28, 2020
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brick	Sikes	ED	**Favorable**
2.	Looke	Brown	HP	**Favorable**
3.			RC	

I. Summary:

SB 120 authorizes a K-12 public school to purchase the opioid antagonist naloxone and allows trained personnel to administer the drug to a student who overdoses on an opioid. The bill requires a participating school district to adopt a protocol developed by a licensed physician and provides liability protections for the physician and school district personnel relating to injuries arising from naloxone use administered by trained school personnel who comply with the protocol.

The bill takes effect July 1, 2020.

II. Present Situation:

Opioid Epidemic

An opioid overdose may cause a person to lose consciousness, stop breathing, and die.[1] In 2017, the number of overdose deaths involving opioids was six times higher nationwide than it was in 1999[2] and, in 2018, opioids killed 3,727 people in Florida.[3] As a result of the opioid epidemic, Governor Rick Scott declared Florida to be in a state of emergency.[4] Subsequent Executive

[1] U.S. Food & Drug Administration, *Statement From FDA Commissioner Scott Gottlieb, M.D., on Unprecedented New Efforts to Support Development of Over-The-Counter Naloxone to Help Reduce Opioid Overdose Deaths* (Jan. 17, 2019), *available at* https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over (last visited Jan. 14, 2020).
[2] Centers for Disease Control and Prevention, *Opioid Overdose* (2018), *available at* https://www.cdc.gov/drugoverdose/epidemic/index.html (last visited Jan. 14, 2020).
[3] Florida Department of Law Enforcement, Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners*, 2018 Annual Report, *available at* https://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2018-Annual-Drug-Report.aspx (last visited Jan. 14, 2020).
[4] Office of the Governor, *Executive Order Number 17-146*, May 3, 2017 (Opioid Epidemic).

Orders extended the state of emergency through April 2, 2019.[5] On April 1, 2019, Governor Ron DeSantis created a Statewide Task Force on Opioid Abuse to research and assess the nature of opioid drug abuse in Florida and develop a statewide strategy to identify best practices to combat the opioid epidemic through education, treatment, prevention, recovery, and law enforcement.[6]

Naloxone

Background

Naloxone is a well-established essential medicine for the treatment of life-threatening opioid overdose in emergency medicine.[7] Naloxone is a safe antidote to a suspected overdose and can save a life when given in time.[8] Research shows that when naloxone and overdose education are available to community members, overdose deaths decrease in those communities.[9] Laypersons administering naloxone have a 75 to 100 percent success rate in reversing the effects of an opioid overdose.[10]

Regulation

Naloxone is a derivative of thebaine,[11] a Schedule II controlled substance in Florida.[12] Schedule II substances may only be dispensed with a prescription from a licensed practitioner,[13] but emergency responders are authorized by law to possess, store, and administer emergency opioid antagonists as necessary.[14] The U.S. Surgeon General developed standards to encourage the distribution of over-the-counter naloxone.[15]

Subject to statutory exceptions, it is illegal for a drug manufacturer or wholesale distributor in Florida to distribute a prescription drug to a person without a prescription.[16] One such statutory exception authorizes a public school to purchase a supply of epinephrine auto-injectors from a

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[5] Office of the Governor, *Executive Order Number 19-36*, February 1, 2019 (Opioid Epidemic Extension).
[6] Office of the Governor, *Executive Order Number 19-97*, April 1, 2019 (Establishing the Office of Drug Control and the Statewide Task Force on Opioid Abuse to Combat Florida's Substance Abuse Crisis).
[7] John Strang, et al., *Take-Home Naloxone for the Emergency Interim Management of Opioid Overdose: The Public Health Application of an Emergency Medicine*, 79(13) Drugs 1395-1418 (July 27, 2019), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6728289/ (last visited Jan. 14, 2020)
[8] U.S. Department of Health and Human Services, Office of the Surgeon General, *U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose* (Apr. 5, 2018), *available at* https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html (last visited Jan. 14, 2020).
[9] *Id.*
[10] Rachael Rzasa Lynn, J. L. Galinkin, *Naloxone dosage for opioid reversal: current evidence and clinical implications*, 9(1) Therapeutic Advances in Drug Safety, 63-88 (2018), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5753997/ (last visited Jan. 14, 2020).
[11] National Institute of Health, U.S. National Library of Medicine, *Naloxone*, https://pubchem.ncbi.nlm.nih.gov/compound/Naloxone (last visited Jan. 14, 2020).
[12] Section 893.03(2)(a)1.s., F.S.
[13] Section 893.04(1)(f), F.S. "Practitioner" means a physician licensed under ch. 458, a dentist licensed under ch. 466, a veterinarian licensed under ch. 474, an osteopathic physician licensed under ch. 459, an advanced practice registered nurse licensed under ch. 464, a naturopath licensed under ch. 462, a certified optometrist licensed under ch. 463, a psychiatric nurse as defined in s. 394.455, F.S., a podiatric physician licensed under ch. 461, or a physician assistant licensed under ch. 458 or ch. 459, provided such practitioner holds a valid federal controlled substance registry number. Section 893.02(23), F.S.
[14] Section 381.887, F.S.
[15] U.S. Food & Drug Administration, *supra* note 1.
[16] Section 499.005(14), F.S.

wholesale distributor or manufacturer.[17] In addition, a manufacturer or wholesale distributor of naloxone may sell a prescription drug to:[18]

- A licensed pharmacist or any person under the licensed pharmacist's supervision while acting within the scope of the licensed pharmacist's practice;
- A licensed practitioner authorized by law to prescribe prescription drugs or any person under the licensed practitioner's supervision while acting within the scope of the licensed practitioner's practice;
- A qualified person who uses prescription drugs for lawful research, teaching, or testing, and not for resale;
- A licensed hospital or other institution that procures such drugs for lawful administration or dispensing by practitioners;
- An officer or employee of a federal, state, or local government; or
- A person that holds a valid permit issued by the Department of Business and Professional Regulation, which authorizes that person to possess prescription drugs.

Administration

Naloxone may be administered to a person through a vein, through a muscle, or through the nasal passage.[19] Naloxone may cost less than a dollar per unit for a simple vial, to several thousand dollars for certain intramuscular auto-injectors.[20]

ADAPT Pharma, Inc., has produced an FDA-approved naloxone nasal spray called Narcan.[21] The Florida Department of Children and Families, as part of its overdose prevention program, purchases Narcan at $75 per carton. Each carton contains two doses of Narcan.[22] The Narcan Nasal Spray School Program, offered through ADAPT Pharma, offers up to two cartons of Narcan to every high school at no cost.[23] New approved naloxone nasal sprays cost between $30 and several hundred dollars per carton.[24]

School Health

District school board personnel may assist students in the administration of certain medication and medical services.[25] County health departments, district school boards, and local school health advisory committees jointly develop school health services plans, which must include provisions for meeting emergency needs at each school.[26] Each school must ensure that at least

[17] Section 1002.20(3)(i), F.S.
[18] Section 499.03(1), F.S.
[19] Strang, *supra* note 7.
[20] *Id*.
[21] *Id*.
[22] Fla. Dep't of Children and Families, *Patterns and Trends of the Opioid Epidemic in Florida*, 20 (2018), *available at* http://www.floridahealth.gov/statistics-and-data/e-forcse/fl-seow-annual-report-2018.pdf (last visited Jan. 14, 2020).
[23] Narcan Nasal Spray, *Community Programs*, *available at* https://www.narcan.com/community/education-awareness-and-training-resources/ (last visited Jan. 14, 2020).
[24] Strang, *supra* note 7.
[25] Section 1006.062, F.S.
[26] Sections 381.0056(4)(a)12. and 1006.062(6), F.S.

two school staff members are currently certified by nationally recognized certifying agencies to provide first aid and cardiopulmonary resuscitation.[27]

At least four states enacted bills to expand naloxone access in schools in 2019.[28]

III. Effect of Proposed Changes:

SB 120 authorizes a school to purchase a supply of the opioid antagonist naloxone from a wholesale distributor, or enter into an arrangement with a wholesale distributor or manufacturer for naloxone at fair-market, free, or reduced prices. A participating school district must adopt a protocol developed by a licensed physician for the administration of the drug by school personnel who are trained to recognize an opioid overdose and to administer naloxone. The school must maintain the naloxone in a secure location on the premises of a participating school.

The bill exempts a school district, its employees and agents, and the physician who provides the standing protocol, from liability for any injury arising from the use of naloxone so long as the naloxone is administered by trained school personnel who follow the standing protocol and whose professional opinion is that the student is having an opioid overdose. The liability protections apply unless the trained school personnel's action is willful and wanton and apply regardless of whether:

- The parents or guardians of the student to whom the naloxone is administered have been provided notice or have signed a statement acknowledging that the school district is not liable; or
- Authorization has been given by the student's parents or guardians or by the student's physician, physician's assistant, or advanced practice registered nurse.

The bill takes effect July 1, 2020.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

[27] Fla. Admin. Code R. 64F-6.004.
[28] Minnesota, Oregon, South Dakota, and Washington. Alyssa Rafa, Education Commission of the States, *Education Policy Responses to the Opioid Crisis* (2019), *available at* https://www.ecs.org/education-policy-responses-to-the-opioid-crisis/, at 3, (last visited Jan. 14, 2020).

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:

SB 120 may have an indeterminate, negative fiscal impact on school districts. The costs to school districts depend on whether or not the district decides to purchase the medication and whether the medication is purchased at fair-market or reduced prices. ADAPT Pharma will provide two cartons of Narcan nasal spray (four doses) free of charge to high schools through the Narcan Nasal Spray School Program.[29]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 1002.20 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

[29] *Supra* note 23.

By Senator Pizzo

38-00009-20 2020120__

A bill to be entitled

An act relating to naloxone in schools; amending s. 1002.20, F.S.; authorizing a public school to purchase a supply or enter into an arrangement to receive a supply of the opioid antagonist naloxone for a certain purpose; specifying requirements for the maintenance of the naloxone; requiring the school district to adopt a protocol for the administration of naloxone; providing that a school district and its employees and agents and the physician who provides the protocol are not liable for any injury arising from the administration of the naloxone pursuant to the protocol; providing exceptions; providing an effective date.

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

Section 1. Paragraph (n) is added to subsection (3) of section 1002.20, Florida Statutes, to read:

1002.20 K-12 student and parent rights.—Parents of public school students must receive accurate and timely information regarding their child's academic progress and must be informed of ways they can help their child to succeed in school. K-12 students and their parents are afforded numerous statutory rights including, but not limited to, the following:

(3) HEALTH ISSUES.—

(n) *Naloxone use and supply.*—

1. A public school may purchase a supply of the opioid antagonist naloxone from a wholesale distributor as defined in

s. 499.003 or may enter into an arrangement with a wholesale distributor or manufacturer as defined in s. 499.003 for naloxone at fair-market, free, or reduced prices for use in the event a student has an opioid overdose. The naloxone must be maintained in a secure location on the public school's premises. The participating school district shall adopt a protocol developed by a licensed physician for the administration of the drug by school personnel who are trained to recognize an opioid overdose and to administer naloxone.

2. The school district and its employees and agents and the physician who provides the standing protocol for school naloxone are not liable for any injury arising from the use of the drug if it is administered by trained school personnel who follow the standing protocol and whose professional opinion is that the student is having an opioid overdose:

a. Unless the trained school personnel's action is willful and wanton;

b. Notwithstanding that the parents or guardians of the student to whom the naloxone is administered have not been provided notice or have not signed a statement acknowledging that the school district is not liable; and

c. Regardless of whether authorization has been given by the student's parents or guardians or by the student's physician, physician's assistant, or advanced practice registered nurse.

Section 2. This act shall take effect July 1, 2020.

The Florida Senate

Committee Agenda Request

To: Senator Gayle Harrell, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 21, 2020

I respectfully request that **SB 120**, relating to Naloxone in Schools, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Senator Jason W.B. Pizzo
Florida Senate, District 38

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/28/20
Meeting Date

120
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Naloxone in Schools

Name Jared Willis

Job Title Dir. of Govt Affairs

Address 2544 Blairstone Pines Drive
Street

Phone 850-284-1996

Tallahassee 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 Florida Osteopathic Medical 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)

1/28/20
Meeting Date

SB 120
Bill Number (if applicable)

Topic Naloxone in Schools

Amendment Barcode (if applicable)

Name Eric Stern

Job Title FL PTA Legislative Committee Member

Address 1747 Orlando Central Pkwy
Street

Phone 800-373-5782

Orlando FL 32809
City *State* *Zip*

Email legislation@flapta.org

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida PTA

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)

1-28
Meeting Date

120
Bill Number (if applicable)

Topic Naloxone

Amendment Barcode (if applicable)

Name Steve Winn

Job Title Executive Director

Address 2554 Blairstone Rd
Street

Tallahassee FL 32301
City *State* *Zip*

Phone

Email

Speaking: ☑ For ☐ Against ☐ Information

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

Representing FOMA

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

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 916
INTRODUCER:	Senator Baxley
SUBJECT:	Program of All-Inclusive Care for the Elderly
DATE:	January 27, 2020 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Kibbey	Brown	HP	**Favorable**
2.			AHS	
3.			AP	

I. Summary:

SB 916 codifies the Program of All-Inclusive Care for the Elderly (PACE) in s. 430.84, F.S. First authorized in 1998, the PACE became operational in Miami-Dade County in 2003 but has not been codified in state law. More than 2,000 Medicaid managed care eligible recipients are currently enrolled in PACE organizations in seven counties.

The bill establishes a statutory process for the review, approval, and oversight of future and current PACE organizations. The bill statutorily exempts all PACE organizations from the requirements of ch. 641, F.S., which regulates health maintenance organizations, prepaid health clinics, and other health care service programs.

The bill enables a prospective PACE organization to apply to the Agency for Health Care Administration (AHCA) without first receiving legislative approval specific to that PACE organization. This may increase the number of PACE applications, resulting in an indeterminate operational and fiscal impact to the AHCA and the Department of Elder Affairs (DOEA). The bill also has an indeterminate fiscal impact to the Florida Medicaid Program.

The bill has an effective date of July 1, 2020.

II. Present Situation:

Program of All-Inclusive Care for the Elderly

The Program of All-Inclusive Care for the Elderly (PACE) is a capitated benefit model authorized by the federal Balanced Budget Act of 1997 (BBA)[1] that features a comprehensive service delivery system and integrated federal Medicare and state Medicaid financing

[1] Specifically, services under the PACE program are authorized under Section 1905(a)(26) of the Social Security Act.

mechanism. The model, which was tested through the federal Centers for Medicare & Medicaid Services (CMS) demonstration projects beginning in the mid-1980s,[2] was developed to address the needs of long-term care clients, providers, and payers.

The PACE operates as a three-way agreement between the federal government, the state administering agency, and a PACE organization. In Florida, the PACE is a Florida Medicaid long-term care managed care plan option providing comprehensive long-term and acute care services which support Medicaid and Medicare enrollees who would otherwise qualify for Medicaid nursing facility services.[3]

The PACE is a unique federal/state partnership. The BBA established the PACE model of care as a permanent entity within the Medicare program and enabled states to provide PACE services to Medicaid beneficiaries as an optional state plan service without a Medicaid waiver.

The federal government established the PACE organization requirements and application process; however, the state is responsible for oversight of the application process, which includes reviewing the initial application and providing an on-site readiness review before a PACE organization can be authorized to serve participants. An approved PACE organization must sign a contract with the CMS and the state Medicaid agency.

The PACE is administered by the Department of Elder Affairs (DOEA) in consultation with the Agency for Health Care Administration (AHCA). The DOEA oversees the contracted PACE organizations but is not a party to the contract between the CMS, the AHCA, and the PACE organizations.[4] The DOEA, the AHCA, and the CMS must approve any applications for new PACE organizations if expansion is authorized by the Legislature through the necessary appropriation of the state matching funds.

A PACE organization must be part of either a city, county, state, or tribal government; a private not-for-profit 501(c)(3) organization; or for-profit entity that is primarily engaged in providing PACE services and must also:

- Have a governing board that includes participant representation;
- Be able to provide the complete service package, regardless of frequency or duration of services;
- Have a physical site to provide primary care, social services, restorative therapies, personal care and supportive services, nutritional counseling, recreational therapy, and meals;
- Have a defined service area;
- Have safeguards against conflicts of interest;
- Have a demonstrated fiscal soundness;
- Have a formal participant bill of rights; and

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[2] United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, *CMS Manual System: Pub. 100-11 Programs of All-Inclusive Care for the Elderly (PACE) Manual* (issued June 9, 2011), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pace111c01.pdf (last visited Jan. 14, 2020).
[3] Department of Elder Affairs and Agency for Health Care Administration, *Program of All-Inclusive Care for the Elderly and Statewide Medicaid Managed Care Long-term Care Program Comparison Report* (January 14, 2014), *available at* https://ahca.myflorida.com/Medicaid/recent_presentations/PACE_Evaluation_2014.pdf (last visited Jan. 14, 2020).
[4] *Id.*

- Have a process to address grievances and appeals.[5]

Eligibility and Benefits

The PACE participants must be at least 55 years of age, live in the PACE center service area, meet eligibility requirements for nursing home care, pursuant to a Comprehensive Assessment and Review for Long-Term Care Services (CARES) pre-admission screening, and be able to live in a community setting without jeopardizing their health or safety. The PACE becomes the sole source of services for these Medicare and Medicaid eligible enrollees. Additionally, by electing to enroll in the PACE, the participant agrees to forgo other options for medical services and receive all of their services through the PACE organization.[6]

Under the PACE, an interdisciplinary team consisting of professional and paraprofessional staff assesses participants' needs, develops care plans, and delivers all services, including acute care and nursing facility services when necessary, which are integrated to provide a seamless delivery model. In most cases, a PACE organization provides social and medical services in a health center with supplemental services through in-home and referral services as necessary. The PACE service package must include all Medicare and Medicaid covered services and other services determined necessary by the multidisciplinary team for the care of the PACE participant.[7]

Before being approved to operate and deliver services, PACE organizations are required to provide evidence of the necessary financial capital to deliver the benefits and services, which include a combined adult day care center and primary care clinic, transportation, and full range of clinical and support staff with the interdisciplinary team of professionals.[8]

By federal law, the first three contract years for a PACE organization are considered a trial period, and the PACE organization is subject to annual reviews to ensure compliance.[9] The site visit reviews include:

- A comprehensive assessment of an organization's fiscal soundness;
- A comprehensive assessment of the organization's capacity to provide all PACE services to all enrolled participants;
- A detailed analysis of the PACE organization's substantial compliance with all the federal statutory requirements and accompanying federal regulations; and
- Compliance with any other elements the Secretary of the U.S. Department of Health and Human Services (Secretary) or the state's administering agency considers necessary and appropriate.[10]

Review of the PACE organization may continue after the trial period by the Secretary or the administering state agency as appropriate, depending upon the PACE organization's performance and compliance with requirements and regulations.

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[5] *Supra* note 2.
[6] *Id.*
[7] *Id.*
[8] *Supra* note 3, at 4.
[9] *See* 42 U.S.C. s. 1395eee(e)(4)(A)(2020).
[10] *Id.*

No deductibles, copayments, coinsurance, or other cost-sharing can be charged by a PACE organization. No other limits relating to amount, duration, or scope of services that might otherwise apply in Medicaid are permitted.[11] The PACE enrollee must accept the PACE center physician as his or her new Medicare primary care physician, if enrolled in Medicare.[12]

Quality of Care Requirements

Each PACE organization is required to develop, implement, maintain, and evaluate an effective data-driven Quality Assurance and Performance Improvement (QAPI) program. The program must incorporate all aspects of the PACE organization's operations, which allows for the identification of areas that need performance improvement. The organization's written QAPI plan must be reviewed by the PACE organization's governing body at least annually. At a minimum, the plan should address the following areas:

- Utilization of services in the PACE organization, especially in key services;
- Participant and caregiver satisfaction with services;
- Data collected during patient assessments to determine if individual and organizational-level outcomes were achieved within a specified time period;
- Effectiveness and safety of direct and contracted services delivered to participants; and
- Outcomes in the organization's non-clinical areas.[13]

Florida PACE

The Florida PACE project was initially authorized in ch. 98-327, Laws of Florida, under the administration of the DOEA operating in consultation with the AHCA.[14] Florida's first PACE organization, located in Miami-Dade County, began serving enrollees in February 2003 with a total of 150 slots. Since then, the Legislature has approved additional slots either as part of the General Appropriations Act (GAA) or general law.

In 2011, the Legislature moved administrative responsibility for the PACE program from the DOEA to the AHCA as part of the expansion of Medicaid managed care into the Statewide Medicaid Managed Care (SMMC) program.[15] Participation by the PACE in the SMMC program is not subject to the procurement requirements or regional plan number limits normally applicable to SMMC plans. Instead, PACE plans may continue to provide services to individuals at such levels and enrollment caps as authorized by the GAA.[16]

Currently, four PACE organizations operate in Florida and provide services to participants within specific zip codes in Broward, Miami-Dade, Charlotte, Collier, Lee, Palm Beach, and Pinellas counties. There are 2,245 individuals enrolled in the four Florida PACE organizations.

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[11] *Supra* note 2.
[12] Department of Elder Affairs and Agency for Health Care Administration, *Program of All-Inclusive Care for the Elderly and Statewide Medicaid Managed Care Long-term Care Program Comparison Report* (January 14, 2014), *available at* https://ahca.myflorida.com/Medicaid/recent_presentations/PACE_Evaluation_2014.pdf (last visited Jan. 14, 2020).
[13] *Id.*
[14] Chapter 2011-135, s. 24, L.O.F., repeals s. 430.707, F.S., effective October 1, 2013, as part of the expansion of Medicaid managed care.
[15] Chapter 2011-135, s. 24, L.O.F., repeals s. 430.707, F.S., effective October 1, 2013.
[16] Section 409.981(4), F.S.

The current PACE approval process requires any entity interested in becoming a PACE organization to submit a comprehensive PACE application to the AHCA, which sets forth details about the adult day care center, staffing, provider network, financial solvency and pro forma financial projections, and policies and procedures, among other elements. The application is similar in detail to the provider applications submitted by managed care plans seeking to provide medical care to Medicaid recipients. PACE providers operating in the same geographic region must establish that there is adequate demand for services so that each provider will be viable. The application requires that documentation be submitted demonstrating that PACE providers in the same geographic region are not competing for the same potential enrollees.

The AHCA and the DOEA review the application and, when the entity has satisfied all requirements, conduct an on-site survey of the entity's readiness to serve PACE enrollees. Once all requirements are met, including full licensure of the PACE center, staffing for key positions, and signed provider network contracts, the AHCA certifies to the CMS that the PACE site is ready. At that time, the CMS reviews the application and readiness certification and, if all requirements are satisfied, executes a three-way agreement with the PACE provider and the AHCA. The PACE provider may then begin enrolling members, subject to an appropriation to fund the slots.

Enrollment and Organizational Slots

Slots are authorized by the Legislature for a specific PACE area; however, slots may not always be fully funded in the same year the program is authorized. Some PACE providers need additional time to complete the application process, obtain necessary licensures, or to finalize operations.

Funding and Rates

Each year since the PACE's inception, the Legislature has appropriated funds for PACE organizations through proviso language in the GAA or through one of the GAA's accompanying implementing or conforming bills.[17] These directives provide specific slot increases or decreases by county or authorization for implementation of a new program. In 2013, Governor Rick Scott vetoed all county allocations with the exception of Palm Beach County, noting that the state's focus should be on the implementation of the SMMC and that effectiveness and the need for additional PACE slots should be re-evaluated after that transition was completed.[18]

PACE organizations receive a capitated Medicaid payment for each enrolled Medicaid long-term care recipient and an enhanced Medicare payment for Medicare enrollees for acute care services from the federal government. The payment amount is established in the GAA and is based on estimates that have been forecast by the Social Services Estimating Conference for the PACE.

Medicaid

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership between the federal and state governments where the federal government establishes the

[17] Chapter 2013-40, L.O.F.
[18] Governor Rick Scott, *Veto Message - SB 1500* (May 20, 2013), p. 28, *available at* http://www.flgov.com/wp-content/uploads/2013/05/Message1.pdf (last visited Jan. 14, 2020).

structure for the program and pays a share of the cost. Each state operates its own Medicaid program under a state plan that must be approved by the CMS. The plan outlines current Medicaid eligibility standards, policies, and reimbursement methodologies.

To qualify for nursing home care under Medicaid, both an individual's income and assets are reviewed. Additionally, a personal needs allowance is applied as part of the eligibility determination process.[19] The current standard income limit in Florida for institutional care or services under the home and community based services waiver is $2,313 for an individual and $4,626 for a couple. There is also an asset limit for either category of $2,000 for an individual or $3,000 for a couple.[20]

In Florida, the Medicaid program is administered by the AHCA. The AHCA, however, delegates certain functions to other state agencies, including the Department of Children and Families (DCF), the Agency for Persons with Disabilities (APD), and the DOEA. The AHCA has overall responsibility for the program and qualifies providers, sets payment levels, and pays for services.

The DCF is responsible for determining financial eligibility for Medicaid recipients. The APD operates one of the larger waiver programs under Medicaid, the Home and Community Based (HCBS) Waiver program, serving individuals with developmental disabilities.

The DOEA assesses Medicaid recipients to determine if they require nursing home care. Specifically, the DOEA determines whether an individual:

- Requires nursing home placement as evidenced by the need for medical observation throughout a 24-hour period and requires medically complex care to be performed on a daily basis under the direct supervision of a health professional because of mental or physical incapacitation;
- Requires or is at imminent risk of nursing home placement as evidenced by the need for observation throughout a 24-hour period and requires care to be performed on a daily basis under the supervision of a health professional because of mental or physical incapacitation; or
- Requires or is at imminent risk of nursing home placement as evidenced by the need for observation throughout a 24-hour period and requires limited care to be performed on a daily basis under the supervision of a health professional because of mild mental or physical incapacitation.

Floridians who need nursing home care, but do not qualify for Medicaid, must pay from their own funds or through insurance.

[19] The personal needs allowance (PNA) of an individual is defined as that portion of an individual's income that is protected to meet the individual's personal needs while in an institution. *See* Department of Children and Families, *Glossary (Chapter 4600) "Personal Needs Allowance," p. 19,* http://www.dcf.state.fl.us/programs/access/docs/esspolicymanual/4600.pdf (last visited Jan. 15, 2020).

[20] Department of Children and Families, *SSI-Related Program-Financial Eligibility Standards: January 2019,* http://www.dcf.state.fl.us/programs/access/docs/esspolicymanual/a_09.pdf (last visited Jan. 15, 2020).

Long-Term Care Managed Care

In 2011, HB 7107[21] was signed into law, increasing the use of managed care plans in Medicaid. The law required both Medicaid LTC services and Managed Medical Assistance (MMA) services to be provided through managed care plans.

LTC Managed Care plans participating in SMMC are required to provide minimum benefits that include nursing home care as well as home and community based services. The minimum benefits include:

- Nursing home care;
- Services provided in assisted living facilities;
- Hospice;
- Adult day care;
- Medical equipment and supplies, including incontinence supplies;
- Personal care;
- Home accessibility adaptation;
- Behavior management;
- Home delivered meals;
- Case management;
- Therapies, including physical, respiratory, speech, and occupational;
- Intermittent and skilled nursing;
- Medication administration;
- Medication management;
- Nutritional assessment and risk reduction;
- Caregiver training;
- Respite care;
- Transportation; and
- Personal emergency response system.

III. Effect of Proposed Changes:

Section 1 creates s. 430.84, F.S., and codifies the PACE within the Florida Statutes. Currently, the program does not have an implementing statute and has been operationalized through annual appropriations, proviso, or bills designed to implement the state budget or conform statute to provisions of the state budget.

Program Creation

The bill authorizes the AHCA, in consultation with the DOEA, to approve entities that have submitted the required application and data to the CMS as PACE organizations pursuant to 42 U.S.C. s. 1395eee (2019). Applications, as required by the CMS, will be reviewed by the AHCA on an ongoing basis, in consultation with the DOEA for initial approval as PACE organizations. Notice of applications must be published in the Florida Administrative Register.

[21] Chapter 2011-134, L.O.F.

A prospective PACE organization must submit an application to the AHCA before submitting a request for program funding. An applicant for a PACE program must meet the following requirements:

- Provide evidence that the applicant can meet all of the federal regulations and requirements established by the CMS by the proposed implementation date;
- Provide market studies which include an estimate of the potential number of participants and which show the geographic area the applicant proposes to serve;
- Develop a business plan of operation, including pro forma financial statement and projections based on the planned implementation date;
- Show evidence of regulatory compliance and meet market studies requirements, if the applicant is an existing PACE organization which seeks to expand to an additional service area; and
- Submit its complete federal PACE application to the AHCA and the CMS within 12 months after date of initial state approval. If the organization fails to timely meet this requirement, the state approval of the application is void.

Quality and Reporting

All PACE organizations are required to meet specific quality and performance standards established by the CMS. The AHCA has the responsibility to oversee and monitor Florida's PACE and the contracted organizations through the data and reports submitted periodically to the AHCA and the CMS.

The bill exempts all PACE organizations from the requirements of chapter 641, the chapter of Florida law that regulates health maintenance organizations, prepaid health clinics, and other health care service programs.

Section 2 provides an effective date of July 1, 2020.

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:

Additional private sector providers that meet the criteria to be a PACE organization and achieve eligibility confirmation status could be approved as PACE sites. Expansion of PACE sites would also mean additional individuals in the community would have access to these services.

C. Government Sector Impact:

SB 916 has an indeterminate fiscal impact to the Florida Medicaid Program.

D. Technical Deficiencies:

None.

VI. Related Issues:

In subsection (4) of section 430.84, the bill directs the AHCA to oversee and monitor the PACE program by using data and reports that the PACE organizations submit periodically to the AHCA and CMS. This subsection requires PACE organizations to meet standards established by the CMS. The AHCA is in the process of developing additional state standards for PACE organizations that will allow comparisons and evaluation between the PACE and the Statewide Medicaid Managed Care Long-Term Care (LTC) program. Because bill limits the AHCA's oversight to only CMS standards, the AHCA has indicated that it may not be able to compare PACE and the LTC managed care program and ensure comparable quality and patient outcomes.[22]

VII. Statutes Affected:

This bill creates section 430.84 of the Florida Statutes.

VIII. Additional Information:

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

None.

[22] Agency for Health Care Administration, *Senate Bill 916 Analysis* (Nov. 4, 2019) (on file with the Senate Committee on Health Policy).

B. Amendments:

None.

By Senator Baxley

12-00748A-20 2020916__

A bill to be entitled

An act relating to the Program of All-Inclusive Care for the Elderly; creating s. 430.84, F.S.; defining terms; authorizing the Agency for Health Care Administration, in consultation with the Department of Elderly Affairs, to approve certain applicants to provide benefits pursuant to the Program of All-Inclusive Care for the Elderly (PACE); specifying requirements and procedures for the submission, publication, review, and initial approval of applications; requiring prospective PACE organizations that are granted initial approval to apply within a certain timeframe for federal approval; providing accountability requirements; exempting PACE organizations from certain requirements; providing an effective date.

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

Section 1. Section 430.84, Florida Statutes, is created to read:

430.84 Program of All-Inclusive Care for the Elderly.—

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

(a) "Agency" means the Agency for Health Care Administration.

(b) "Applicant" means an entity that has filed an application with the agency for consideration as a Program of All-Inclusive Care for the Elderly (PACE) organization.

(c) "CMS" means the Centers for Medicare and Medicaid

Services within the United States Department of Health and Human Services.

(d) "Department" means the Department of Elderly Affairs.

(e) "PACE organization" means an entity under contract with the agency to deliver PACE services.

(f) "Participant" means an individual receiving services from a PACE organization and who has been determined by the department to need the level of care required under the state Medicaid plan for coverage of nursing facility services.

(2) PROGRAM CREATION.—The agency, in consultation with the department, may approve entities that have submitted applications required by the CMS to the agency for review and consideration which contain the data and information required in subsection (3) to provide benefits pursuant to the PACE program as established in 42 U.S.C. s. 1395eee and in accordance with the requirements set forth in this section.

(3) PACE ORGANIZATION SELECTION.—The agency, in consultation with the department, shall on a continuous basis review and consider applications required by the CMS for PACE which have been submitted to the agency by entities seeking initial state approval to become PACE organizations. Notice of such applications must be published in the Florida Administrative Register.

(a) A prospective PACE organization shall submit application documents to the agency before requesting program funding. Application documents submitted to and reviewed by the agency, in consultation with the department, must include all of the following:

1. Evidence that the applicant is able to meet all of the

applicable federal regulations and requirements established by the CMS for participation as a PACE organization by the proposed implementation date.

2. Market studies, including an estimate of the number of potential participants and the geographic service area in which the applicant proposes to serve.

3. A business plan of operation, including pro forma financial statements and projections, based on the proposed implementation date.

(b) Each applicant must propose to serve a unique and defined geographic service area without duplication of services or target populations. No more than one PACE organization may be authorized to provide services within any unique and defined geographic service area.

(c) An existing PACE organization seeking authority to serve an additional geographic service area not previously authorized by the agency or the Legislature must meet the requirements set forth in paragraphs (a) and (b).

(d) Any prospective PACE organization that is granted initial state approval by the agency, in consultation with the department, shall submit its complete federal PACE application, in accordance with the application process and guidelines established by the CMS, to the agency and the CMS within 12 months after the date of initial state approval, or such approval is void.

(4) ACCOUNTABILITY.—All PACE organizations must meet specific quality and performance standards established by the CMS for the PACE program. The agency shall oversee and monitor the PACE program and organizations based upon data and reports

periodically submitted by PACE organizations to the agency and the CMS. A PACE organization is exempt from the requirements of chapter 641.

Section 2. This act shall take effect July 1, 2020.

THE FLORIDA SENATE

COMMITTEES:
Ethics and Elections, *Chair*
Appropriations Subcommittee on Education
Education
Finance and Tax
Health Policy
Judiciary

JOINT COMMITTEE:
Joint Legislative Auditing Committee

SENATOR DENNIS BAXLEY
12th District

January 6, 2020

The Honorable Chair Gayle Harrell
310 Senate Office Building
Tallahassee, Florida 32399

Dear Chair Harrell,

I would like to request that SB 916 Program of All-Inclusive Care for the Elderly be heard in the next Health Policy Committee meeting.

This bill authorizes the Agency for Health Care Administration in consultation with the Department of Elderly Affairs to approve a new Program of All-Inclusive Care for the Elderly (PACE) in the state.

Thank you for your favorable consideration.

Onward & Upward,

Senator Dennis K. Baxley
Senate District 12

DKB/dd

cc: Allen Brown, Staff Director

320 Senate Office Building, 404 South Monroe St, Tallahassee, Florida 32399-1100 ● (850) 487-5012
Email: baxley.dennis@flsenate.gov

2020 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

BILL INFORMATION	
BILL NUMBER:	SB 916
BILL TITLE:	Program of All-Inclusive Care for the Elderly
BILL SPONSOR:	Senator Dennis Baxley
EFFECTIVE DATE:	July 1, 2020

COMMITTEES OF REFERENCE
1) Health Policy
2) Appropriations Subcommittee on Health and Human Services
3) Appropriations
4)
5)

CURRENT COMMITTEE
Not Applicable

SIMILAR BILLS	
BILL NUMBER:	Not Applicable
SPONSOR:	Not Applicable

PREVIOUS LEGISLATION	
BILL NUMBER:	SB 778
SPONSOR:	Senator Baxley
YEAR:	2019
LAST ACTION:	Died in Appropriations 5/3/2019

IDENTICAL BILLS	
BILL NUMBER:	HB 833
SPONSOR:	Representative Bob Rommel

Is this bill part of an agency package?
Y ___ N _X__

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	November 14, 2019
LEAD AGENCY ANALYST:	Karen Williams
ADDITIONAL ANALYST(S):	
LEGAL ANALYST:	
FISCAL ANALYST:	Paula McKnight Robinson

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

Senate Bill (SB) 916 creates section 430.84, F.S., which establishes the requirements for an organization seeking approval to operate as a Program of All-Inclusive Care for the Elderly (PACE) in Florida. The bill also establishes requirements related to organization selection and accountability. The language requires prospective PACE organizations to apply to the Agency for Health Care Administration (Agency) for state approval prior to receiving program funding and provides a list of materials applicants must submit as part of the application process. The bill establishes a limit of 1 PACE organization within any defined service area and requires an application submission to CMS within 12 months after the date of initial state approval. SB 916 also requires all PACE organizations to meet the specific PACE quality and performance standards established by the Centers for Medicare and Medicaid Services (CMS). If the bill limits the Agency's oversight to only CMS standards, then the Agency may not be able to compare PACE and the Long-term Care (LTC) managed care program and ensure comparable quality and patient outcomes.

In large part, the changes codify in Florida Statutes the current federal PACE regulations and state operational practices. One difference is that prospective PACE organizations can apply to the Agency without first receiving legislative approval. This may increase the number of PACE applications.

The changes in this bill will have an indeterminate operational and fiscal impact to the Agency as additional staff resources may be needed to complete the PACE application review process if additional PACE organizations apply. There is an indeterminate fiscal impact to the Florida Medicaid program as Agency staff are required to travel to conduct mandatory on-site visits prior to final approval of a PACE application. The travel cost can be absorbed within existing resources.

SB 916 has an effective date of July 1, 2020.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

The Program of All-Inclusive Care for the Elderly (PACE) is a Medicare and Medicaid program that helps people meet their health and long-term care needs in the community instead of going to a nursing home or other care facility. PACE programs primarily organize their services in a PACE Center, which in Florida is licensed as an adult day care center. Participants come to the center, often several times a week, for primary care, nursing, recreation, therapy, supervision, and socialization.

In order to enroll in PACE, federal law requires individuals meet the following criteria:

- Individuals age 55 years or older
- Individuals determined by the state to need the level of care required under the State Medicaid plan for coverage of nursing facility services
- Individuals who reside in the service area of the PACE organization
- Individuals who are able to live in a community setting without jeopardizing their health or safety

Individuals who choose to enroll in PACE have both their medical and long-term care needs managed through a single organization. Here are some of the services PACE covers:

- Adult day care (including doctor, recreational therapy, and nursing services)
- Dentistry
- Emergency services
- Home care
- Hospital care
- Laboratory/x-ray services
- Meals (home-delivered meals and meals provided at the Adult Day Care Center)
- Medical specialty services
- Nursing home care
- Nutritional counseling

- Occupational therapy
- Physical therapy
- Prescription drugs
- Primary care

The Agency for Health Care Administration (Agency) is the single state agency responsible for the administration of the Florida Medicaid and PACE programs; both programs are authorized under Title XIX of the Social Security Act. This authority includes establishing and maintaining a Medicaid State Plan, approved by the federal Centers for Medicare and Medicaid Services (CMS). A Medicaid State Plan is an agreement between a state and the federal government describing how that state administers its Medicaid programs. Within the Medicaid State Plan, states establish and maintain a PACE Program Agreement that is approved by CMS. The PACE Program Agreement is an agreement between a state administering agency, the PACE organization, and the federal government describing how that state administers the PACE program. It establishes the group of individuals covered by each PACE organization and the geographic service area and details covered services, payment methodologies, and other administrative and organizational requirements. The Agency must also maintain compliance with federal regulations necessary to operate the PACE program as funded through the General Appropriations Act and directed by the Florida Legislature.

In addition to services covered under Medicaid, PACE includes all Medicare-covered services for individuals eligible for Medicare (known as dual eligible). For dual eligibles, PACE organizations receive both Medicare and Medicaid capitated payments and are responsible for providing the full continuum of medical and long-term care services. Individuals receive all their services from providers in the PACE network.

Currently, four PACE organizations operate in Florida and provide services to participants within specific ZIP codes in Broward, Miami-Dade, Charlotte, Collier, Lee, Palm Beach, and Pinellas counties. There are 2,245 individuals enrolled in the four Florida PACE organizations. To determine whether prospective enrollees require nursing home level of care, the Department of Elder Affairs Comprehensive Assessment and Review for Long-Term Care Services (CARES) unit performs level of care assessments.

Current Application/Enrollment Process for PACE Organizations

In order to operate as a PACE organization in any state, the PACE organization must meet the requirements as outlined in Code of Federal Regulations (CFR), 42 CFR 460. Federal regulations require a PACE organization to receive approval from CMS to operate.

In order to operate the PACE program in Florida, each service area must have funds appropriated through the General Appropriations Act (GAA) as passed by the Legislature and approved by the Governor each fiscal year. The GAA also includes an allocation of "slots," which is the maximum number of individuals that may be served in each service area. There is currently no formal process for estimating or designating new slots specific to each PACE organization or service location. The lack of methodology needed to accurately determine the appropriate number of slots can complicate the approach of prospective and existing PACE organizations when applying, expanding, and managing current operations, and has sometimes led to under-spending in past fiscal years. Underspending can also occur if the timing of the appropriations do not align with federal approval to operate as a PACE organization.

The following outlines the current process by which PACE program applicants, recognized by the Legislature, can enroll as a PACE provider in Florida:

- The PACE program applicant must notify the Agency, in writing, regarding its intent to apply and must provide a copy of the application to the Agency prior to submitting the application to the Centers for Medicare and Medicaid Services (CMS).
- Applicants must send the Agency all supplemental documentation required in 42 CFR 460 for the application review process. The Agency reviews and verifies that the applicant meets all the requirements. The Agency then forwards the application to CMS with a certification that the State has reviewed and certifies the application is complete and in compliance.

- CMS has an annual application submission window. To meet the CMS application submission deadline, applicants must send the notification, application, and all supplemental documentation to the Agency for review prior to the CMS deadline.

- Per 42 CFR 460.18, CMS evaluates an application for approval as a PACE organization on the basis of the following information: (a) Information contained in the application; (b) Information obtained through onsite visits conducted by CMS or the state administering agency; (c) Information obtained by the state administering agency.
- CMS will either approve or deny the application. CMS may also request additional information in order to make a determination.
- In addition to federal approval, all PACE organizations must enroll as a Medicaid provider and receive an Adult Day Care License through the Agency.

Administration of PACE

To administer PACE, the Agency has an Interagency Agreement with the Department of Elder Affairs (DOEA). The Agency and DOEA coordinate the reviews for initial and service area expansion applications and any proposed amendments to the PACE Program Agreement (see Title 42 Code of Federal Regulations Section 460). The Agency and DOEA also collaborate in the oversight, monitoring, and data collection activities of PACE organizations. DOEA compiles funding and population projections on a monthly basis to ensure the program has reasonable growth capacity. The Agency, in collaboration with CMS, conducts biennial audits of each PACE organization. The PACE organization also submits quarterly reports to CMS on the organizations' quality and performance.

2. EFFECT OF THE BILL:

Senate Bill 916 creates section 430.84, F.S., which codifies the requirements for an organization seeking approval to operate a PACE program in Florida. The bill also establishes requirements related to organization selection and accountability. The language requires prospective PACE organizations to apply to the Agency for state approval prior to receiving program funding. In addition, the bill provides a list of materials applicants must submit as part of the application process.

SB 916 also requires all PACE organizations to meet the specific quality and performance standards established by CMS for PACE. This section establishes requirements related to the PACE program that currently do not exist in state law, but are defined at the federal level through the Federal Code of Regulations (CFR), 42 CFR 460 or are codified in the PACE Program Agreement. The Agency and DOEA already comply with the requirements referenced in the creation of this section. The ability for prospective PACE organizations to submit applications prior to requesting program funding may increase the number of applicants, and additional Agency staff may be needed to complete the PACE application review process if more PACE organizations apply.

SB 916 states that the PACE organization must meet quality and performance standards established by CMS and that the Agency will oversee and monitor the PACE program using data and reports that the PACE organizations submit periodically to the Agency and CMS. The Agency is in the process of developing additional state standards for PACE organizations that will allow comparisons and evaluation between the PACE and the Statewide Medicaid Managed Care (SMMC) Long-Term Care (LTC) program. If the bill limits the Agency's oversight to only CMS standards, then the Agency may not be able to compare PACE and the LTC managed care program and ensure comparable quality and patient outcomes.

SB 916 clarifies that PACE organizations are exempt from Chapter 641, F.S., which is the primary regulatory statutes for health maintenance organizations, prepaid health clinics, and health care services. This change has no impact on the Agency's operational procedures as multiple citations in current law, such as Chapter 2017-129 Laws of Florida, exempt PACE organizations from Chapter 641, F.S..

SB 916 poses an indeterminate operational and fiscal impact to the Agency. An increase in application submissions would require more staff review time and on-site reviews in accordance with 42 CFR 460. This would result in additional travel expenses for the Agency.

This act will take effect on July 1, 2020.

3. DOES THE BILL DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES? Y ___ N _X__

If yes, explain:	
Is the change consistent with the agency's core mission?	Y _X__ N ___
Rule(s) impacted (provide references to F.A.C., etc.):	Not Applicable

4. WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?

Proponents and summary of position:	
Opponents and summary of position:	

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y ___ N __X__

If yes, provide a description:	
Date Due:	
Bill Section Number(s):	

6. ARE THERE ANY GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSION, ETC.? REQURIED BY THIS BILL? Y ___ N _X__

Board:	Not Applicable
Board Purpose:	Not Applicable
Who Appointments:	Not Applicable
Appointee Term:	Not Applicable
Changes:	Not Applicable
Bill Section Number(s):	Not Applicable

FISCAL ANALYSIS

1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT? Y ___ N _X__

Revenues:	Not Applicable
Expenditures:	Not Applicable
Does the legislation increase local taxes or fees? If yes, explain.	No

If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	Not Applicable

2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT? Y _X__ N ___

Revenues:	Not Applicable
Expenditures:	The changes in this bill will have an operational impact to the Agency that can be completed using current Agency resources, and will have an indeterminate fiscal impact to the Florida Medicaid Program. There is an indeterminate number of new recipients that will be eligible for retroactive payments for additional PACE case months. The time between the determination of medical eligibility and financial eligibility may vary causing the number of monthly capitation payments to be indeterminate.
Does the legislation contain a State Government appropriation?	No
If yes, was this appropriated last year?	Not Applicable

3. DOES THE BILL HAVE A THE FISCAL IMPACT TO THE PRIVATE SECTOR? Y __N _X__

Revenues:	
Expenditures:	
Other:	

4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y ___ N _X__

If yes, explain impact.	
Bill Section Number:	

TECHNOLOGY IMPACT

1. DOES THE BILL IMPACT THE AGENCY'S TECHNOLOGY SYSTEMS (I.E. IT SUPPORT, LICENSING SOFTWARE, DATA STORAGE, ETC.)? Y ___ N _X__

If yes, describe the anticipated impact to the agency including any fiscal impact.	

FEDERAL IMPACT

1. DOES THE BILL HAVE A FEDERAL IMPACT (I.E. FEDERAL COMPLIANCE, FEDERAL FUNDING, FEDERAL AGENCY INVOLVEMENT, ETC.)? Y ___ N ___

If yes, describe the anticipated impact including any fiscal impact.	

ADDITIONAL COMMENTS

LEGAL – GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	None.

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/28/20
Meeting Date

SB 916
Bill Number (if applicable)

Topic Program of Inclusive Care for Elders

Amendment Barcode (if applicable)

Name Dorene Barker

Job Title Associate State Director

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Tallahassee FL 32308
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Phone 850 228 6387

Email dobarker@aarp.org

Speaking: ☑ For ☐ Against ☐ Information

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

Representing AARP FL

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

1-28-20 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) 916

Meeting Date *Bill Number (if applicable)*

Topic PACE *Amendment Barcode (if applicable)*

Name Cliff Bauer

Job Title Pres

Address 5200 NE 2nd Ave Phone

Street

Miami FL 33137 Email cbauer@miamijewish health.org

City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information Waive Speaking: ☒ In Support ☐ Against

(The Chair will read this information into the record.)

Representing FL PACE

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)

11/20/19
Meeting Date

9/6
Bill Number (if applicable)

Topic PACE

Amendment Barcode (if applicable)

Name Matt Hudson

Job Title Executive Director Florida PACE Providers Association

Address 9470 Healthpark Cir
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Phone 239 2487107

Ft Myers FL 33908
City *State* *Zip*

Email Matt.Hudson@Flpace.org

Speaking: ☐ For ☐ Against ☒ Information

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

Representing Florida PACE Providers 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

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 1374
INTRODUCER:	Senator Harrell
SUBJECT:	Regional Perinatal Intensive Care Centers
DATE:	January 27, 2020
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Favorable**
2.			AHS	
3.			AP	

I. Summary:

SB 1374 amends several sections of law governing the designation of, and requirements for, regional perinatal intensive care centers (RPICC). The bill expands the maximum number of RPICCs that the Department of Health (DOH) may designate from 11 to 22. The bill also adds additional criteria that the DOH must use when adopting rules for the designation, development, and operation of a RPICC and when selecting and designating new RPICCs.

The bill takes effect July 1, 2020.

II. Present Situation:

Regional Perinatal Intensive Care Centers

History of RPICCs

RPICCs are hospitals that are designated by the DOH to work to improve the outcome of pregnancy and the quality of life from birth. RPICCs provide obstetrical services to women who have a high-risk pregnancy and care for newborns with special health needs, such as critical illness or low birth weight.

The goals of a RPICC include reducing the risk of serious illness for pregnant women and newborns and providing the best medical care to women with high-risk pregnancies and newborns who are sick or born prematurely. Currently, RPICC services are provided at 11 hospitals around the state located in Pensacola, Jacksonville, Gainesville, Orlando, Tampa, St. Petersburg, West Palm, Hollywood, Ft. Lauderdale, Miami, and Ft. Myers, and two obstetrical satellite clinics.[1]

[1] See http://www.floridahealth.gov/programs-and-services/childrens-health/cms-specialty-programs/regional-perinatal-intensive-care-centers-program/index.html (last visited Jan. 16, 2020).

RPICCs were established by the Legislature in 1976 with the intent to prevent neonatal diseases and disabilities that have debilitating, costly, and often fatal consequences.[2] At that time, the Legislature authorized 10 such centers in a geographic area which experiences at least 10,000 live births per year. In 1994, the Legislature added one additional RPICC, bringing the total to 11, and the number of RPICCs has not been increased since.[3]

Current RPICC Requirements

Currently, ss. 383.15-383.19, F.S., establish the requirements for RPICCs. Section 383.17, F.S., allows the DOH to contract with health care providers to establish RPICCs. Section 383.18, F.S., requires that such contracts provide that patients will receive services from the RPICC and that parents or guardians of patients who participate in the program and who comply with Medicaid eligibility requirements, as determined by the DOH, are not additionally charged for treatment and care that has been provided by the RPICC. When determining which hospitals to contract with, the DOH must give priority to establishing RPICCs in hospitals that demonstrate an interest in perinatal intensive care by meeting program standards and may not contract with a private, for-profit hospital that does not accept county, state, or federal funds or indigent patients.[4]

Section 383.19, F.S., requires the DOH to adopt rules to specify standards for RPICCs, including:

- The need to provide services through a RPICC and the requirements of the population to be served.
- Equipment.
- Facilities.
- Staffing and qualifications of personnel.
- Transportation services.
- Data collection.
- Definitions of terms.[5]

Failure to comply with these standards is grounds for the DOH to terminate a RPICC's contract.

RPICC Medicaid Reimbursement

Fee-for-service reimbursement for RPICC services provided to Medicaid recipients is paid according to Medicaid fee schedules (neonatal and obstetrical).

Statute requires that Medicaid reimbursement for in-center obstetrical physician services be based upon the obstetrical care group payment system. Medicaid reimbursement for in-center neonatal physician services is based upon the neonatal care group payment system. These prospective payment systems, developed by the DOH, must place patients into homogeneous groups based on clinical factors, severity of illness, and intensity of care. Payment for outpatient

[2] Chapter 76-54, L.O.F.
[3] Chapter 94-140
[4] Section 383.19(4) and (5), F.S.
[5] See Rules 64C-6.001-6.003, F.A.C.

obstetrical services and other related services, such as consultations, are determined based on the usual Medicaid method of payment for outpatient medical services.[6]

- The payment systems used to fulfill the statute were created and administered by the University of Florida.
- The University of Florida (UF) held a long-running contract with the Agency for Health Care Administration (AHCA) to operate a payment system for physician specialists who provide obstetrical services to women with high-risk pregnancy or who provide care for newborns with special health needs, such as critical illness or low birth weight. UF also hosted a data system to maintain demographic and medical information of Medicaid recipients receiving services in RPICCs.
- The contract with UF ended June 30, 2019, and the AHCA is working with UF to establish a new contract to fulfill the statutory mandate.[7]

In State Fiscal Year 2018-2019, RPICCs were added as an eligible hospital group in the Low Income Pool (LIP). The AHCA created a RPICC-only tier in the LIP model, which allowed a number of hospitals to increase the percentage of their charity care that may be reimbursed under the LIP. This creates an incentive for more hospitals to obtain the RPICC designation.

The base fees for physician services provided in RPICCs are higher than the fees on the non-RPICC physician fee schedule for the same procedure codes. For example, the RPICC base rates for C-sections and vaginal deliveries are 56 percent higher than the physician fee schedule for those procedures.[8]

Comparison				
Procd	Description	Practitioner	RPICC	Percent Difference
59515	C-Section	$ 1,144	$1,785	56.03%
59614	Vaginal Delivery	$ 1,444	$1,785	56.03%

III. Effect of Proposed Changes:

SB 1374 amends various statutes related to RPICCs as follows:

Section 1 of the bill amends s. 383.16, F.S., to add definitions for "agency," meaning the AHCA, and "district," meaning AHCA planning districts as established in s. 408.032, F.S.

Section 4 of the bill amends s. 383.19, F.S., to include levels of care, educational outreach, participation in quality collaborations within and outside a RPICC's district, and support of rural hospitals to the list of standards for which the DOH must adopt rules. The bill also adds additional criteria that the DOH must use to select and designate RPICCs, including:

- Demonstrating a commitment to improving access to health services, including timely use of personal health services to achieve the best health outcomes;

[6] *See* s. 383.19(2), F.S.
[7] Agency for Health Care Administration, Medicaid Comments on Draft RPICC Bill (on file with the Senate Committee on Health Policy).
[8] Id.

- Maintaining a facility birth volume of at least 3,000 live births per year; and
- Actively participating in one or more perinatal quality collaborations as defined by the DOH in rule.

The bill increases the maximum number of RPICCs allowed to be designated from 11 to 22. The DOH is required to designate at least one RPICC in each of the AHCA planning districts[9] and one additional RPICC in any district in which 20,000 or more resident live births occur per year.[10]

The bill also specifies that Medicaid reimbursements for services provided to members of a managed care plan must be paid in accordance with the provider payment provisions of part IV of ch. 409, F.S. (Medicaid Managed Care) and that fee-for-service reimbursements must be based upon obstetrical or neonatal group payment systems developed by the DOH, as applicable.

The bill also requires the DOH, in consultation with the AHCA, to develop and implement a statewide process to engage perinatal stakeholders for the purpose of determining appropriate and efficacious levels of maternal care provided by RPICCs. The process must be completed no later than July 1, 2023, and must seek to standardize RPICCs internal assessments of levels of maternal care guided by methodologies and tools developed by the federal Centers for Disease Control and Prevention.

Sections 2, 3, 5, and 6 of the bill amend ss. 383.17, 383.18, 409.908, and 409.967, F.S., to make clarifying, conforming, and technical changes.

The bill takes effect July 1, 2020.

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.

[9] AHCA planning districts are established in s. 408.032, F.S.
[10] Based on 2018 birth rates, available from the DOH (http://www.flhealthcharts.com/charts/default.aspx), AHCA districts 4, 6, 7, 9, 10, and 11 have a sufficient volume of births to require the DOH to designate a second RPICC in those districts.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 1374 may have an indeterminate positive fiscal impact on facilities and providers that are newly designated to provide RPICC services.

C. Government Sector Impact:

The bill may have an indeterminate negative fiscal impact on the state since the bill increases the number of RPICCs that may be designated and which may receive enhanced reimbursement rates from the Medicaid program.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 383.16, 383.17, 383.18, 383.19, 409.908, and 409.975.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Harrell

25-01225B-20 20201374__

A bill to be entitled

An act relating to regional perinatal intensive care centers; amending s. 383.16, F.S.; defining and revising terms; amending s. 383.17, F.S.; authorizing the Department of Health to designate regional perinatal intensive care centers; amending s. 383.18, F.S.; providing that designation by the department is required for participation in the regional perinatal intensive care centers program; amending s. 383.19, F.S.; specifying standards that must be included in department rules relating to the designation, development, and operation of a regional perinatal intensive care center; authorizing the department to designate two regional perinatal intensive care centers in a district under certain circumstances; specifying reimbursement parameters for certain services provided in a regional perinatal intensive care center setting; providing parameters for removal of a regional perinatal intensive care center's designation; specifying criteria centers must meet for the department's selection and designation as regional perinatal intensive care centers; requiring the department, in consultation with the agency, to develop and implement a process by a specified date to determine levels of maternal care provided by regional perinatal intensive care centers; revising the contents of certain annual reports that regional perinatal intensive care centers are required to submit to the department; requiring the department to

conduct an onsite review of each center at least once every 3 years; amending s. 409.908, F.S.; conforming provisions to changes made by the act; amending s. 409.975, F.S.; conforming a cross-reference; providing an effective date.

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

Section 1. Present subsections (1), (2), and (3) of section 383.16, Florida Statutes, are redesignated as subsections (2), (4), and (5), respectively, new subsections (1) and (3) are added to that section, and present subsection (2) of that section is amended, to read:

383.16 Definitions; ss. 383.15-383.19.—As used in ss. 383.15-383.19, the term:

(1) "Agency" means the Agency for Health Care Administration.

(3) "District" has the same meaning as in s. 408.032.

(4)~~(2)~~ "Regional perinatal intensive care center" or "center" means a unit designated by the department, located within a hospital, and specifically designed to provide a full range of perinatal health services to its patients.

Section 2. Section 383.17, Florida Statutes, is amended to read:

383.17 Regional perinatal intensive care centers program; authority.—The department may designate and contract with health care providers in establishing and maintaining centers in accordance with ss. 383.15-383.19. The cost of administering the regional perinatal intensive care centers program shall be paid

by the department from funds appropriated for this purpose.

Section 3. Section 383.18, Florida Statutes, is amended to read:

383.18 Designations; contracts; conditions.—Participation in the regional perinatal intensive care centers program under ss. 383.15-383.19 is contingent upon the department designating and entering into a contract with a provider. The contract must ~~shall~~ provide that patients will receive services from the center and that parents or guardians of patients who participate in the program and who are in compliance with Medicaid eligibility requirements as determined by the department are not additionally charged for treatment and care that ~~which~~ has been contracted for by the department. Financial eligibility for the program is based on the Medicaid income guidelines for pregnant women and for children younger than ~~under~~ 1 year of age. Funding must ~~shall~~ be provided in accordance with ss. 383.19 and 409.908.

Section 4. Section 383.19, Florida Statutes, is amended to read:

383.19 Standards; funding; ineligibility.—

(1) The department shall adopt rules that specify standards for designation, development, and operation of a center which must include, but need not be ~~are not~~ limited to:

(a) The need to provide services through a regional perinatal intensive care center and the requirements of the population to be served.

(b) Equipment.

(c) Facilities.

(d) Staffing and qualifications of personnel.

(e) Transportation services.

(f) Data collection.

(g) Levels of care.

(h) Educational outreach.

(i) Access to consultative specialist services.

(j) Participation in quality collaborations, both within and outside of the center's district.

(k) Support of rural hospitals, as defined in s. 395.602.

(l) ~~(g)~~ Definitions of terms.

(2) The department shall designate at least one center to serve a geographic area representing each district ~~region~~ of the state, and one additional center may be designated in any district in which at least 20,000 resident ~~10,000~~ live births occur per year, as reported by the department's Bureau of Vital Statistics, but in no case may there be more than 22 ~~11~~ regional perinatal intensive care centers established unless specifically authorized in the General Appropriations Act or in this subsection.

(3) Medicaid reimbursement must ~~shall~~ be made for services provided to patients who are Medicaid recipients. Medicaid reimbursement for in-center and outpatient obstetrical and neonatal physician services must be paid as follows:

(a) Reimbursement for such services provided at centers to members of a managed care plan as defined in s. 409.962 must be paid in accordance with the provider payment provisions of part IV of chapter 409; or

(b) Reimbursement for such services provided at centers on a fee-for-service basis must ~~shall~~ be based upon the obstetrical care group payment system or~~. Medicaid reimbursement for in-~~

~~center neonatal physician services shall be based upon~~ the neonatal care group payment system, as applicable. These prospective payment systems, developed by the department, must place patients into homogeneous groups based on clinical factors, severity of illness, and intensity of care. ~~Outpatient obstetrical services and other~~ Related services provided on a fee-for-service basis, such as consultations, must ~~shall~~ be reimbursed based on the usual Medicaid method of fee-for-service payment for such ~~outpatient~~ medical services.

(4) ~~(3)~~ Failure to comply with any standard ~~the standards~~ established under this section, department rules, or the terms of the contract between the department and a center constitutes grounds for terminating the contract and removal of the center's designation.

(5) ~~(4)~~ The department shall select and designate centers that do all of the following: ~~give priority to establishing centers in hospitals that~~

(a) Demonstrate an interest in perinatal intensive care by meeting program standards established in this section and by the department.

(b) Demonstrate a commitment to improving access to health services, including the timely use of personal health services to achieve the best health outcomes.

(c) Maintain a facility birth volume of at least 3,000 live births per year.

(d) Actively participate in one or more perinatal quality collaborations as defined by department rule.

(6) No later than July 1, 2023, the department, in consultation with the agency, shall develop and implement a

statewide process to engage perinatal stakeholders for the purpose of determining appropriate and efficacious levels of maternal care provided by centers. The statewide process must seek to standardize the centers' internal assessments of levels of maternal care guided by methodologies and tools developed by the federal Centers for Disease Control and Prevention.

(7) ~~(5)~~ A private, for-profit hospital that does not accept county, state, or federal funds or indigent patients is not eligible to participate under ss. 383.15-383.19.

(8) ~~(6)~~ Each hospital that is designated by and contracts with the department to provide services under the terms of ss. 383.15-383.19 shall prepare and submit to the department an annual report that includes, but is not limited to, the number of clients served, quality improvement measures and projects that the center has engaged in, and the costs of services in the center. The department shall annually conduct a programmatic and financial evaluation of each center and shall conduct an onsite review of each center at least once every 3 years.

Section 5. Paragraph (c) of subsection (12) of section 409.908, Florida Statutes, is amended to read:

409.908 Reimbursement of Medicaid providers.—Subject to specific appropriations, the agency shall reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in the rules of the agency and in policy manuals and handbooks incorporated by reference therein. These methodologies may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding pursuant to s. 287.057, and other mechanisms the agency considers efficient and effective for purchasing services or

goods on behalf of recipients. If a provider is reimbursed based on cost reporting and submits a cost report late and that cost report would have been used to set a lower reimbursement rate for a rate semester, then the provider's rate for that semester shall be retroactively calculated using the new cost report, and full payment at the recalculated rate shall be effected retroactively. Medicare-granted extensions for filing cost reports, if applicable, shall also apply to Medicaid cost reports. Payment for Medicaid compensable services made on behalf of Medicaid eligible persons is subject to the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216. Further, nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act, provided the adjustment is consistent with legislative intent.

(12)

(c) Notwithstanding paragraph (b), reimbursement fees to physicians for providing total obstetrical services to Medicaid recipients, which include prenatal, delivery, and postpartum care, shall be at least $1,500 per delivery for a pregnant woman with low medical risk and at least $2,000 per delivery for a pregnant woman with high medical risk. However, reimbursement to physicians working in regional perinatal intensive care centers designated pursuant to chapter 383, for services to certain pregnant Medicaid recipients with a high medical risk, must ~~may~~

be made according to s. 383.19(3) ~~obstetrical care and neonatal care groupings and rates established by the agency~~. Nurse midwives licensed under part I of chapter 464 or midwives licensed under chapter 467 shall be reimbursed at no less than 80 percent of the low medical risk fee. The agency shall by rule determine, for the purpose of this paragraph, what constitutes a high or low medical risk pregnant woman and shall not pay more based solely on the fact that a caesarean section was performed, rather than a vaginal delivery. The agency shall by rule determine a prorated payment for obstetrical services in cases where only part of the total prenatal, delivery, or postpartum care was performed. The Department of Health shall adopt rules for appropriate insurance coverage for midwives licensed under chapter 467. Prior to the issuance and renewal of an active license, or reactivation of an inactive license for midwives licensed under chapter 467, such licensees shall submit proof of coverage with each application.

Section 6. Paragraph (b) of subsection (1) of section 409.975, Florida Statutes, is amended to read:

409.975 Managed care plan accountability.—In addition to the requirements of s. 409.967, plans and providers participating in the managed medical assistance program shall comply with the requirements of this section.

(1) PROVIDER NETWORKS.—Managed care plans must develop and maintain provider networks that meet the medical needs of their enrollees in accordance with standards established pursuant to s. 409.967(2)(c). Except as provided in this section, managed care plans may limit the providers in their networks based on credentials, quality indicators, and price.

(b) Certain providers are statewide resources and essential providers for all managed care plans in all regions. All managed care plans must include these essential providers in their networks. Statewide essential providers include:

1. Faculty plans of Florida medical schools.

2. Regional perinatal intensive care centers as defined in s. 383.16(4) ~~s. 383.16(2)~~.

3. Hospitals licensed as specialty children's hospitals as defined in s. 395.002(27).

4. Accredited and integrated systems serving medically complex children which comprise separately licensed, but commonly owned, health care providers delivering at least the following services: medical group home, in-home and outpatient nursing care and therapies, pharmacy services, durable medical equipment, and Prescribed Pediatric Extended Care.

Managed care plans that have not contracted with all statewide essential providers in all regions as of the first date of recipient enrollment must continue to negotiate in good faith. Payments to physicians on the faculty of nonparticipating Florida medical schools shall be made at the applicable Medicaid rate. Payments for services rendered by regional perinatal intensive care centers shall be made at the applicable Medicaid rate as of the first day of the contract between the agency and the plan. Except for payments for emergency services, payments to nonparticipating specialty children's hospitals shall equal the highest rate established by contract between that provider and any other Medicaid managed care plan.

Section 7. This act shall take effect July 1, 2020.

Medicaid Comments on Draft RPICC Bill

Current Reimbursement Structure

RPICCs are reimbursed for services provided to Medicaid recipients in the fee-for-service delivery system through Medicaid fee schedules (neonatal and obstetrical).

- Statute requires that Medicaid reimbursement for in-center obstetrical physician services shall be based upon the obstetrical care group payment system. Medicaid reimbursement for in-center neonatal physician services shall be based upon the neonatal care group payment system. These prospective payment systems, developed by the Department of Health, must place patients into homogeneous groups based on clinical factors, severity of illness, and intensity of care. Outpatient obstetrical services and other related services, such as consultations, shall be reimbursed based on the usual Medicaid method of payment for outpatient medical services.
    - The payment systems used to fulfill the statute were created and administered by the University of Florida.
    - The University of Florida held a long-running contract with the Agency to operate a payment system for physician specialists who provide obstetrical services to women with high-risk pregnancy or who provide care for newborns with special health needs, such as critical illness or low birth weight. UF also hosted a data system to maintain demographic and medical information of Medicaid recipients receiving services in RPICCs.
    - The contract with UF ended 6/30/19, and the Agency is working with UF to establish a new contract to fulfill the statutory mandate.

In state fiscal year 2018-19 RPICCs were added as an eligible hospital ownership group in the Low Income Pool (LIP). Based on this, the Agency created a RPICC only tier in the LIP model, which allowed a number of hospitals to increase the percentage of their charity care that is covered by the LIP. This creates an incentive for more hospitals to obtain the RPICC designation.

Impact Review

The proposed bill is amending multiple portions of the Florida Department of Health's statute to allow flexibility for the Department of designate and contract with providers to render these services. Additionally, the proposed bill details additional requirements for the Department to require of RPICCs, including levels of care and outreach. These changes do not have an impact on Florida Medicaid coverage or reimbursement.

While the Agency's role is limited to coverage and reimbursement of RPICC facilities and services, the Department has a more active role including licensure, quality improvement, and reporting.

The proposed language permits up to 22 centers statewide, doubling the current limitation of 11 centers. Additionally, the proposed bill requires a new Florida Medicaid reimbursement methodology of inpatient, outpatient, and physician RPICC services in these centers, titled "managed medical assistance methodologies". This change is statute would eliminate the contract with the University of Florida. The bill text is unclear and does not provide a definition nor parameters of the new methodology of inpatient, outpatient, and physician covered and reimbursed RPICC services. The Agency pays plans a capitated payment rate and the plans may negotiate mutually acceptable rates with the individual providers.

If the intent of the bill is to create a new global methodology for both centers and physician services by

way of one global payment, this has an operational and fiscal impact on the Agency. Operational impacts include methodology design, as well as updates to Agency authorities, rules, fee schedules, and system edits. Additionally, the bill language does not modify Chapter 409, F.S. to mandate health plans to follow a prescribed reimbursement methodology. Unknown fiscal impacts include updates to the inpatient, outpatient, and practitioner methodology.

The RPICC base fees are higher than the fees on the physician fee schedule for the same procedure codes. Removing the RPICC specific fee schedule may reduce the Medicaid expenditures for the services on the fee schedules.

Below is a comparison of the highest fee per procedure code on the RPICC fee schedule and the highest fee on the Physician fee schedule for comparable codes. (There are no comparable procedure codes on the neonatal RPICC fee schedule and the physician fee schedule.)

Comparison				
Procd	Description	Practitioner	RPICC	Percent Difference
59515	C-Section	$ 1,144.00	$1,785.00	56.03%
59614	Vaginal Delivery	$ 1,144.00	$1,785.00	56.03%

The total expenditures for RPICC physician fee schedules for SFY 2018-19 are below. Please note that additional services are provided in RPICCs that are not included on this particular fee schedule. These expenditures will shift to the physician fee schedule rather than the RPICC fee schedule based on the changes proposed in the bill.

Obstetrical					
Procd	Mod	Description	FFS Expend	Encounter Expend	Total
59410	TG	Vaginal delivery with post-delivery care	$ 1,209,882	$ 2,144,051	$3,353,933
59515	TG	Cesarean delivery with post-delivery care	$ 1,216,412	$ 2,399,811	$3,616,223
59614	TG	Vaginal delivery after prior cesarean delivery with post-delivery care	$ 12,272	$ 57,834	$ 70,106
59430	TG	Post-delivery care	$ -	$ 3,716	$ 3,716
Total			**$ 2,438,566**	**$ 4,605,412**	**$7,043,978**

Neonatal					
Procd	Mod	Description	FFS Expend	Encounter Expend	Total
99499	TG	Evaluation and management service	$ 251,939	$ 92,032	$ 343,971
Total			**$ 251,939**	**$ 92,032**	**$ 343,971**

Notes:

-Data provided by Medicaid Data Analytics.

-Data provided is SFY 2018-19 by date of service.

This bill may allow additional facilities to be designated as RPICCs. This may impact the LIP model by including additional hospitals in the RPICC tier.

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/28/20
Meeting Date

1374
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic SB 1374

Name David Robinson

Job Title President FL Chapter AAP

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing FL Chapter AAP

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)

OPPAGA Review of Florida's Organ Donation and Transplantation System

Presentation to the Senate Committee on Health Policy

Becky Vickers, Chief Legislative Analyst

OPPAGA

Office of Program Policy Analysis and Government Accountability

JANUARY 28, 2020

Project Scope

OPPAGA examined Florida's organ donation and transplantation system and addressed the following

- Description of the organ donation and transplantation system
- Florida's performance in donor registration over time
- Projected impact on Florida of changes to national organ allocation policies
- Factors that enhance organ transplant success
- Challenges associated with organ donation and transplantation in Florida
- Legislation other states have passed to improve organ availability
- Options the Legislature could consider to improve organ availability in Florida

Roles of Federal Entities in the Organ Donation and Transplantation System

Federal Entities

U.S. Department of Health and Human Services

- Oversees the two federal agencies responsible for regulating organ procurement and transplantation (CMS & HRSA)

Centers for Medicare and Medicaid Services (CMS)

- Monitors procurement and transplant program success and quality

Health Resources and Services Administration (HRSA)

- Oversees the Organ Procurement and Transplantation Network and contractors (United Network for Organ Sharing and Scientific Registry of Transplant Recipients)

Private/Nonprofit Entities

Organ Procurement and Transplantation Network (OPTN)

- Maintains a national registry for organ matching and carries out numerous other responsibilities relating to organ procurement and transplantation

United Network for Organ Sharing (UNOS)

- Operates OPTN under contract with HRSA

Scientific Registry of Transplant Recipients

- Provides statistical and other analytic support to OPTN for the formulation and evaluation of organ allocation

Roles of State Entities in the Organ Donation and Transplantation System

Entity	Level	Role Within the Organ Donation and Transplantation System
Agency for Health Care Administration	State	Contracts with Donate Life Florida for online donor registration and education; coordinates with DHSMV to obtain donor registry funding; certifies and monitors organ procurement organizations for compliance and collects fees
Donate Life Florida	Private/ Nonprofit	Contracts with AHCA to operate a statewide online donor registry and provide donor education
Department of Highway Safety and Motor Vehicles	State	Coordinates with county tax collector offices; encourages and registers organ donors; provides donor educational materials; collects voluntary financial contributions to the donor registry
County Tax Collector Offices	Local	Encourage and register organ donors when issuing identification cards and driver licenses; may provide donor educational materials; collect voluntary financial contributions to the donor registry
Organ Procurement Organizations (OPOs) (Certified by CMS)	Regional Within the State	Follow policies set by CMS and OPTN; primarily responsible for procuring organs and matching donor organs to patients on waitlists and coordinating with hospital transplant centers for transport of matched organs
Transplant Centers	Local/Private/ Nonprofit	Evaluate patients to determine eligibility to be placed on waitlists and suitability of and procuring organs at donor hospitals after being contacted by an OPO; perform transplant surgeries and pre- and post-transplant care
Donor Hospitals	Local/ Private/ Nonprofit	Responsible for timely notification of OPO in their region of death or imminent death of a patient who is a viable organ donor

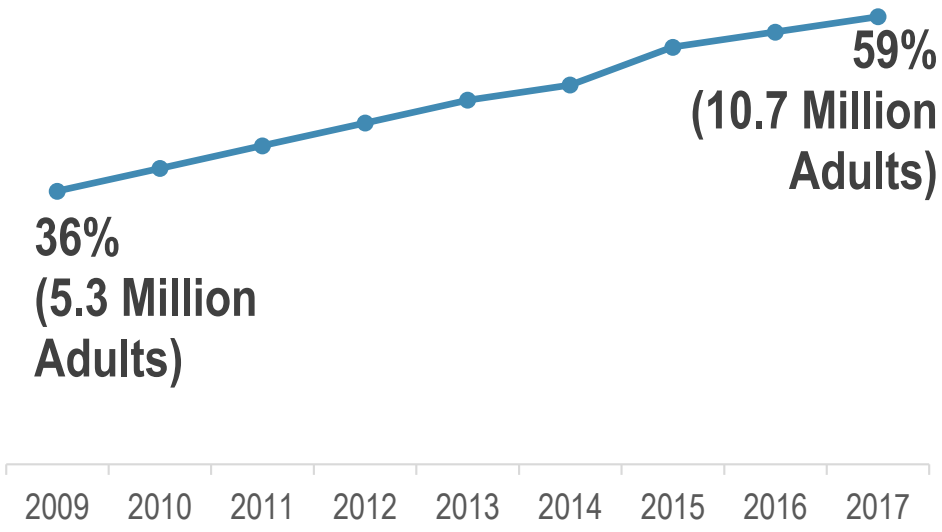
Key Findings

- Florida's donor registration rate has increased over time and compares favorably to peer states, but there is room for improvement
- National organ allocation policy changes will negatively affect Florida's supply of kidneys and livers
- Factors contributing to transplant success include multidisciplinary teams and higher volume at transplant centers
- Stakeholder-identified challenges include misunderstanding or lack of support for organ donation and needing financial support for living donation
- AHCA's statutory fees exceed its costs; the excess could be used for donor education
- To increase organ availability, other states have passed legislation to support living donation and increase donor registration

Florida's Donor Registration Rate Has Increased and Compares Favorably to Peer States

Donor Registration Rate

Florida's donor registration rate has increased from 36% of adults 18 and older in 2009 to 59% in 2017



Peer State Comparison

Florida performs better than its peer states in national rank for donor registrations

State	National Rank for Donor Registrations
Florida	33
Texas	41
California	44
Pennsylvania	45
New York	50

OPTN Policy Changes Affect Organ Allocation Nationally

In the past few years, OPTN has attempted to address a perceived equity issue in the allocation of organs

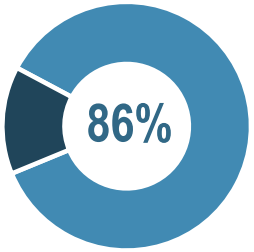
- Allocation was traditionally based on OPO donation service areas (DSAs) or OPTN regions

Since 2017, OPTN committees have made or adopted proposals to change organ allocation policies for lungs, livers, hearts, kidneys, and pancreases

- These policies change from allocating organs based on wait lists within DSAs or regions to allocating organs based on wait lists within nautical mile circles around donor hospitals (250 to 500 nautical miles, depending on the policy)
- The lung and heart policies have been implemented, while the kidney and pancreas policies are approved and awaiting implementation
- The liver allocation proposal was on hold due to a lawsuit, but based on a recent court decision, OPTN has announced it is moving forward

UNOS Estimates That Policy Changes Will Negatively Affect Florida's Allocation of Kidneys and Livers

Organ	Annual Number of Transplants Pre-Change	Annual Number of Transplants Post-Change	Difference	Percentage Difference
Lung—Actual Volume over 1.5 Years	248	302	+54	+22%
—Projected Average	245	262	+17	+7%
Heart—Projected Average	273	294	+21	+8%
Kidney-Pancreas—Projected Average	46	64	+18	+39%
Liver—Projected Average	459	408	-51	-11%
Kidney—Projected Average	738	558	-180	-24%



As of June 2019, 4,706 people on Florida wait lists were waiting for a kidney, which represents the vast majority (86%) on wait lists

- An additional 9% were waiting for a liver

Stakeholders and Research Studies Identified Several Factors Contributing to Post-Transplant Success

- Multidisciplinary teams
  - Multidisciplinary teams bring together a variety of skills to treat patients pre- and post-transplant

- Higher volume
  - Several surgeons reported that higher volume is associated with better outcomes
  - Many academic studies conclude that volume and patient outcomes are positively related but do not identify consistent minimum volume thresholds
  - OPPAGA Report No. 19-11 recommended that the Legislature consider directing AHCA to create an advisory panel of transplant hospital representatives to examine clinical research and data and develop recommended volume thresholds

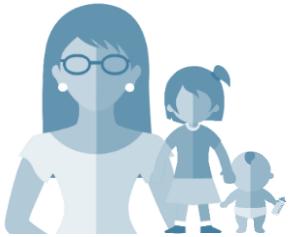
- Other factors identified in academic research
  - Include patient demographics and health characteristics or hospital and center-specific characteristics, such as staffing ratios and surgeon skill

- Post-transplant care
  - Access to needed medications, adhering to medication schedules, regular follow-up care, and maintaining a healthy lifestyle

Stakeholders Identified Several Challenges to Florida's System

Misunderstanding or lack of support for organ donation

Needing financial support to cover the costs incurred by living donors



Issues in hospital communication with families

Lack of consistent organ donation education in tax collector offices

AHCA's Fees and Revenues are Designed to be Used for Multiple Purposes, Including Education

AHCA collects fees from OPOs and tissue and eye banks

- Statutes require AHCA to use the fees to cover its regulatory costs for these entities, support the donor registry and donor education, and the costs of an advisory board that no longer meets

AHCA collected **$670,039** in fees for FY 2018-19, but only spent **$78,228** on regulating OPOs and tissue and eye banks

AHCA paid Donate Life Florida the revenues DHSMV and county tax collectors collected in voluntary contributions and left the excess revenues in its trust fund

- Donate Life Florida operates the state's donor registry and provides donor education under contract with AHCA

States Have Passed Legislation to Address Living Organ Donation and Improve Registration

To improve organ availability through living organ donation

- Require certain employers to offer paid leave to living organ donors
- Offer tax credits or tax deductions to living donors or to employers who allow employees a leave of absence for living organ donation
- Prohibit insurance providers from denying coverage to living donors based solely on their status as living donors

To improve donor registration

- Focus on education and public awareness of donor registration
- Expand the opportunities to register as an organ donor

Legislative Options to Improve Organ Availability

- Increase the rate of living organ donation
- Increase public support for organ donation
- Increase the number of registered donors

Florida Legislative Options to Improve Organ Availability

- Education
  - Increase public education about both living and deceased organ donation
  - Add the topic of organ donation to continuing education requirements for health care professionals and to high school curriculum requirements (e.g., health science classes)
- Employers

  - Offer employers a corporate income tax or insurance premium tax credit for expenses incurred related to paying an employee or obtaining temporary assistance during the employee's leave of absence for living organ donation
  - Require state and local government employers to offer paid leave for living organ donation
- Coverage

  - Allow Medicaid to cover medical expenses incurred by living organ donors
  - Prohibit insurers from denying coverage to living organ donors based solely on their status as living donors

Florida Legislative Options to Improve Organ Availability

- Funding
  - Direct AHCA to use all excess revenues from fees paid by OPOs and tissue and eye banks for public education on donation

- Registration
  - Require county tax collectors to allow prominent display of organ donation educational materials in their offices
  - Expand the opportunities to register as an organ donor to include additional points of access such as hunting and fishing licenses and state agency webpages

Summary

Organ Allocation	National organ allocation policy changes will negatively affect Florida's supply of kidneys and livers; most people on Florida wait lists (86%) need kidneys
Transplant Success	Post-transplant success can be enhanced by multidisciplinary teams and higher volume at transplant centers
Barriers	Challenges stakeholders identified include misunderstanding or lack of support for organ donation and living donors needing financial support to cover their costs
Other States	To increase organ availability, other states have implemented legislation to support living organ donation and increase donor registration

Summary of Legislative Options for Consideration

- Education
  - Increase public education about both living and deceased organ donation
  - Add the topic of organ donation to education requirements for health care professionals and to high school curriculum requirements

- Employers
  - Offer employers tax credits for expenses related to employees acting as living donors
  - Require state and local government employers to offer paid leave for living organ donation

- Coverage
  - Allow Medicaid to cover living donor medical expenses
  - Prohibit insurers from denying coverage to living organ donors

- Funding
  - Direct AHCA to use all excess revenues from fees paid by OPOs and tissue and eye banks for public education on donation

- Registration
  - Require county tax collectors to allow prominent display of organ donation educational materials in their offices
  - Expand the opportunities to register as an organ donor to include additional points of access such as hunting and fishing licenses and state agency webpages

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FLORIDA LEGISLATURE OFFICE OF PROGRAM POLICY ANALYSIS AND GOVERNMENT ACCOUNTABILITY

OPPAGA supports the Florida Legislature by providing data, evaluative research, and objective analyses that assist legislative budget and policy deliberations.

OPPAGA
Office of Program Policy Analysis and Government Accountability
Research Memorandum

January 22, 2020

OPPAGA Review of Florida's Organ Donation and Transplantation System

SCOPE

As directed by the Legislature, OPPAGA examined Florida's organ donation and transplantation system, including its performance, challenges, and opportunities for improvement. This research memorandum provides background information on the system, federal and state policy changes, and stakeholder revenues and costs. The memo addresses seven questions.

1. How does the organ donation and transplantation system function and what are the roles of its key players?
2. How have federal and state organ donation and transplantation policies changed over the past 25 years?
3. What are the projected impacts on Florida of changes to OPTN national organ allocation policies?
4. How has Florida's organ donation and transplantation system performed over time and in comparison to other states?
5. What factors enhance transplant success and what challenges are associated with organ donation and transplantation?
6. What policies have other states and countries pursued to improve organ availability?
7. What options could the Legislature consider to improve organ availability in Florida?

SUMMARY

The organ donation and transplantation system consists of an extensive network of federal, state, and local entities, as well as individual organ donors, recipients, and individuals on organ transplant waitlists. The process of organ donation relies on coordination among these entities to match organs from donors to individuals on organ transplant waitlists.

Two federal agencies oversee all organ transplant programs across the U.S. At the state level, the Agency for Health Care Administration (AHCA), the Department of Highway Safety and Motor Vehicles (DHSMV), county tax collectors, four Organ Procurement Organizations (OPOs), 12 transplant centers, and donor hospitals comprise the state's organ donation and transplantation system. (See Exhibit 1.)

Exhibit 1
Multiple Entities at the Federal, State, Regional, Local, and Private Levels Participate in the Oversight and Implementation of Florida's Organ Donation and Transplantation System

Entity	Level	Role Within the Organ Donation and Transplantation System
U.S. Department of Health and Human Services	Federal	Oversees the two federal agencies responsible for organ procurement and transplantation regulation
Centers for Medicare and Medicaid Services (CMS)	Federal	Monitors procurement and transplant program success and quality
Health Resources and Services Administration (HRSA)	Federal	Oversees the Organ Procurement and Transplantation Network and contractors (United Network for Organ Sharing and Scientific Registry of Transplant Recipients)
Scientific Registry of Transplant Recipients	Private/Nonprofit	Provides statistical and other analytic support to OPTN for the formulation and evaluation of organ allocation
Organ Procurement and Transplantation Network (OPTN)	Private/Nonprofit	Maintains a national registry for organ matching and carries out numerous other responsibilities relating to organ procurement and transplantation
United Network for Organ Sharing (UNOS)	Private/Nonprofit	Operates OPTN under contract with HRSA
Agency for Health Care Administration	State	Contracts with Donate Life Florida for online donor registration and education system; coordinates with DHSMV to obtain donor registry funding; certifies and monitors organ procurement organizations for compliance and collects fees
Donate Life Florida	Private/Nonprofit	Contracts with AHCA to operate a statewide online donor registry and to provide donor education
Department of Highway Safety and Motor Vehicles	State	Coordinates with county tax collector offices where donor education and registration occur when issuing driver licenses and identification cards; encourages and registers organ donors when issuing identification cards and driver licenses; provides donor educational materials; collects voluntary financial contributions to donor registry
County Tax Collector Offices	Local	Encourage and register organ donors when issuing identification cards and driver licenses; may provide donor educational materials; collect voluntary financial contributions to donor registry
Organ Procurement Organizations (Certified by CMS)	Regional Within the State	Follow policies set by CMS and OPTN; primarily responsible for procuring organs and matching donor organs to patients on waitlists and coordinating with hospital transplant centers for transport of matched organs
Transplant Centers	Local/Private/ Nonprofit	Evaluate patients to determine eligibility to be placed on waitlists and suitability of and procuring organs at donor hospitals after being contacted by an OPO; perform transplant surgeries and conduct pre- and post-transplant care
Donor Hospitals	Local/ Private/ Nonprofit	Responsible for timely notification of OPO in their region of death or imminent death of a patient who is a viable organ donor

Source: OPPAGA analysis of state and federal laws and rules and stakeholder interviews.

Florida has improved its rate of donor registration over time, and the number of organ transplants performed has increased. The state compares favorably to the rest of the nation in how quickly people on waitlists receive transplants but fares similarly or worse in mortality rates. Federal and state policies related to the organ donation and transplantation system have been modified over the years, and recent federal policy changes have potential positive and negative impacts for Florida. Since 2017, OPTN committees have made or adopted proposals to change allocation policies for lungs, livers, hearts, kidneys, and pancreases. UNOS projections indicate that these changes would have positive impacts on Florida for lung, heart, and kidney-pancreas transplants, but the changes would have

negative impacts for kidney and liver transplants.[1] These policy changes are particularly important for Florida due to the fact that kidney and liver transplants are the most common types of transplants in the state. In addition, Florida's population age 65 and above is projected to continue to increase, and individuals in this age group in Florida have a higher rate of kidney transplants than the U.S. as a whole.[2]

Factors that may lead to higher transplant success rates include multidisciplinary teams, volume, patient demographics and hospital and center characteristics, post-transplant care, and regulation of the organ transplantation system. Our research also identified some of the challenges regarding organ donation and transplantation. These challenges include misunderstanding or lack of support for organ donation; need for financial support to cover the costs incurred by living donors; and hospital personnel mishandling communication with families. Other states have considered or adopted legislation to increase organ donor availability through policies to increase both the number of living donors and registered organ donors. Other countries have implemented policies that aim to increase organ donation and availability rates and decrease the time patients spend on waitlists. We present options for the Legislature's consideration to improve organ availability in Florida by increasing the rate of living donation and increasing organ donor registration.

QUESTIONS AND ANSWERS

How Does the Organ Donation and Transplantation System Function and What Are the Roles of Its Key Players?

Federal Entities' Roles

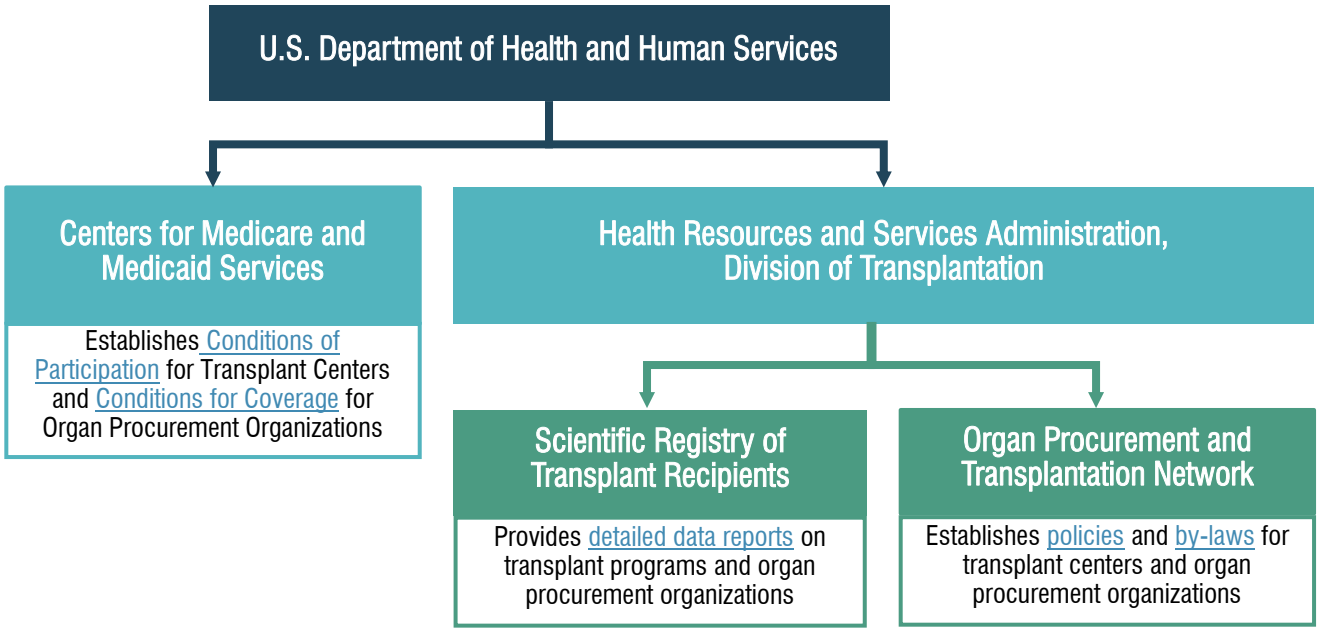
The Centers for Medicare and Medicaid Services and the Organ Procurement and Transplantation Network are the primary federal agencies with oversight of organ transplantation policies and practices. At the federal level, two agencies in the U.S. Department of Health and Human Services (HHS) oversee organ transplant programs: the Centers for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA). CMS monitors transplant program success and quality, holds transplant centers accountable through its published Medicare Conditions of Participation, and requires all transplant centers to develop, implement, and maintain a written, comprehensive, data-driven quality assessment and performance improvement program designed to monitor and evaluate performance of all of their transplantation services. CMS has also established extensive requirements for organ procurement organizations (OPOs). There are 58 OPOs in the U.S. that are responsible for working with donor hospitals to help place donor organs for transplant. CMS requirements for OPOs are designed to ensure quality as a condition of Medicare and Medicaid coverage and recertification every four years.[3] (See Exhibit 2.)

[1] UNOS also provided data for the impact of changes in the pancreas allocation process. However, there were too few transplants to show a meaningful difference.

[2] In 2018, 20.9% of kidney transplants nationwide were for the age group 65 and above, compared to 26.8% of kidney transplants in Florida. (The nationwide figure is from UNOS, which provided data for all states combined, including Florida.)

[3] These requirements include standards for donation outcome measures; participation in OPTN; relationships with hospitals, critical access hospitals, and tissue banks; administration and governing body; human resources; data reporting; information management; requesting consent; evaluation and management of potential donors and organ placement and recovery; organ preparation and transport; quality assessment and performance improvement; and emergency preparedness. See CFR Title 42 §486.301 to 486.360.

Exhibit 2
Federal Oversight of the Organ Donation and Transplantation System



Source: OPPAGA analysis of HHS and HRSA organizational charts and documents.

The Organ Procurement and Transplantation Network (OPTN) is the private nonprofit established in 1984 by the National Organ Transplant Act.[4] The act directed the HHS secretary to contract for the establishment and operation of OPTN. Federal law gives OPTN numerous responsibilities, including establishing a national list of individuals who need organs, a national system to match organs and individuals, membership criteria, and medical criteria for allocating organs and providing the public an opportunity to comment with respect to such criteria.[5] OPTN is also required to maintain a 24-hour telephone service to facilitate matching organs with individuals included in the list, assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients, and adopt and use standards of quality for the acquisition and transportation of donated organs. Among its other responsibilities, OPTN is also required to coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers; provide information to physicians and other health professionals regarding organ donation; collect, analyze, and publish data concerning organ donation and transplants; carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation; and work actively to increase the supply of donated organs.

In 2000, HHS established a final rule that provided a regulatory framework for the structure and operations of OPTN.[6] The rule includes making the OPTN board of directors responsible for developing, with the advice of the OPTN membership and other interested parties, policies within the mission of OPTN as set forth in the act and the secretary's contract for operation of OPTN, including policies for equitable allocation of cadaveric organs. The allocation policies must meet several

[4] 1984 Public Law 98-507.
[5] Title 42 USC 274.
[6] CFR Title 42 Part 121.

provisions, including being based on sound medical judgment, seeking to achieve the best use of donated organs, preserving the ability of a transplant program to decline an offer of an organ, being specific to each organ type or combination of types, and not being based on a candidate's place of residence or place of listing, with exceptions.[7] The final rule requires that the board of directors shall provide opportunities for OPTN membership and other interested parties to comment on proposed policies and take their comments into account.[8] Compliance with the policies is voluntary, but the OPTN board can recommend that the secretary make the policy enforceable.[9] However, OPTN has never asked for enforcement of one of its policies.

OPTN has established operational rules that include transplant policies and membership requirements with by-laws for transplant centers and organ procurement organizations.[10] The United Network for Organ Sharing (UNOS), a private, non-profit organization under contract with HRSA, manages OPTN and develops the requirements for its operation. Under contract with HHS, the Scientific Registry of Transplant Recipients (SRTR) is responsible for providing statistical and other analytic support to OPTN for the formulation and evaluation of organ allocation. OPTN also uses SRTR data to evaluate transplant center performance.

OPTN establishes OPO performance requirements and reviews an OPO whose observed organ yield rates fall below the expected rates by more than a specified threshold. OPTN has additional OPO membership requirements for quality assessment and performance improvement, the relationship with transplant hospitals, laboratory testing services, tissue bank services, education plans, organ allocation plans, personnel, patient confidentiality, and donation after circulatory death protocols.

OPTN's Membership and Professional Standard Committee (MPSC) evaluates transplant program compliance through medical peer review and by monitoring the SRTR's analyses of transplant programs' one-year patient and graft survival rates. In addition to transplant program quality, OPTN also monitors programs' waitlist data integrity, and organ allocation policy compliance, and conducts on-site surveys, desk reviews, and patient safety investigations.

The MPSC plays a large role in the accountability of OPOs and transplant programs and can take action against them by issuing warning letters or letters of reprimand, requiring corrective action plans, or recommending that the OPTN board of directors place the transplant program/member on probation or declare the member to be not in good standing. Based on review and hearing of the MPSC's recommendations, the OPTN board of directors can notify the HHS secretary, who can take further action such as removing one or more of the member's designated transplant programs or terminating the member's ability to receive Medicare or Medicaid funding.

UNOS also assists with the regulation and oversight of the U.S. organ transplantation system. UNOS's Department of Member Quality works with the OPTN MPSC to monitor transplant member performance and ensure that all transplant programs are in compliance with transplant standards. Like the MPSC, UNOS member quality staff conduct various ongoing reviews to evaluate OPTN member compliance with OPTN bylaws and policies. When reviews identify non-compliance, the UNOS member quality staff compile information on the cases for the MPSC to make decisions on the

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[7] CFR Title 42 §121.8.

[8] See Making OPTN Policy for a description of the OPTN policy making process.

[9] Per CFR Title 42 §121.4. To make a policy enforceable, the OPTN board must provide the secretary with the proposed policy at least 60 days before implementation. If OPTN does refer the policy for enforcement, per CFR Title 42 §121.4, the secretary sends significant proposed policies to the Advisory Committee on Organ Transplantation established under CFR Title 42 §121.12, and otherwise follows the process outlined in the CFR.

[10] See the OPTN *Organ Procurement and Transplantation Network Policies* and *Organ Procurement and Transplantation Network Bylaws*.

appropriate monitoring or action. Overall, the role that UNOS staff plays in the regulatory process varies based on the type of review (e.g., peer visits, transplant program activity, transplant program outcomes, patient safety compliance check, and member compliance).

State, Regional, and Local Entities' Roles

The primary state agencies involved in the organ donation and transplantation system in Florida are the Agency for Health Care Administration and the Department of Highway Safety and Motor Vehicles, with assistance from county tax collectors. AHCA is required by statute to contract for a statewide organ donor registry coupled with a program for donor education.[11] Accordingly, the agency contracts with Donate Life Florida for an online donor registration and education system. AHCA also coordinates with DHSMV in obtaining funding for the donor registry. Recently, CMS gave AHCA and similar agencies in other states responsibility for conducting on-site surveys of transplant centers for compliance with CMS regulations. In addition, AHCA is required by statutes to establish a program for the certification of organizations that procure organs, tissue, and eyes for transplantation, to set forth appropriate standards and guidelines for these organizations, and to monitor them for compliance.[12,13] AHCA is also responsible for collecting fees from organ procurement organizations and tissue and eye banks to support the cost of the certification program, an advisory board, the donor registry, and organ and tissue donation education.[14,15]

Several Non-Federal Entities Play Important Roles in Florida's Organ Donation and Transplantation System

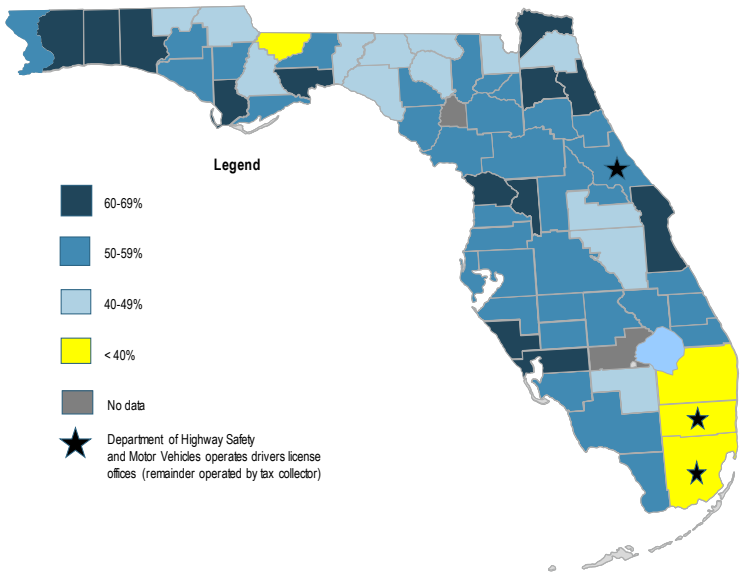
- Agency for Health Care Administration
- Department of Highway Safety and Motor Vehicles
- County Tax Collectors
- Donate Life Florida
- Organ Procurement Organizations
- Donor Hospitals
- Transplant Centers

Driver license offices operated by DHSMV and county tax collectors encourage and register organ donors when issuing identification cards and driver licenses. Driver license employees ask applicants if they want to be an organ donor and, if so, to enter their information into the state's driver license data system, which sends a nightly download of this information to Donate Life Florida. DHSMV also collects voluntary contributions to the donor registry that citizens submit when paying for an identification card, driver license, or motor vehicle registration. Nearly 90% of Florida's registrations are via driver license offices. (See Appendix A for details on the demographic characteristics of donor registrants.)

[11] Section 765.5155, *F.S.*
[12] Section 765.541, *F.S.*
[13] OPPAGA excluded tissue and eye banks from the scope of this review.
[14] Section 765.544, *F.S.*
[15] Section 765.543, *F.S.*, creates an Organ and Tissue Procurement and Transplantation Advisory Board to assist AHCA and the Florida Medical Examiners Commission, but AHCA reports that the board has not been active since 2015.

Several other entities play a significant role in Florida's organ donation and transplantation system. Donate Life Florida contracts with AHCA to operate a statewide online donor registry and to provide a donor education program. Donate Life Florida is a non-profit organization established in 1997 from a coalition of organ, tissue, and eye recovery programs in Florida and other individuals and organizations. Funding for Donate Life Florida is provided by the organ procurement organizations and voluntary contributions made by Floridians during license or motor vehicle transactions, and other fund-raising initiatives or private donations. As of December 31, 2018, over 10 million people were enrolled in the Joshua Abbott Organ and Tissue Donor Registry that Donate Life Florida operates. There is some regional variation in donor registration rates across Florida. Florida's three largest counties by population (Miami-Dade, Broward, and Palm Beach) have the three lowest donor registration rates at 35%, 31%, and 36%, respectively, with the exception of Gadsden County, which has a 35% registration rate.[16] (See Exhibit 3.)

Exhibit 3
Organ Donor Registration Rates by County, December 2018



Source: OPPAGA analysis of data from the *Donate Life Florida 2018 Annual Report.*

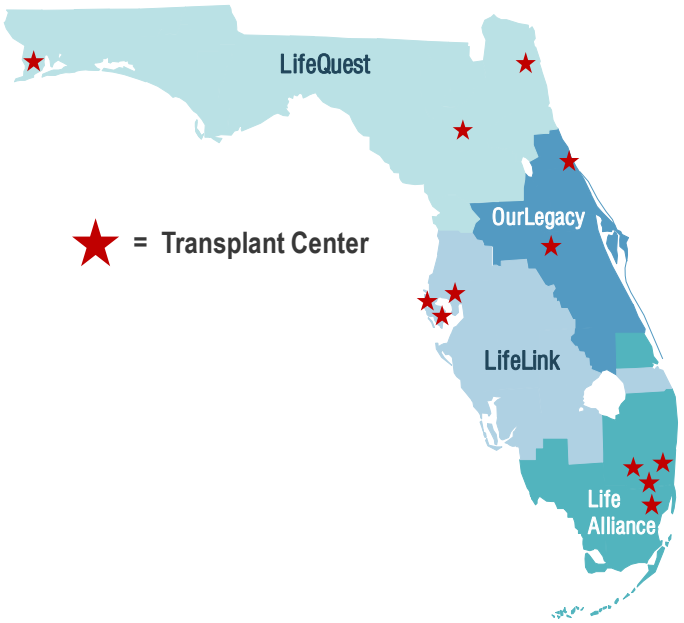
The state has four Organ Procurement Organizations (OPOs), each of which is responsible for a donation service area. (See Exhibit 4.) OPOs must be certified by the Centers for Medicare and Medicaid Services and abide by CMS regulations as well as be members of OPTN and follow OPTN's policies. OPOs are primarily responsible for procuring organs from deceased donors, using a national database to match donor organs to patients on waiting lists, and coordinating with hospital transplant centers for transport of matched organs. To increase donor registration, they provide education on organ donation to employees of driver license offices and place educational materials in these offices. OPOs offer opportunities for volunteering to raise awareness about the importance of registering as a donor.

Any of the state's Class I or Class II hospitals can act as a donor hospital for organ donation. Hospitals are responsible for timely notification of the applicable OPO in their area of a death or imminent death of a patient who is a viable organ donor. The state has 12 hospital transplant centers with responsibilities that include evaluating patients to determine waiting list eligibility and suitability and procurement of organs at donor hospitals.[17] They perform transplant surgeries and conduct pre- and post-transplant care.

[16] Donor registration rates are the percentage of customers who say "yes" when asked, "Do you want to be a donor?" during a driver license transaction; the registration rate for Florida overall is 49%.
[17] This excludes transplant centers that only perform bone marrow transplants. It also excludes Gulf Coast Medical Center, which had a transplant program that ceased operation at the end of 2018.

The organ donation system includes both living and deceased donors; hospitals, OPOs, and transplant centers work together to procure organs from deceased donors. Living donors may donate one kidney, one lung, or a portion of the liver, pancreas, or intestine. From 1988 through October 2019, 30% of Florida donors were living donors, compared to about 43% nationally.[18] Most living donations are from family members or friends. Potential living donors are evaluated by the transplant center where they intend to make the donation to determine their suitability to donate. Generally, living donors should be physically fit, in good health, between the ages of 18 and 60, and should not have (or have had) diabetes, cancer, high blood pressure, kidney disease, or heart disease.

Exhibit 4
Florida Has Four OPOs and 12 Transplant Centers



Source: Donate Life Florida and the Agency for Health Care Administration.

Deceased individuals may donate kidneys, livers, lungs, hearts, pancreases, and intestines.[19] Deceased donation is limited to very specific circumstances, and nationally, less than 1% of all U.S. deaths are candidates for organ donation. The typical process of deceased donation occurs after a patient comes to a hospital because of illness or accident. The medical team puts the patient on mechanical support, which keeps blood flowing to the organs. To be medically eligible for donation, the potential donor must

- be declared brain dead and be on a ventilator to maintain heart function and blood flow to organs; or after circulatory death, have an irreversible loss of function of the heart and lungs and be taken off of ventilated support until their heart stops beating;
- not have cancer or certain infections or diseases; and
- be in good health.[20]

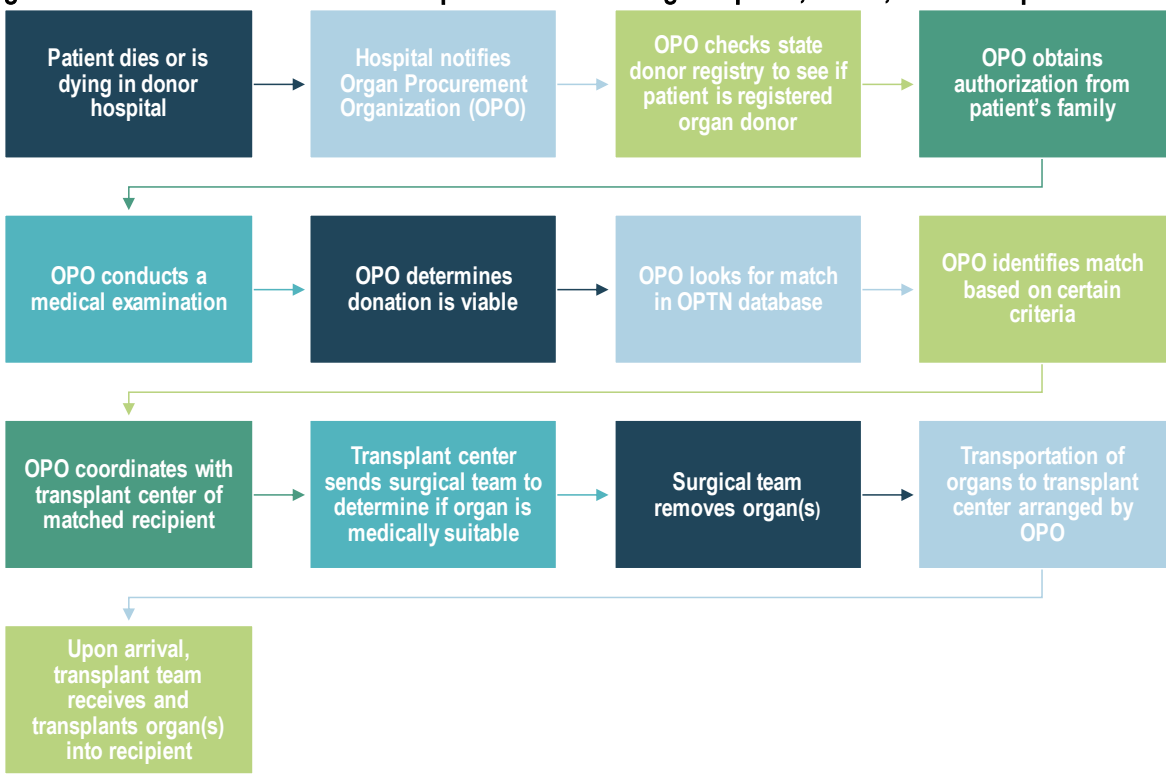
When a patient is near death or has died and is a viable organ donor, Florida hospitals are required to contact their regional OPO. The hospital gives the OPO information about the deceased patient to confirm whether they have the potential to be a donor; if they have the potential, an OPO representative travels immediately to the hospital. Once notified, the OPO checks the state donor registry to determine if the deceased is a registered organ donor. If not, the OPO representative will ask the next of kin for authorization to donate the organs.[21]

[18] The nationwide figure is from UNOS, which provided data for all states combined, including Florida.
[19] In 2014, hands and faces were added to the organ transplant list.
[20] The potential organs procured from circulatory death are lungs, livers, pancreases, and kidneys. Hearts and intestines cannot be recovered after circulatory death.
[21] Although the 2006 Revised Uniform Anatomical Gift Act and s. 765.512(1)(b), *F.S.*, established that next-of-kin cannot override a donor's decision to donate organs, two of Florida's OPOs nonetheless described a process wherein they would honor the family's wishes if the family is vehemently opposed to donation, even if it contradicted the deceased person's donor registry status.

If the OPO's evaluation indicates donation is viable, the OPO representative will find a match for the organs by entering information into the UNOS national database of all patients in the U.S. waiting for a transplant. The database generates a list of patients who match the donor, and the OPO then offers each available organ to the transplant team of each matched patient by contacting hospitals in sequence. Once a match is identified, the OPO coordinates with the transplant center that accepts an organ. Transplant centers at certain hospitals around the state send surgical teams to the donor hospitals to procure their assigned organs or rely on a surgical team that is at the donor hospital to procure another organ. The OPO representative will arrange for the transport of the organ via ambulance, helicopter, or commercial airline, depending on the organ and the distance. The transplant team and the recipient will be waiting at the hospital to transplant the organ as soon as it arrives. (See Exhibit 5.)

Exhibit 5

The Organ Donation Process Is a Multi-Step Process Involving Hospitals, OPOs, and Transplant Centers



Source: OPPAGA analysis of the Health Resources and Services Administration's "The Deceased Donation Process" and interviews.

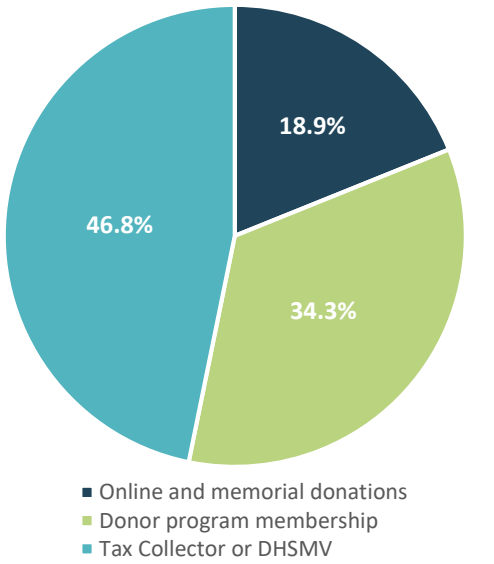
In Florida, multiple entities collect and expend funds associated with organ donation and transplantation. AHCA pays Donate Life Florida from voluntary contributions collected by the Department of Highway Safety and Motor Vehicles. AHCA reports that its five-year contract with Donate Life Florida is for up to $320,000; the agency allots the organization approximately $64,000 per calendar year and makes quarterly payments based on historical accounts of voluntary donations. AHCA receives a quarterly invoice from Donate Life Florida with a DHSMV file listing donations. DHSMV pays the amount to AHCA, which then pays Donate Life Florida. (See Exhibit 6.)

Exhibit 6
AHCA Pays Donate Life Florida Quarterly From Donations Collected by the Department of Highway Safety and Motor Vehicles

	Fiscal Year			
Quarter	2015-16	2016-17	2017-18	2018-19
July-September	$6,063.93[1]	$4,560.72	$7,452.49	$7,082.93
October-December	4,621.71	5.344.78	6,866.88	5,131.43
January-March	5,817.11	8,175.99	7,016.58	7,715.33
April-June[2]	34,298.44	33,101.31	19,669.33	62,060.01
Total	**$50,801.09**	**$51,182.80**	**$41,005.28**	**$81,989.70**

[1] AHCA reports that it paid Donate Life Florida for the first quarter of Fiscal Year 2015-16 under a prior contract.
[2] AHCA reports that April is National Donate Life Month and Donate Life Florida members work with driver license office employees and management to help increase donor awareness and registrations through an annual campaign, which may result in increased donations during this time period.
Source: Agency for Health Care Administration.

Exhibit 7
Donate Life Florida Revenues, Calendar Year 2018



Source: OPPAGA analysis of data from the *Donate Life Florida 2018 Annual Report*.

Donate Life Florida collects additional revenues from donations and OPO member dues. Donate Life Florida reports collecting $105,233 in calendar year 2018 in voluntary contributions from the public (from online and memorial donations or driver license offices), and another $55,025 from member dues paid by OPOs, for a total of $160,258. (See Exhibit 7.)

Fees paid by OPOs, tissue banks, and eye banks exceed AHCA's costs, but AHCA has not used the remaining revenues for donation education. We asked AHCA how much it collected in fees from OPOs, tissue banks, and eye banks in Fiscal Year 2018-19, and how it used these revenues. AHCA is required by statute to spend fee revenues for the implementation, administration, and operation of a certification program for OPOs and tissue and eye banks, an advisory board, donor registry maintenance, and organ and tissue donor education.[22] AHCA provided data showing it collected $670,039 in fees from OPOs, tissue banks, and eye banks in Fiscal Year 2018-19. However, the agency reports that it only spent $78,228 on the certification program and left the remainder in the Health Care Trust Fund rather than spending it on organ and tissue donor education.[23,24] (See Exhibit 8.) In addition, AHCA reports that the advisory board has not been active since 2015.

[22] Section 765.544, *F.S.*
[23] As discussed earlier, AHCA is required by s. 765.541, *F.S.*, to establish a program for the certification of organizations that procure organs, tissue, and eyes for transplantation, to set forth appropriate standards and guidelines for these organizations, and to monitor them for compliance.
[24] The Health Care Trust Fund was established in s. 408.16, *F.S.*

Exhibit 8
AHCA Spent Approximately $78,000 on the Certification Program in Fiscal Year 2018-19

Expense Category	Total Expenditures
Salary	$70,588
Expenses	7,278
Contracted Services	247
Leased Equipment	115
Total Expenditures	**$78,228**

Source: Agency for Health Care Administration.

OPO annual reports show that three of Florida's four OPOs report greater revenues than expenditures in Fiscal Year 2017-18. During organ procurement, OPOs pay fees to hospitals that are a percentage of the charges involved in the procurement process. They obtain revenues by charging transplant centers for organs. The Life Alliance Organ Recovery Agency's (LAORA) annual report showed that its expenditures exceeded its revenues. LAORA administrators reported that in Fiscal Year 2017-18, they were in the initial stages of implementing and negotiating a new case rate with hospitals. The OPO also added staff during this time, contributing to higher expenses. (See Exhibit 9.)

Exhibit 9
Three of Four Florida OPOs Reported Higher Revenues Than Expenditures for Fiscal Year 2017-18

OPO	Life Alliance	Life Link	Life Quest	Our Legacy
Total Revenue	$19,297,045	$22,344,900	$14,892,963	$19,329,030
Total Expenditures	20,962,176	19,882,958	13,120,243	19,068,059
Difference	**($1,665,131)**	**$2,461,942**	**$1,772,720**	**$260,971**

Source: Organ Procurement Agency annual reports to the Agency for Health Care Administration.

Transplant centers report a wide range of charges for transplants. Hospitals report charges for organ transplantation surgical stays to AHCA's Florida Center for Health Information and Transparency. Data for 2017 show that average charges for organ transplants ranged from a high of $1.3 million for a heart transplant to a low of $252,000 for a kidney transplant. (See Exhibit 10.) These reported charges are the raw charges and do not reflect rate negotiations with payers and also do not include physician charges.[25]

[25] The payer for the transplant may be the recipient's insurance, Medicare, or Medicaid.

Exhibit 10
Hospitals Report Varying Charges for Transplants[1,2]

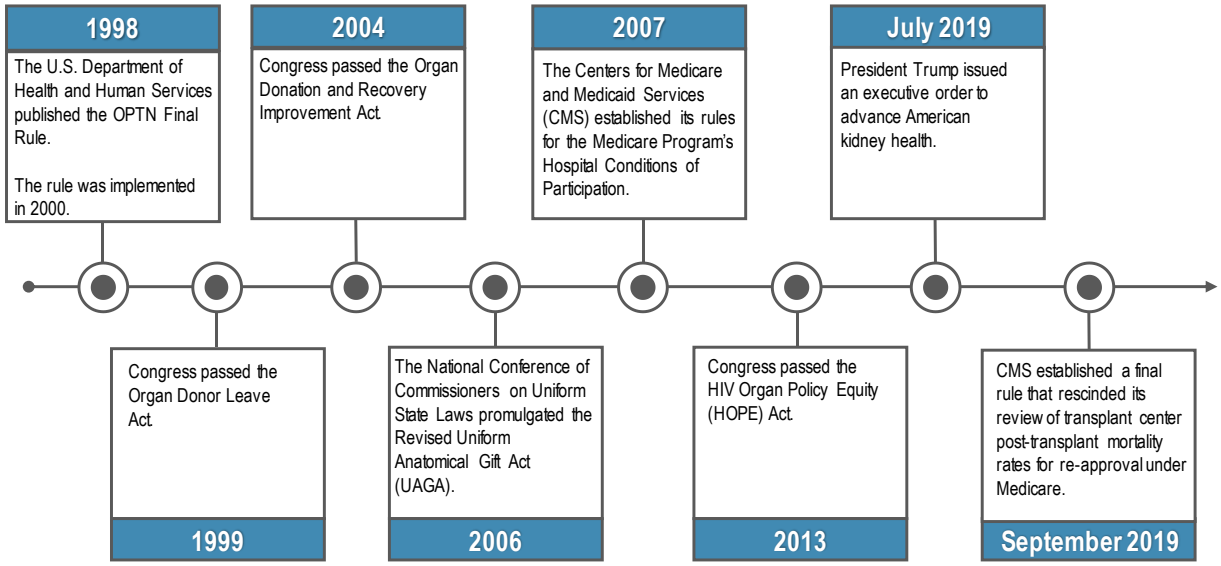
Medicare Severity Diagnosis Related Group (MS-DRG)	Number of Hospital Discharges	Hospital Reported Charges	Average Charges
Heart Transplant or Implant of Heart Assist System, With Major Complication or Co-Morbidity	426	$533,953,848	$1,253,413
Heart Transplant or Implant of Heart Assist System	53	39,147,691	738,636
Lung Transplant	78	51,430,044	659,360
Allogeneic Bone Marrow Transplant	511	317,290,325	620,920
Liver Transplant, With Major Complication or Co-Morbidity or Intestinal Transplant	345	182,654,247	529,433
Simultaneous Pancreas/Kidney Transplant	57	24,545,970	430,631
Autologous Bone Marrow Transplant	47	19,507,922	415,062
Liver Transplant	136	47,851,968	351,853
Autologous Bone Marrow Transplant, With Complications or Co-Morbidity, or Major Complications or Co-Morbidity	504	168,372,045	334,072
Kidney Transplant	1,054	265,580,847	251,974
Total/Average	**3,211**	**$1,650,334,907**	**$513,963**

[1] AHCA states that charges shown are the raw charges, and that patients rarely are required to pay the full charges, so the charge comparison may not be the most meaningful indicator of what you can expect to pay. Actual amounts paid may be significantly less due to rate negotiations with payers. Physician charges are not included.
[2] AHCA's data inquiry tool excludes results from those with fewer than 30 records.
Source: OPPAGA analysis of data from AHCA's Florida Center for Health Information and Transparency.

How Have Federal and State Organ Donation and Transplantation Policies Changed Over the Past 25 Years?

Over the past 25 years, the U.S. Congress, various federal agencies, and the President have made several key policy changes that have affected the organ donation and transplantation system. (See Exhibit 11.)

Exhibit 11
Major Federal Policy Changes to the Organ Transplantation and Donation System



Source: OPPAGA analysis of federal legislation.

In the 1990s, new transplant techniques were developed and the country's transplant system grew rapidly, with the demand for organ transplants exceeding the supply of organs. In an attempt to improve the system, in 1998, the U.S. Department of Health and Human Services published what OPTN refers to as the "final rule," which governs OPTN operations. The OPTN final rule was intended to improve the effectiveness and equity of the organ transplantation system, further the development of a nationwide organ allocation system, and encourage organ donation. HHS implemented the rule in March 2000.

Around the same time, Congress passed two laws to aid in living organ donation. The 1999 Organ Donor Leave Act entitles an employee in or under an executive agency to leave without loss of or reduction in pay to serve as a bone marrow or organ donor. In 2004, Congress passed the Organ Donation and Recovery Improvement Act, which allows the HHS secretary to award grants to states, transplant centers, or OPOs; grants are for the reimbursement of travel and subsistence expenses for living organ donors and for organ donor awareness and education efforts. Both of these grant programs are still offered through HHS's Division of Transplantation.

In 2006, the National Conference of Commissioners on Uniform State Laws promulgated the Revised Uniform Anatomical Gift Act. The original act was promulgated in 1968 to address a critical organ shortage by providing additional ways for making organ, eye, and tissue donations, and it was enacted by all states. The national conference made revisions in 1987 and again in 2006 to address changes in the field of transplantation. The 2006 changes include

- strengthening the language barring others from overriding a donor's decision to donate organs;
- facilitating donations by expanding the list of those who may make an anatomical gift for another individual during that individual's lifetime to include health care agents and, under certain circumstances, parents or guardians;
- enabling procurement organizations to gain access to documents of gifts in donor registries, medical records, and the records of a state motor vehicle department; and
- updating the act to allow for electronic records and signatures.

In 2007, CMS established its rules for the Medicare Program's Hospital Conditions of Participation, requiring all transplant programs to comply with these requirements. The requirements are meant to protect the health and safety of both transplant recipients and living donors, and they focus on a transplant program's ability to perform successful transplants and deliver quality care as evidenced through outcomes, policies, and procedures.

More recently, the 2013 Congress passed the HIV Organ Policy Equity Act, which permits donated, HIV-positive organs to be used for transplantation in HIV-positive patients. This shortens the waitlist for organs by allowing for greater use of HIV-negative organs in HIV-negative patients.

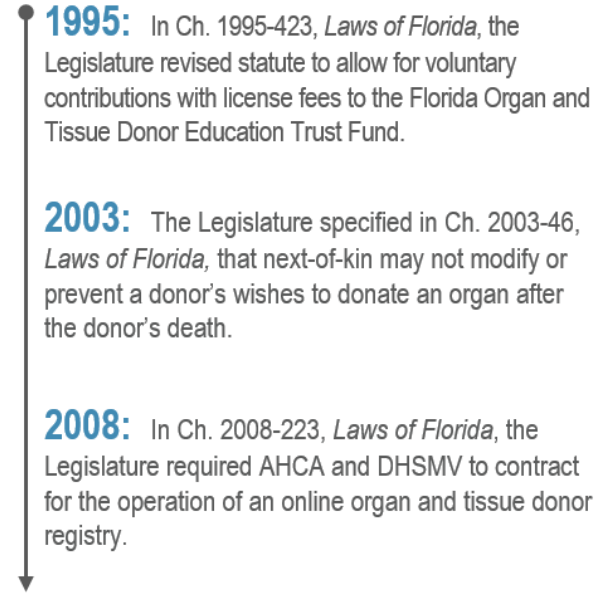
In July 2019, President Trump issued an executive order to advance American kidney health, as kidney disease is the ninth-leading cause of death in the U.S. The executive order requires the HHS secretary to

- select a payment model to test innovations in compensation for providers of kidney care services based on kidney patient cost and quality outcomes;
- select a payment model to encourage greater use of home dialysis and kidney transplants for Medicare beneficiaries on dialysis;
- encourage the development of an artificial kidney;

- increase utilization of available organs through establishing better metrics to evaluate OPO performance and streamlining the kidney matching process; and
- propose a regulation to remove financial barriers to living organ donation.

Finally, in September 2019, CMS established a final rule that rescinded its review of transplant center post-transplant mortality rates for re-approval under Medicare. CMS cited stakeholder input and research studies that concluded that CMS's assessment was causing some transplant centers to be more conservative than they would be otherwise regarding the patients and organs they will take because of concern over losing their Medicare funding. CMS expressed concern that as a result, fewer patients had access to life-saving transplants and that viable organs were being discarded. The expected outcome of this final rule is an increase in organ transplants and a decrease in discarded organs. As part of this final rule, CMS also rescinded review of transplant center clinical experience (volume) for re-approval. CMS retained review of mortality rates and clinical experience only for initial Medicare approval of transplant centers.

Exhibit 12
Major State Policy Changes to Florida's Organ Transplantation and Donation System



Source: OPPAGA analysis of Florida legislation.

While many changes affecting Florida's organ donation and transplantation system have occurred at the federal level, the Florida Legislature has passed a few key policy changes in the last 25 years. (See Exhibit 12.)

In Ch. 1995-423, *Laws of Florida*, the Legislature revised statutes to allow people to make a voluntary contribution with their license fees to the Florida Organ and Tissue Donor Education Trust Fund for organ and tissue donor education. This same law clarified that an anatomical gift made by an adult and not revoked by the donor does not require the consent of any person after the donor's death. It also charged AHCA and DHSMV with developing and implementing a statewide, electronic donor registry.

Several years later, in Ch. 2003-46, *Laws of Florida*, the Legislature specified that next-of-kin may not modify or prevent a donor's wishes to donate an organ after the donor's death.[26] It also clarified that organ and tissue donor cards, living wills and advance directives, driver licenses, and other written forms serve as evidence of legally sufficient informed consent to donate an organ. In Ch. 2008-223, *Laws of Florida*, the Legislature further amended the list of items that can serve as evidence of a decedent's informed consent to donate to include entry in the organ and tissue registry.[27] This law required AHCA and DHSMV to contract for the operation of an online organ and tissue donor registry, designated as the Joshua Abbott Organ and Tissue Registry, and an education program regarding the laws surrounding organ donation and the need for organs in Florida.

[26] Chapter 2003-46, *Laws of Florida*.
[27] Chapter 2008-223, *Laws of Florida*.

What Are the Projected Impacts on Florida of Changes to OPTN National Organ Allocation Policies?

In the past few years, Organ Procurement and Transplantation Network committees have attempted to address a perceived equity issue in the allocation of organs, which has traditionally been based on organ procurement organization donation service areas (DSAs) or OPTN regions. A DSA is the geographic area designated by CMS that is served by one OPO, one or more transplant centers, and one or more donor hospitals. A region is 1 of 11 geographic areas in the country used for the administration of organ allocation and appropriate geographic representation within the OPTN policy structure. The stated rationale for changing the current allocation methodology that uses DSAs and regions is that this methodology is contrary to the OPTN final rule, which states that policies regarding organ allocation shall not be based on a candidate's place of residence or place of listing.

To this end, in 2018, the OPTN/UNOS Ad Hoc Geography Committee was formed to establish principles and a framework to guide how OPTN policies should address future geographic distribution of organs. The OPTN/UNOS board of directors adopted a set of principles developed by the Geography Committee to guide future organ transplant policy relating to geographic aspects of organ distribution. The adopted statement of principle states that deceased donor organs are a national resource to be distributed as broadly as feasible. Any geographic constraints pertaining to the principles of organ distribution must be rationally determined and consistently applied. Using this principle statement, OPTN has proposed and, in some cases, implemented organ-specific allocation policy changes over time. Since 2017, OPTN committees have made or adopted proposals to change allocation policies for lungs, livers, hearts, kidneys, and pancreases.[28]

Lung Allocation Policy Change

In 2017, OPTN implemented a policy change for lung allocation that removed the DSA method of allocation for deceased donor lungs and replaced it with a 250 nautical mile circle around the donor hospital. This policy change was in response to a lawsuit filed by a transplant candidate in New York that argued that the use of DSAs as the first unit of allocation for lungs from deceased adult donors under the OPTN Lung Allocation Policy was in direct conflict with the OPTN final rule. The complaint further argued that the allocation policy discriminated against people such as the plaintiff based on geography and not on medical priority. The plaintiff sought an injunction to require the acting HHS secretary to enjoin HHS and OPTN from applying the aspect of the Lung Allocation Policy that used the DSA as a primary unit of allocation for deceased adult lungs. The Administrator of the Health Resources and Services Administration directed OPTN to review the lung allocation policy and determine whether any changes needed to be made. OPTN subsequently implemented a new lung allocation policy that has gone into effect.

Liver Allocation Policy Change and Current Lawsuit

In 2018, OPTN proposed a policy change for liver allocation that eliminates the use of DSAs for organ allocation and replaces it with a broader framework with the stated intent to decrease waitlist mortality rates and allow for more equity in access for liver transplant candidates. Prior to this policy proposal, liver organ distribution policies used DSAs and OPTN regions as geographic units. Under the

[28] The proposed liver allocation policy also includes intestine distribution.

new policy, livers will first be offered to the most urgent liver transplant candidates listed at transplant hospitals within a radius of 500 nautical miles of the donor hospital. Livers would next be offered to candidates at hospitals within distances of 150, 250, and 500 nautical miles of the donor hospital, based on medical urgency. The revised policy was implemented briefly but has been on hold due to a lawsuit. A group of hospitals and individual patients filed suit, arguing that HHS and UNOS violated the Administrative Procedures Act (APA) by failing to follow established procedures during the policy's development and that these actions were arbitrary, capricious, and unlawful.[29,30] The group also claimed that HHS and UNOS actions constituted a violation of the Due Process Clause of the Fifth Amendment.[31] In a separate motion, the plaintiffs asked the district court to issue a temporary restraining order to prevent the new policy from taking effect.[32]

While plaintiffs made three arguments, the district court denied the group's motion based solely on an analysis of the initial claim that the policy failed to follow proper rule making procedures during the policy's development. The new policy went into effect briefly until the plaintiffs filed an appeal and asked the district court for an injunction pending appeal. The injunction was granted and placed the previous liver allocation policy in effect. The appellate court determined that the district court correctly decided that HHS and UNOS's interpretation of the rule making procedure was the more reasonable one but remanded the case to the district court to decide the remaining two claims.[33] At the time of our review, the parties were in discovery, with the district court determining what, if any, additional information will be exchanged. Implementation of the policy is still on hold.

Heart Allocation Policy Change

In 2019, OPTN approved a policy change for heart allocation that replaced the DSA-level of allocation for deceased donor hearts with a 250 nautical mile circle around the donor hospital. The goal of this change is to make heart allocation policy more consistent with the final rule and provide more equity in access to transplantation regardless of a candidate's place of listing. This policy is expected to go into effect in January 2020.

Kidney and Pancreas Allocation Policy Change

Also in 2019, OPTN proposed additional policy changes for both kidney and pancreas allocation that would remove the DSA and regional boundaries used in the current organ allocation system and allocate using a 500 nautical mile circle around the donor hospital. The goal of these proposals is to provide consistent distribution units and promote patient access to transplant. Both proposals were open for public comment until October 2019 and were pending further action at the time of our review.

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[29] The plaintiffs argue that because the liver-allocation policy is a significant policy, the defendants violated the law by neither referring the policy or publishing the policy in accordance with 42 CFR §121.4(b), which states that "[t]he Secretary will refer significant proposed policies to the Advisory Committee on Organ Transplantation established under § 121.12, and publish them in the Federal Register for public comment." HHS and UNOS disagree and claim that the provision only applies when the policy at issue is one that OPTN's board recommends to be enforceable or when the policy at issue is one that relates to such other matters as the secretary directs in accordance with the opening provisions of the statute.

[30] In Count II, the plaintiffs assert that HHS and UNOS's decision to approve the April 2019 policy in a limited time frame was arbitrary and capricious.

[31] In Count III, the plaintiffs contend that they were not given notice or meaningful opportunity to be heard before the policy was adopted in violation of the Fifth Amendment, which provides individuals with the right to be heard regarding "governmental decisions which deprive individuals of ['life,'] liberty' or 'property' interests." *Mathews v. Elderidge*, 424 US 319, 332 (1971).

[32] To determine if the court should issue injunctive relief, the court must decide, among other things, that the party requesting relief has a substantial likelihood of success on the merits. The standard for obtaining preliminary injunctive relief is "(1) substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest." *McDonalds' Corp. v. Robertson*, 147 F.3d 1301, 1306 (11th Cir. 1998).

[33] The appellate court indicated that the remaining issues to be decided by the district court are context intensive and fact dependent and will hinge on whether UNOS is an agency under the APA.

Exhibit 13 summarizes the actual and projected effects on Florida of the federal organ allocation policy changes based on data provided by UNOS. The most significant negative effect results from the kidney and liver allocation proposals. The number of transplants for both organs would decrease under the new policies, with an 11% decrease for livers and a 24% decrease for kidneys.

Exhibit 13
UNOS Projects That Changes in Organ Allocation Policies Will Have Both Positive and Negative Effects on Florida[1,2]

Organ	Annual Number of Transplants Pre-Change	Annual Number of Transplants Post-Change	Difference	Percentage Difference
Lung—Actual Volume over 1.5 Years	248	302	+54	+22%
—Projected Average	245	262	+17	+7%
Liver—Projected Average	459	408	**-51**	**-11%**
Heart—Projected Average	273	294	+21	+8%
Kidney—Projected Average	738	558	**-180**	**-24%**
Kidney-Pancreas—Projected Average	46	64	+18	+39%

[1] For the projected averages, UNOS provided data showing what happened in 2017 under the distribution model in use at that time and what would have happened in 2017 under the revised distribution model.
[2] UNOS also provided data for the impact of changes in the pancreas allocation process. However, there were too few transplants to show a meaningful difference.
Source: United Network for Organ Sharing.

How Has Florida's Organ Donation and Transplantation System Performed Over Time and in Comparison to Other States?

Florida's Donor Registry Trend

Florida has improved its rate of donor registration over time. Donor registries are an important tool in increasing the availability of organs for transplant. Florida has improved its rate of donor registration over time, both in whole numbers and as a percentage of the population. In 2009, Florida had 5,275,904 registered donors, compared to 10,674,300 in 2018. As a percentage, Florida increased its donor registration rate of adults 18 and older from 36% in 2009 to 59% in 2017. (See Appendix B for more information on the trends in donor registration.) In 2018 (the most recent data available), 38% of eligible deaths were registered donors.[34]

Exhibit 14
Florida Performs Better Than Its Peer States in National Rank for Donor Registrations

State	National Rank for Donor Registrations
Florida	33
Texas	41
California	44
Pennsylvania	45
New York	50

Source: OPPAGA analysis of data from *Donate Life America, 2018 Annual Update.*

Florida also compares favorably to peer states in its rate of donor registration. Florida is the third most populous state, after California and Texas, followed by New York and Pennsylvania. It ranks higher than these states in the percentage of adults registered as donors. (See Exhibit 14).

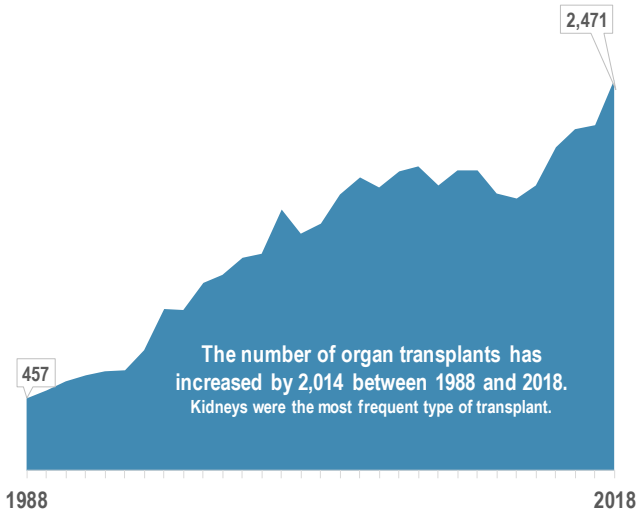
[34] Nationally, 33% of eligible deaths were registered donors.

Florida's Trend for Organ Transplants and Actual Number of Donors

Florida is similar to the rest of the nation with an upward trend in organ transplants performed in 2018. (See Exhibit 15.) Nationally, the number of organ transplants from deceased and living donors increased 5% from 2017 to 2018. In Florida, the number of organ transplants from deceased and living donors increased about 7% from 2017 to 2018; transplants from living donations increased by 14% and transplants from deceased donation increased by 4%.

Nationally, some of the increase in deceased donation is due to the increased usage of donors with medical criteria that would have excluded them from donation previously. Nearly 20% of donors in 2018 donated after circulatory death as opposed to brain death, 9% involved organs with a kidney donor profile index of 86% or higher, and more donors were 50 or older or identified as having increased risk for blood-borne disease.[35,36]

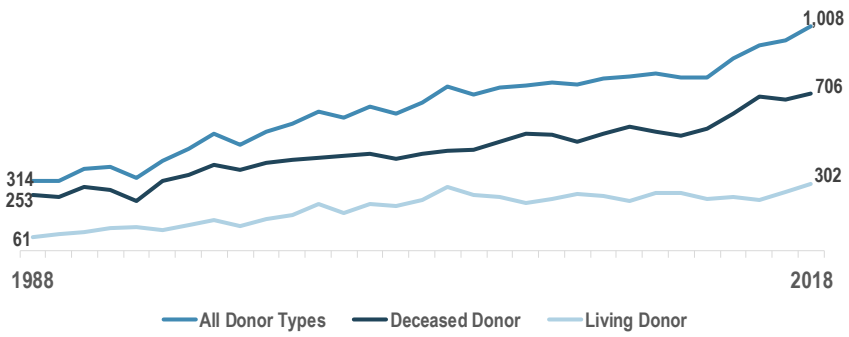
Exhibit 15
The Number of Florida Transplants Has Increased



Source: OPPAGA analysis of OPTN data.

There are many factors determining whether a potential deceased donor becomes an actual donor. For deceased donations, an OPO needs to gain consent from the deceased person's family, the transplant hospital needs to accept the organ, and the organ must be successfully and quickly delivered to the donor hospital. Florida has increased its numbers of actual organ donors over time, including deceased donors and living donors. (See Exhibit 16). Nationally, in 2018, about 81% of the transplants involved organs from deceased donors, while in Florida, 70% of transplants were from deceased donors, which has remained roughly consistent over time.

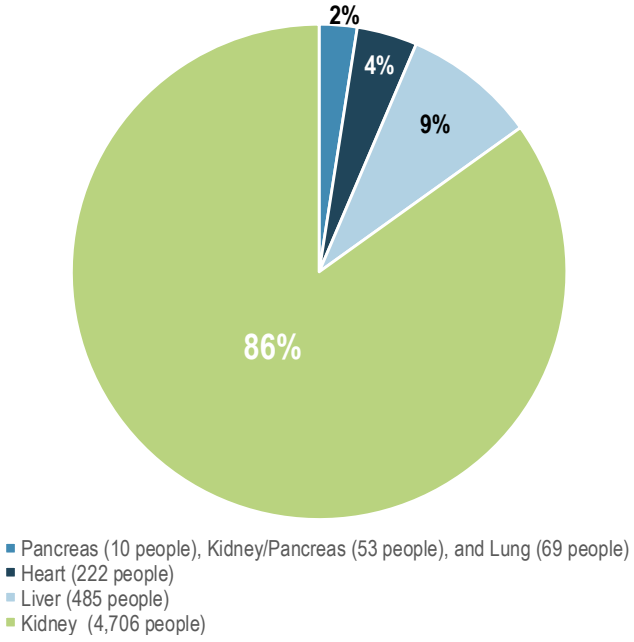
Exhibit 16
The Number of Florida Organ Donors Has Increased Over Time



Source: OPPAGA analysis of OPTN data.

[35] Organ Transplants in United States Set Sixth Consecutive Record in 2018 (2019).
[36] Higher scores are associated with shorter expected functioning of the kidney relative to all the kidneys recovered in the U.S. during the last year. A kidney with a score of 86% is expected to have shorter longevity than 86% of all recovered kidneys.

Exhibit 17
The Vast Majority of People on Florida's Transplant Waitlist Are Waiting for a Kidney[1]



[1] An additional 13 people were waiting for other types of transplants: 3 for a heart-lung transplant, 8 for an intestine transplant, and 2 for an abdominal wall transplant.
Source: OPPAGA analysis of OPTN data, June 4, 2019.

Florida's Waitlist Outcomes

Florida compares favorably to the rest of the nation in how quickly people on waitlists receive transplants but fares similarly or worse in mortality rates. Each year, the number of people on a waitlist for organ donation grows and continues to outpace both the number of donors and organ transplants. As of June 4, 2019, Florida had 5,461 people on an organ transplant waitlist. Of those, 86% were waiting for a kidney. (See Exhibit 17.) Nationally, this compares to almost 84% of people on an organ waitlist who are waiting for a kidney.

The Scientific Registry of Transplant Recipients produces outcome assessments for all transplant programs in the U.S. using a five-tier metric for *getting a deceased donor transplant faster*.[37] This metric assesses how quickly those on the waitlist get a transplant during the two-year period evaluated relative to how quickly they would be expected to get a transplant based on national data. The metric provides a measure of the rate at which the program finds deceased donor organs for its candidates.[38,39] Tiers 1 and 2 indicate that the center is performing worse than expected, Tier 3 that the center is performing roughly as expected, and Tiers 4 and 5 that the center is performing better than expected.[40]

Florida's organ transplant programs generally do better than the rest of the nation based on SRTR's measure for getting adults a deceased donor transplant faster after controlling for the characteristics of the population served. As of July 2019, 47% of Florida's 45 rated transplant programs were in the top two of five performance tiers for getting a deceased donor transplant faster, compared to just 27% of the programs in the rest of the U.S.[41] (See Exhibit 18.)

[37] A transplant program is organ specific within a single transplant center. Transplant centers that conduct transplants for more than one organ would thus have more than one transplant program, and multiple rankings.
[38] The strength of the tier-rating system is that it controls for the characteristics of the patients served, the organs used, and the volume of transplants conducted. The tiers are based on the ratio of how many on the waitlist actually received a transplant relative to how many would be expected to receive a transplant given their age, how sick they are, and how many transplants are conducted at the program. If Florida's transplant centers had older and sicker transplant patients, the tier ranking they received would not penalize them for these factors; rather, it should reflect their performance. The tier ranking also takes into account the likelihood of getting an especially high or low tier score due to a small volume of transplants.
[39] SRTR excludes individuals who undergo living donor transplants from the analysis.
[40] Ratings are based on a probabilistic estimate, thus a specific rating represents a range of outcomes that are driven by both performance relative to expected performance as well as the volume of transplants in a program. For details about the computation of the rating tiers, see SRTR's *Calculating the 5-tier Assessments: A Guide for Pre-and Posttransplant Metrics*.
[41] Two programs in Florida and 106 programs elsewhere had no rating.

Exhibit 18
Florida Had a Higher Percentage of Programs That SRTR Assessed as Better Than Expected for Adults Getting a Deceased Donor Transplant Faster Than the Rest of the U.S.[1]

Adults Getting a Transplant Faster Tier Rating: Higher Score Is Better	Percentage of Florida's Transplant Programs Within Tier (n=45)	Percentage of Rest of U.S. Within Tier (n=785)
1	7%	8%
2	16%	34%
3	31%	31%
4	22%	19%
5	24%	8%
Better Than Expected (Tiers 4 and 5)	**47%**	**27%**
Worse Than Expected (Tiers 1 and 2)	22%	42%

[1] Numbers are rounded; totals are rounded only after summing original unrounded numbers.

Source: OPPAGA analysis of SRTR outcome assessment data, July 1, 2017 to June 30, 2019, program-specific reports.

SRTR also assesses all transplant programs in the U.S. using a five-tier system for survival on the waiting list, where higher tiers show better outcomes.[42] The five-tier assessment for survival on the waiting list is based on a measure of how many patients die compared to how many are expected to die while waiting for an organ transplant. Tiers 1 and 2 indicate that the center is performing worse than expected, Tier 3 that the center is performing roughly as expected, and Tiers 4 and 5 that the center is performing better than expected.

Compared to the rest of the nation, Florida's programs perform similarly or worse than would be expected based on SRTR's measure for mortality while on the waiting list. (See Exhibit 19.) While Florida had a similar percentage of programs rated in the top two performance tiers for adult survival on the waiting list, the state had 29% of transplant programs in the bottom two tiers, or worse than expected, compared to 21% for the rest of the nation. (See Appendix C for the performance of individual Florida transplant centers and programs.)

Exhibit 19
Florida Had a Higher Percentage of Programs That SRTR Assessed as Worse Than Expected For Adult Waitlist Mortality Than the Rest of the U.S.[1]

Adult Waitlist Mortality Tier Rating: Higher Score Is Better	Percentage of Florida's Transplant Programs Within Tier (n=45)	Percentage of Rest of U.S. Within Tier (n=785)
1	9%	5%
2	20%	16%
3	33%	44%
4	31%	27%
5	7%	8%
Better Than Expected (Tiers 4 and 5)	38%	35%
Worse Than Expected (Tiers 1 and 2)	**29%**	**21%**

[1] Numbers are rounded; totals are rounded only after summing original unrounded numbers.
Source: OPPAGA analysis of SRTR outcome assessment data, July 1, 2017 to June 30, 2019, program-specific reports.

[42] The tiers are based on the ratio of how many actually died on the waitlist relative to how many would be expected to die given the ages of people on the waitlist, how sick they are, and how many transplants are conducted at the program.

OPPAGA's analysis of data from UNOS shows that Florida compares similarly or favorably to the nation for kidney and liver waitlist trends.[43] OPPAGA analyzed UNOS data showing outcomes of patients within three years of being placed on a transplant waitlist in Florida and in other states between 1988 and 2015. Florida's trend in waitlist registrations added for kidneys generally follows the same pattern of increase as the U.S. as a whole, with an increase in registrations over time. As registrations (demand for kidneys) grew rapidly, likely outstripping the growth in supply of kidneys, there was a decline in the percentage of new registrants who were able to receive a kidney. However, Florida's percentage of patients who received a deceased donor transplant within three years of registering on the waitlist has remained better than the nation as a whole over time. In addition, Florida's percentage of patient deaths within three years of registering on the waitlist for a kidney has been similar to or slightly lower than the rest of the nation since 1988. (See Exhibit 20.)

Exhibit 20
Florida Compares Similarly or Favorably to the Nation for Kidney Waitlist Trends

	Florida		United States	
Waitlist Measure	1988	2015	1988	2015
Number of Waitlist Registrations Added	463	1,951	11,553	34,648
Percentage of Deceased Donor Transplants Within Three Years of Registering on Waitlist	73%	31%	59%	22%
Percentage of Deaths Within Three Years of Registering on Waitlist[1]	5%	12%	6%	12%

[1] The measure reflects the percentage of registrants who were removed from the waitlist due to death or being too sick to transplant, or who died after exiting the waitlist for other reasons.
Source: OPPAGA analysis of UNOS data.

OPPAGA's analysis of UNOS data on liver waitlist trends yielded similar results as for kidney waitlist trends. Florida has increased the number of waitlist registrations for livers over time, a trend that roughly mirrors the pattern in the rest of the U.S. However, Florida has generally maintained relatively high transplantation rates for livers compared to the nation as a whole. Florida has also maintained a relatively low waitlist death rate for liver transplants compared to the nation as a whole. (See Exhibit 21.) These results provide useful descriptive information but should be viewed with caution, as they do not take into account differences in patient characteristics such as illness or age over time or across states or differences in organ transplant quantity or quality. (See Appendix D for more details on these analyses.)

Exhibit 21
Florida Compares Similarly or Favorably to the Nation for Liver Waitlist Trends

	Florida		United States	
Waitlist Measure	1997	2015	1997	2015
Number of Waitlist Registrations Added	579	702	8,021	11,297
Percentage of Deceased Donor Transplants Within Three Years of Registering on Waitlist	61%	69%	49%	54%
Percentage of Deaths Within Three Years of Registering on Waitlist[1]	17%	11%	20%	20%

[1] The measure reflects the percentage of registrants who were removed from the waitlist due to death or being too sick to transplant, or who died after exiting the waitlist for other reasons.
Source: OPPAGA analysis of UNOS data.

[43] For organs other than kidney and liver, the small number of organs showed a high degree of annual variability and made it difficult to draw conclusions about rates. We do not present a comparison of different organs because transplantation and death rates can be very different for different states. The mix and size of organ programs available in a state can change the apparent pooled relative outcomes for otherwise identical organ-by-organ performance.

What Factors Enhance Transplant Success and What Challenges Are Associated With Organ Donation and Transplantation?

Factors for Transplant Success Rates

We interviewed transplant center surgeons and administrators representing five of Florida's transplant centers and asked them about the factors that lead to higher transplant success rates. The two most consistent responses were multidisciplinary teams and transplant center volume; stakeholders also identified several other factors important to success.

Transplantation is a complex health care issue and multidisciplinary teams bring together a variety of skills to treat patients pre- and post-transplant. These teams include surgeons; infectious disease specialists; nephrologists, if applicable; pharmacists; and social workers that help the patient at varying stages of care. Team collaboration and coordination of care can enhance communication, create a level of comfort among the team members, and provide efficient, comprehensive care for the patient, which is important for a successful transplant.

Several surgeons reported that higher volume is associated with better outcomes, as transplant teams are often able to improve skills and develop routines as they gain more experience. As teams perform a greater number of transplants, they also encounter a greater variety of unique complications and are able to develop protocols to address such anomalies. Performing more transplants also allows teams to develop a routine, which enhances efficiency and allows for better communication among the transplant team members.

Researchers also cite volume as a factor involved in increasing transplant procedure success rates. There is consensus among researchers that patient volume is positively related to successful outcomes for organ transplants.[44] Volume is viewed as a proxy for quality and expertise because large volumes enhance opportunities for surgeons to practice critical, high-risk surgeries, and developing skills and perfecting techniques leads to better outcomes.[45] Studies have suggested that higher volume medical centers have, on average, better short-term and long-term patient survival rates.[46]

While many academic studies have assessed the relationship between volume and patient outcomes for transplant surgeries, these studies do not provide consistent minimum volume recommendations. Many of these studies have estimated the relationship between volume and quality but have used widely different ranges of volumes to define low, medium, and high volume transplant centers.[47]

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[44] *OPPAGA Review of Tertiary Health Services Licensing Standards*, OPPAGA Report No. 19-11, November 2019.

[45] Alhamad, et al., "Transplant center volume and the risk of pancreas allograft failure," *Transplantation 101*(11), 2017: 2757; Sonnenberg, et al., "Association of kidney transplant center volume with 3-year clinical outcomes," *American Journal of Kidney Diseases*, 2019.

[46] Grimm, et al., "The influence of institutional volume on the incidence of complications and their effect on mortality after heart transplantation," *The Journal of Heart and Lung Transplantation 34* (11), 2015: 1390-1397; Barbas, et al., "The volume-outcome relationship in deceased donor kidney transplantation and implications for regionalization," *Annals of Surgery 267*(6), 2018: 1169-1172.

[47] For example, recent studies of adult heart transplantation thresholds for high volume transplant centers range from 9 to 48 or more procedures per year; adult liver transplants studies' thresholds for high volume centers range from 21 to 176 or more procedures per year; and pediatric lung transplant studies' thresholds for high volume range from 4 to 11 or more procedures per year. For more information, see Appendix A in OPPAGA Report No. 19-11, November 2019.

Academic studies identify several other factors related to transplant success and quality. Specifically, these studies highlight factors such as patient demographics and health characteristics or hospital and center-specific characteristics, such as staffing ratios and the surgeon's skill.[48] For example, one study of pancreas transplants shows that although there was a relationship between low-volume centers and inferior outcomes, some low-volume pancreas transplant programs have excellent outcomes. The researchers noted that surgical expertise, recipient selection criteria, pre- and post-operative multidisciplinary care and follow-up care were also part of the complex explanation for a transplant program's success.[49]

Factors That May Lead to Higher Transplant Success Rates

- Multidisciplinary teams
- Volume
- Factors such as patient demographics and health characteristics, hospital and center characteristics
- Post-transplant care
- Regulation of the organ transplantation system

According to several studies, post-transplant care is another important factor related to transplant success. Improvement of and access to medications that prevent organ rejection have helped increase the success of organ transplant procedures.[50] Ensuring that patients adhere to their schedule for taking medication is important to transplant success.[51] Along with this, making medication affordable or providing financial assistance to patients can be crucial in guaranteeing that they are able to have access to the medications they need to live successfully post-transplant.[52] Minimizing the common complications of organ transplant procedures is also important, and this is best done through regular follow-up care with physicians and maintaining a healthy lifestyle.[53]

Federal regulatory oversight over transplant center performance and quality may also affect transplant success. For example, the OPTN Membership and Professional Standard Committee conducts reviews of transplant program performance to identify underperforming programs and requires implementation of quality assessment and performance improvement measures. A key source of performance information the MPSC uses is data from SRTR on transplant program one-year post-transplant graft and patient mortality rates. The Centers for Medicare and Medicaid Services conducts a one-year post transplant graft and patient survival rate review for initial approval of a transplant center but rescinded this review for re-approvals in a final rule published on September 30, 2019. Instead, CMS expects transplant programs to continue to use their quality assessment and performance improvement programs to monitor quality of care. CMS stated that the quality improvement programs and CMS surveys will be sufficient to ensure transplant programs continue to achieve and maintain high standards of care.

Challenges Associated With the Organ Donation and Transplantation System

In our interviews with representatives of transplant centers, four Organ Procurement Organizations, and other stakeholders, we asked about hurdles or barriers in the state's organ donation and transplantation system. Challenges noted by these stakeholders include the following.

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[48] Sonnenberg, et al., 2019; Scully, et al., "Waiting list outcomes in pediatric lung transplantation: Poor results for children listed in adult transplant programs," *The Journal of Heart and Lung Transplantation 36*(11), 2017: 1201-1208; Hayes et al., "Transplant center volume and outcomes in lung transplantation for cystic fibrosis," *Transplant International 30*, 2017: 371–377.

[49] Alhamad, et al., 2017.

[50] Keller, C., "Solid Organ Transplantation Overview and Selection Criteria," *American Journal of Managed Care 21*, 2015.

[51] Mathis, A.S., "Managed Care Implications of Improving Long-Term Outcomes in Organ Transplantation," *American Journal of Managed Care 21*, 2015.

[52] Mathis, A.S., 2015.

[53] Keller, C., 2015; Mathis, A.S., 2015.

- ***Misunderstanding or lack of support for organ donation*.** Stakeholders reported that people do not always realize the importance of organ donation and registering as an organ donor, or they have fears or misunderstanding about what it means to register. For example, a representative of an OPO in south Florida reported that the extremely racially and culturally diverse population they serve presents barriers related to language, mistrust of the medical community, fear of deportation, and anti-donation cultural beliefs.[54] Another reported barrier is that families sometimes believe that a hospital wants to declare a family member brain dead so that they can take their organs. Another stakeholder said that people might not think about the fact than when they die, someone else could benefit from their organs. To help overcome such barriers, stakeholders recommended additional public education about organ donation and its importance.
- ***Needing financial support to cover the costs incurred by living donors*.** Living donation in Florida is below the national level; living organ donors make up 43% of all organ donors in the U.S. since 1988, while only 30% of Florida's organ donors have been living donors during the same timeframe. One barrier noted by stakeholders is the financial burden of living donation. For example, a stakeholder from a transplant center reported that a family member was not able to afford the expense of donating an organ to a patient on Medicaid, and that Medicaid would not cover these expenses. We verified with AHCA that Medicaid does not reimburse for living donor medical expenses, but AHCA reported that Medicare will cover the cost of living kidney donation for end-stage renal disease. Although Medicaid covers the recipient cost of an adult or pediatric kidney transplant, a bone marrow transplant, or a pediatric liver transplant in which the recipient may be able to receive the organ from a living donor, it does not cover the expenses incurred by the living donor for these types of donations.[55] Another stakeholder mentioned that, while many potential living donors are dedicated to the process, numerous financial constraints can be a major barrier.[56] According to UNOS, a transplant recipient's insurance typically covers the donor's medical costs, including the donation surgery and living donor evaluation. However, other expenses are not covered by insurance, which could include annual physicals, travel, lodging, lost wages, and other non-medical expenses. The National Living Donor Assistance Center may help with some of these expenses for eligible recipients.[57]
- ***Issues identified in hospital communication with families.*** Two OPOs reported that the communication from hospital personnel with grieving families could make a difference in whether a family chooses to agree to donation. According to these stakeholders, if the hospital notifies the OPO in time to support the family through the process, the family is more likely to agree to donation. However, if the hospital does not notify the OPO until it is time to end life support, and hospital personnel have been abrupt with the family or otherwise seem lacking in compassion, the family may be angry and see disagreeing to donation as one thing they can control. These two OPOs and one other recommended additional education on organ donation for health care professionals. State law already provides for such education of nurses and physicians. Section 464.013(3), *Florida Statutes*, requires the Board of Nursing to prescribe by rule up to 30 hours of continuing education biennially for nurses.[58] Similarly, s. 456.013, *Florida*

[54] A systematic review of studies that explored community attitudes toward organ donation substantiates their perceptions. It found that the decision to donate was influenced by culture and medical mistrust, among other factors. See Irving et. al "Factors That Influence the Decision to Be an Organ Donor: A Systematic Review of Qualitative Literature," Nephrology Dialysis Transplant 27 (2012): 2526-2533.

[55] Although the costs associated with living donation have not been systematically captured, a review of 10 studies that collected data on costs that donors incurred found that an average of 9 to 45% of living kidney donors incurred at least some costs as a result of donation. See Clarke, et al. "The Direct and Indirect Economic Costs Incurred by Living Kidney Donors—a Systematic Review," *Nephrology Dialysis Transplantation*, 21 (2006): 1764-1765.

[56] The rate of living kidney donation is much higher for people with higher incomes in both African-American and white populations. See Gill et al, "The Effect of Race and Income on Living Kidney Donation in the United States," *Journal of American Nephrology* 24(11): 2013, 1872-1879.

[57] The National Living Donor Assistance Center is funded by a federal grant awarded by the Health Resources and Services Administration (HRSA). Priority is given to those who cannot otherwise afford the travel and subsidence expenses associated with donation.

[58] Section 464.013(3), *F.S.*

Statutes, directs the Board of Medicine and the Board of Osteopathic Medicine to require licensees to periodically demonstrate their professional competency by completing at least 40 hours of continuing education every two years.[59]

- ***Lack of consistent organ donation education in tax collector offices.*** Tax collectors around the state provide driver license and motor vehicle services in partnership with the Department of Highway Safety and Motor Vehicles, with nearly 90% of Florida's donor registrations coming through driver license offices. Typically, staff filling out the computerized driver license application ask people if they consent to become an organ donor. If so, this information is transferred overnight to the state donor registry. The OPOs work to educate driver license staff and place promotional materials in driver license offices to educate the public. One OPO reported that a tax collector in its donation service area does not allow the OPO to engage in these educational activities in the tax collector's offices. The tax collector said that their offices keep organ donor educational materials at a vendor station with information on license plate options, but organ donor registration is not the responsibility of tax collector staff. Their focus is on customer wait times.

What Policies Have Other States and Countries Pursued to Improve Organ Availability?

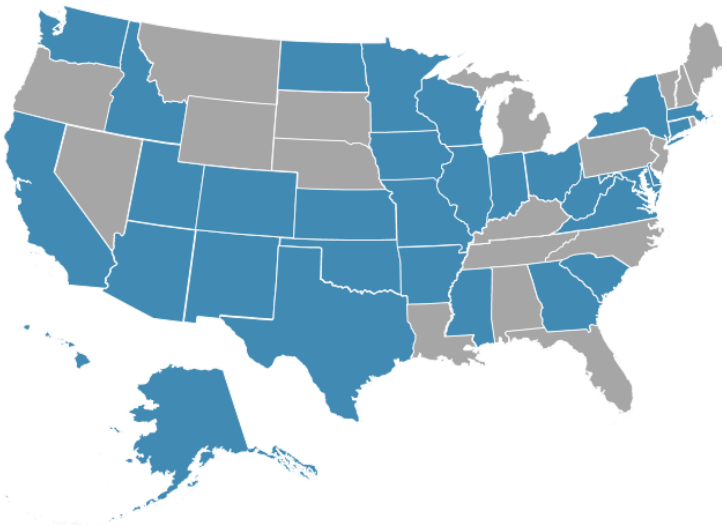
To mitigate the organ shortage in the U.S., many states have considered or adopted legislation to increase organ donor availability, with policies to increase both registered and living donors. To improve organ availability through living organ donation, other states have passed legislation

- requiring certain employers to offer paid leave to living organ donors;
- offering tax credits or tax deductions to living donors or to employers who allow employees a leave of absence for living organ donation; and
- prohibiting insurance providers from denying coverage to living donors based solely on their status as living donors.

[59] Section 456.013, *F.S.*

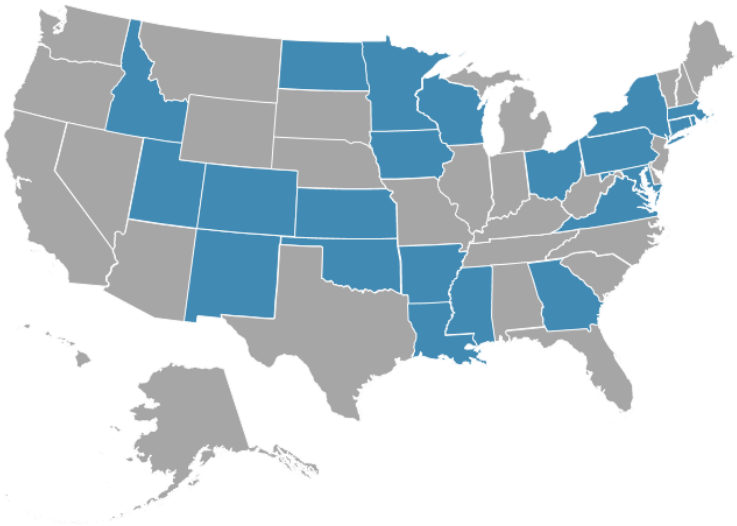
Many states have passed donor leave legislation to make living organ donation a more affordable and viable option. OPPAGA identified 31 states that have laws offering paid leave to living organ donors employed by certain entities. (See Exhibit 22.) These entities include state, county, school, and private sector employers. For example, California, Georgia, and Texas offer state employees a leave of absence of up to 30 days without a reduction in salary to serve as an organ donor. In regards to unpaid leave, according to the U.S. Department of Labor, organ donation qualifies for unpaid, job-protected leave under the Family Medical Leave Act when it involves inpatient care or continuing treatment. These leave laws provide greater opportunities for living donors.

Exhibit 22
States With Donor Leave Laws



Source: OPPAGA analysis of state legislation.

Exhibit 23
States Offering Donor Tax Deductions and Credits



Source: OPPAGA analysis of state legislation.

OPPAGA identified 22 states that currently offer tax deductions or credits for living organ donation.[60] (See Exhibit 23.) Most of these states offer personal income tax deductions and credits, while three offer employer tax credits. For personal income tax, some states, such as Georgia and New York, offer a tax deduction of up to $10,000 for expenses related to organ donation. Other states, such as Colorado, offer employers a tax credit for expenses incurred related to paying an employee or receiving temporary replacement help during the employee's leave of absence for organ donation. These laws may help provide incentives for living organ donation.

Some states, such as Arizona, Colorado, and New York, have also enacted legislation that prohibits insurance providers from denying coverage to living donors based solely on their status as living donors. These laws prohibit discrimination of living donors in receiving coverage such as life, disability, and long-term care insurance. While some states have also enacted legislation to specify that this protection extends to health care coverage as well, the Patient Protection and Affordable Care

[60] Florida does not have a state income tax, so tax deductions and credits may not be applicable.

Act prohibits insurance companies from denying health insurance coverage or charging more for premiums due to a pre-existing condition.

While living donation is the focus of some policies, many states also focus on increasing donor registration. To improve organ availability through increased donor registration, others states have passed or proposed legislation

- focusing on education and public awareness of donor registration;
- expanding the opportunities to register as an organ donor;
- implementing a presumed consent organ donation system; and
- giving registered organ donors priority in organ allocation.

To increase public awareness of organ donor registration, some states, in addition to Florida, have established a fund for education and public awareness campaigns.[61] Texas recently passed legislation designating February 26 as Bone Marrow, Blood, and Organ Donation Registry Day to focus attention on these causes.

Some states have considered or passed policies to expand the opportunities to register as an organ donor. In these policies, residents have the option to register on library card applications or college and university applications, in addition to driver's licenses. Texas and West Virginia passed legislation requiring hunting and fishing licenses to include the election to be an organ donor. In Missouri, a proposed policy would authorize all state agencies and departments to include a link to the donor registry on their website, though this initiative has not passed.

Options Implemented by Other States

To improve organ availability through living organ donation:

- Employee paid leave for living donors
- Employer tax credits or deductions
- Prohibition of denial of insurance coverage for living donors

To improve organ availability through increased donor registration:

- Education and public awareness
- Increased opportunities to register as a donor

Though the legislation was not successful, some states have recently considered proposals to change the donor registry system in their state. One policy proposed in states such as Colorado and New York would create a presumed consent system of organ donation. In this system, residents would be registered as organ donors unless they stated otherwise when applying for their driver license or at some other pre-determined time. New Jersey considered a system where registered organ donors would receive priority in organ allocation if they ever needed an organ, but this is another legislative proposal that has not passed.

Other countries have implemented policies that aim to increase organ donation and availability rates and decrease the time patients spend on waitlists. These policies encompass two main models of organ donation systems that are frequently used throughout the world and mentioned in literature: presumed consent and organ allocation priority. Literature also discusses an additional concept of an organ donor registration system, mandated choice, though we could not identify any countries that use this model.

[61] Arkansas, Illinois, Louisiana, and New York have established a fund for education and public awareness of organ donor registration.

Presumed consent, also known as the opt-out system, is an organ donation system where every citizen is presumed to be an organ donor upon death unless they specifically opt out. Many countries use the presumed consent model, including Austria, England, France, Scotland, Singapore, Spain, and Wales. Proponents of presumed consent organ donation state that the model will increase donation rates, remove next-of-kin interference with the donor's donation decision, and remove the stress that grieving relatives feel when forced to make donation decisions on behalf of their loved ones.[62] Opponents believe that the model will lead to increased levels of mistrust towards medical professionals and the loss of patient autonomy.[63]

Some of the countries that have implemented a presumed consent model have experienced increases in their overall organ donation rates.[64] However, there is a lack of empirical evidence citing presumed consent as the sole reason for the increase.[65] For example, in Spain, the increase in organ donation coincided with a transformation of the organ donation system, specifically growth in the number of hospital coordinators. Hospital coordinators are medical doctors located in hospitals who are in charge of the entire organ donation process and report directly to the hospital director, cutting out middle management. This system is unique to Spain and has been another factor credited with the country's rise in organ donation.[66] In addition, some countries have experienced reduced donation rates after implementing the presumed consent model, and some have reverted back to their prior system of organ donation. In Chile, the detrimental effects of implementing a presumed consent model centered on the concern that the Chilean people were not informed of the implications and scope of the new opt-out system.[67] However, in France and Brazil, decreased donation rates were attributed to increased levels of mistrust towards medical professionals after the presumed consent model was implemented.[68]

Organ allocation priority systems allow countries to offer priority status on the waiting list to individuals who have expressed their consent to donate their organs after death. In this system, a registered potential donor will have a priority advantage over someone on the waitlist who did not consent to being an organ donor. In 1987, Singapore enacted the Human Organ Transplant Act, which established an organ allocation priority system. Those who choose to opt-out of the donor registry receive lower priority if they ever need an organ. In 2008, Israel also enacted legislation to offer an organ allocation priority system. The Israeli Organ Transplantation Law imposes a three-year waiting period after signing up as an organ donor to eliminate an individual's ability to engage in strategic behavior to get priority in organ allocation, and the law still prioritizes medical necessity as the main concern when allocating organs.[69] The Israeli legislation has been credited with increasing the number of individuals registered as organ donors.[70]

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[62] Prabhu, P., "Is Presumed Consent an Ethically Acceptable Way of Obtaining Organs for Transplant?," *Journal of the Intensive Care Society 20*(2), 2019; Zink, S. et al., "Presumed vs Expressed Consent in the US and Internationally," *Ethics Journal of the American Medical Association 7*(9), 2005; Zuniga-Fajuri, A., "Increasing Organ Donation by Presumed Consent and Allocation Priority: Chile," *Bulletin of the World Health Organization 93*, 2015.

[63] Prabhu, P., 2019; Shepherd et al., "An International Comparison of Deceased and Living Organ Donation/Transplant Rates in Opt-In and Opt-Out Systems: A Panel Study," BMC Medicine *12*(131), 2014; Zink, S. et al., 2005.

[64] Austria experienced a quadrupled donation rate within eight years of shifting to a presumed consent model.

[65] Gallagher, S., "The Spanish Model's Capacity to Save Lives by Increasing Organ Donation Rates," *Temple International and Comparative Law Journal 18*, 2004; Shepherd et al., 2014.

[66] Gallagher, S., 2004.

[67] Zuniga-Fajuri, A., 2015.

[68] Shepherd et al., 2014.

[69] Levy, M., "State Incentives to Promote Organ Donation: Honoring the Principles of Reciprocity and Solidarity Inherent in the Gift Relationship," *Journal of Law and the Biosciences*, 2018.

[70] Levy, M., 2018; Zuniga-Fajuri, A., 2015.

Mandated choice is a concept where individuals are required to opt into or out of the transplant registry at a certain point, such as when filing a tax return or renewing a driver license. While completing these tasks, the individual is required to respond to questions regarding organ donation before the task can be considered complete. In such a system, an individual's decision is legally binding upon the individual's death. The model requires individuals to record their choice, but it does not require individuals to register as an organ donor. For example, a person would still receive their driver license or tax return if they chose not to register as an organ donor.[71]

Proponents state that requiring people to make a choice regarding organ donation will reduce the number of individuals that die without ever expressing their decision regarding organ donation.[72] While a choice is required, a person's autonomy is still protected in not requiring them to make a specific choice. In addition, proponents believe that this model eliminates the next-of-kin's ability to reverse the donor's decision regarding their own body and organs.[73] It also removes the burden from families of making a consent decision during an emotional time.[74]

Opponents of the mandated choice model state that it may be a financial burden to some states or countries to maintain a system of every citizen's organ donation choice and educate the public about this system.[75,76] Researchers have noted that some people also feel that mandated choice is a coercive system because individuals are forced to register their decision, and it may not increase donation greatly because many may err on the side of perceived caution and withhold consent.[77]

What Options Could the Legislature Consider to Improve Organ Availability in Florida?

Two ways to improve organ availability in Florida are to increase the rate of living donation and increase organ donor registration. Increasing the rate of living donation would help offset federal changes in organ allocation policies, as these organs would stay within the state. Of all organ donors in Florida since 1988, 30% of donors were living rather than deceased, which is below the national level of 43%. According to research and stakeholders we interviewed, a major barrier to living donation is that people may not be able to afford the cost of the procedure and/or loss of income from being out of work. Another way to increase organ availability is to increase the rate of organ donor registration, even though some of these organs will go out of the state.

To improve organ availability in Florida, the Legislature could consider a number of options implemented in other states, proposed by stakeholders, or identified through OPPAGA fieldwork. These options would increase support for living donation and awareness and education surrounding organ donation in general. Options include

- offering employers a corporate income tax or insurance premium tax credit for expenses incurred related to paying an employee or obtaining temporary assistance during the employee's leave of absence for living organ donation;

[71] Cotter, H., "Increasing Consent for Organ Donation: Mandated Choice, Individual Autonomy, and Informed Consent," *Health Matrix: The Journal of Law-Medicine 21*(2), 2012.
[72] Cotter, H., 2012.
[73] Cotter, H., 2012.
[74] Spellman, D., "Encouragement is Not Enough: The Benefits of Instituting a Mandated Choice Organ Procurement System," *Syracuse Law Review 56*, 2006.
[75] Cotter, H., 2012; Spellman, D., 2006.
[76] Donate Life America currently operates a national donor registry in the U.S.
[77] Cotter, H., 2012; Spellman, D., 2006.

- increasing public education about both living and deceased organ donation;
- adding the topic of organ donation to continuing education requirements for health care professionals;
- expanding Medicaid coverage to include medical expenses incurred by living organ donors;
- prohibiting insurers from denying coverage to living organ donors based solely on their status as living donors; and
- requiring state and local government employers to offer paid leave for living organ donation.

The Legislature could also consider options to improve organ availability in Florida through increased donor registration. Options include

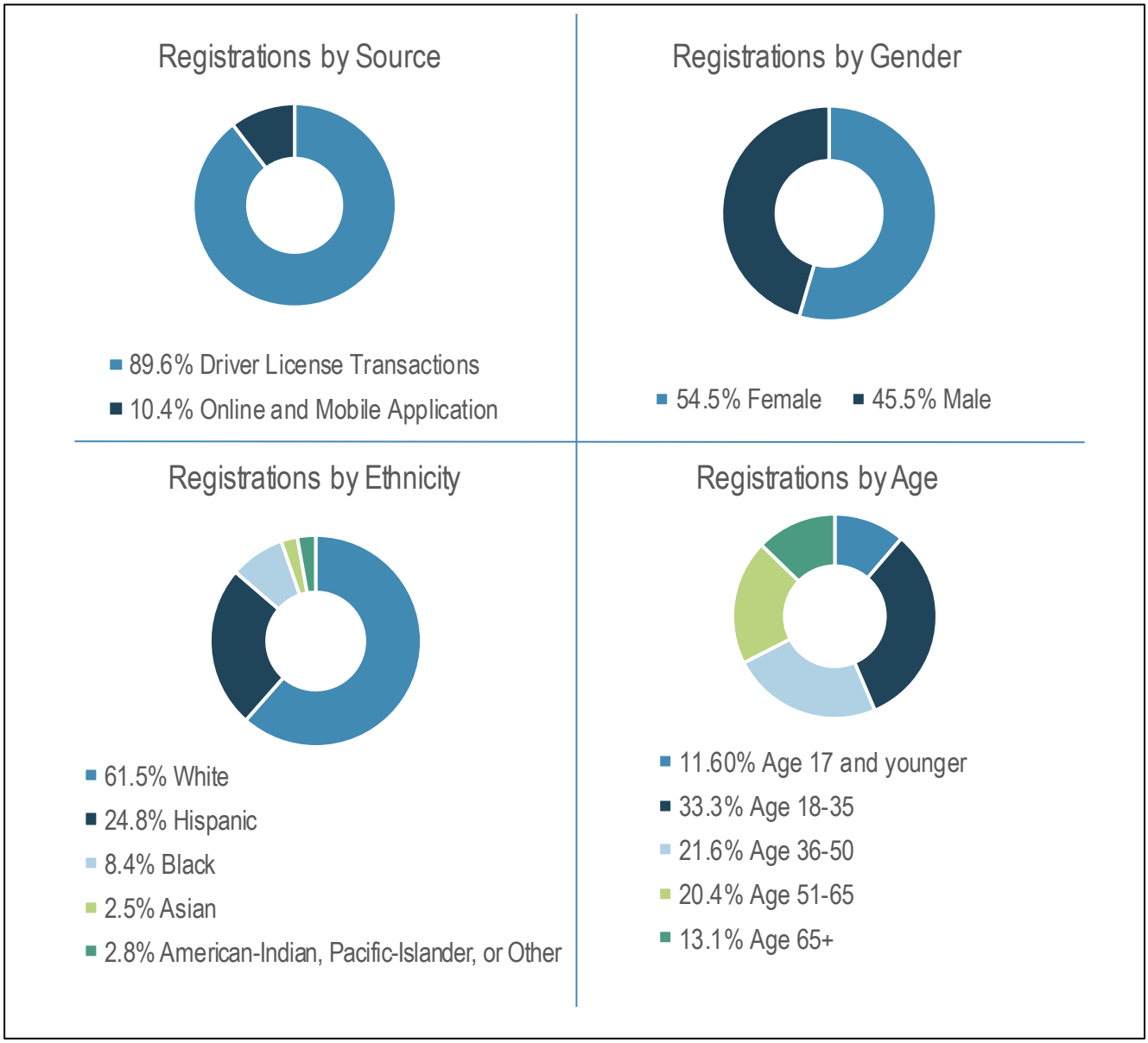
- directing AHCA to use all excess revenues from fees paid by OPOs and tissue and eye banks for public education on donation;
- increasing public education about donor registration;
- adding the topic of organ donation to high school curriculum requirements (e.g., health science classes) to increase familiarity when teenagers first apply for a driver license;
- requiring county tax collectors to allow prominent display of organ donation educational materials in their offices; and
- expanding the opportunities to register as an organ donor to include additional points of access such as hunting and fishing licenses and state agency webpages.

APPENDIX A

Source and Demographic Characteristics of Donor Registrations

In 2018, the majority (89.6%) of organ donor registrations in Florida were from driver license transactions. Slightly more females than males registered to be donors during the period (54.5% compared to 45.5%). The most frequently represented ethnicities among organ donor registrants in Florida were white (61.5%) and Hispanic (24.8%). The age group with the highest frequency of donor registrations was the 18-35 age group. (See Exhibit A-1.)

Exhibit A-1
Most Donor Registrations in Florida Are From Driver License Transactions



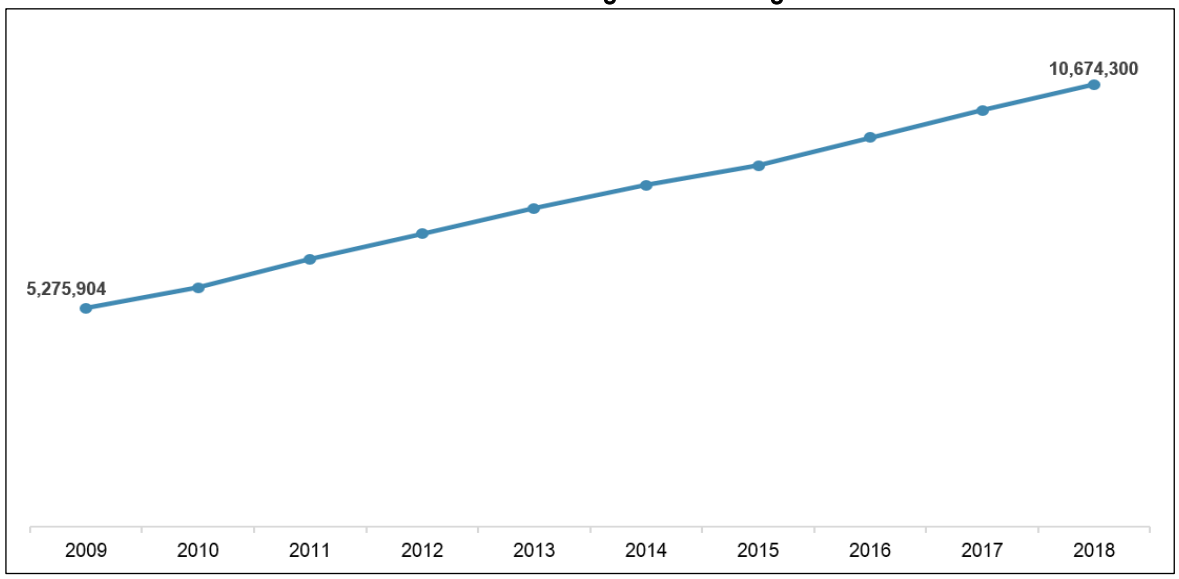
Source: OPPAGA analysis of data from the *Donate Life Florida 2018 Annual Report*.

APPENDIX B

Florida's Donor Registration Rate Over Time

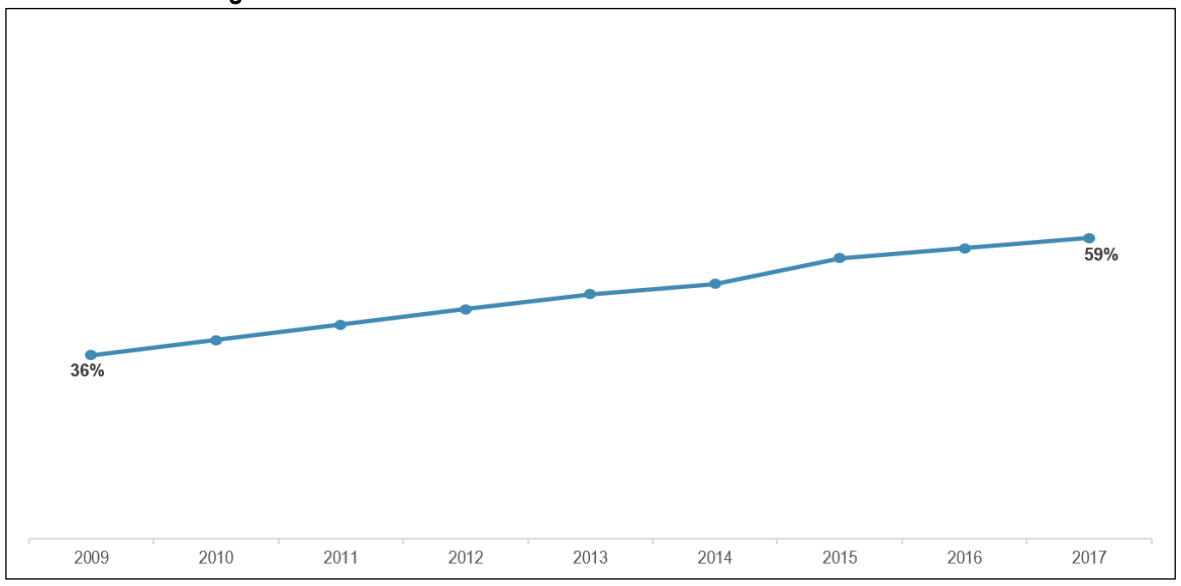
Florida has improved its donor registration rate over time, both in whole numbers and as a percentage of the population. In 2009, Florida had 5,275,904 registered donors, compared to 10,674,300 in 2018. (See Exhibit B-1.) As a percentage, Florida increased its donor registration rate of adults 18 and older from 36% in 2009 to 59% in 2017. (See Exhibit B-2.)

Exhibit B-1
Florida Has More Than Doubled the Number of Organ Donor Registrants From 2009 to 2018



Source: OPPAGA analysis of Donate Life Florida data.

Exhibit B-2
Florida's Donor Registration Rate Has Increased From 36% in 2009 to 59% in 2017



Source: OPPAGA analysis of Donate Life America data.

APPENDIX C

Florida Adult Transplant Program Performance Based on SRTR Program-Specific Five-Tier Assessment Results

Florida's 12 transplant centers each administer one or more organ-specific transplant programs. The Scientific Registry of Transplant Recipients (SRTR) produces outcome assessments for all transplant programs in the U.S. using a five-tier assessment system.[78] The SRTR tiers rank transplant programs on metrics that include adults "getting a deceased donor transplant faster" and adult survival on the waitlist.[79] "Getting a deceased donor transplant faster" is a measure of how quickly those on the wait list get a transplant during the two-year period evaluated relative to how quickly they would be expected to get a transplant based on national data. The metric provides a measure of the rate at which the program finds deceased donor organs for its candidates.[80]

The SRTR tier rankings are as follows.

- Tiers 1 and 2: the program is performing worse than expected.
- Tier 3: the transplant program is performing roughly as expected.
- Tiers 4 and 5: the program is performing better than expected.[81]

Additional details on each transplant program can be found in SRTR's searchable database. Exhibits C-1 through C-3 show the outcomes for Florida transplant centers for adult transplant programs categorized by the number of programs each transplant center administers (six or more programs, two to three programs, and one program).[82] Exhibit C-4 shows the same five-tier assessment results organized by transplant program and organ type.

Transplant Centers With Six or More Transplant Programs

Florida's five transplant centers with six or more transplant programs are AdventHealth Orlando, Jackson Memorial Hospital University of Miami School of Medicine, Mayo Clinic Florida, Tampa General Hospital, and UF Health Shands. Among these programs, AdventHealth Orlando and Tampa General are the only two transplant centers that were rated as expected or better than expected for every organ program for adults getting a transplant faster. None of these centers were rated as expected or better than expected for every organ program for adult survival on the waitlist. Mayo Clinic Florida, Tampa General Hospital, and UF Health Shands were the only transplant centers that had only one program that was rated as worse than expected for adult survival on the waitlist.

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[78] A transplant program is organ-specific within a single transplant center. Transplant centers that conduct transplants for more than one organ would thus have more than one transplant program and multiple rankings.

[79] The strength of the tier-rating system is that it controls for patient characteristics, organs used, and volume of transplants conducted. If Florida's transplant centers had older and sicker transplant patients, the tier ranking they received would not penalize them for these factors; rather, it should reflect their performance. The tier ranking also takes into account the likelihood of getting an especially high or low tier score due to a small volume of transplants.

[80] SRTR excludes individuals who undergo living donor transplants from the analysis.

[81] Ratings are based on a probabilistic estimate; thus, a specific rating represents a range of outcomes that are driven by both performance relative to expected performance as well as the volume of transplants in a program. For details about the computation of the rating tiers, see SRTR's Calculating the Five-Tier Assessments: A Guide for Pre-and Posttransplant Metrics.

[82] This analysis excludes the pediatric transplant program at the Johns Hopkins All Children's Hospital. It includes the transplant program at the Gulf Coast Medical Center, which was operational during the time period of the assessment but ceased operation at the end of 2018.

Of these large transplant centers, there were nine programs that were rated as worse than expected for adults getting a deceased donor transplant faster; of these nine, four were in UF Health Shands, three were in Jackson Memorial, and two were in Mayo Clinic. Of these large transplant centers, there were 11 programs that were rated as worse than expected for adult survival on the waitlist. More than half of them (six) were in Jackson Memorial. (See Exhibit C-1.)

Exhibit C-1
SRTR Five-Tier Assessment Results for the Five Transplant Centers With Six or More Adult Transplant Programs

Transplant Clinic/Organ Program[1]	Adults Getting a Deceased Donor Transplant Faster	Adult Survival on the Waitlist[2]
AdventHealth Orlando		
Heart	Better Than Expected	Worse Than Expected
Kidney	Better Than Expected	Worse Than Expected
Kidney-Pancreas	Better Than Expected	Better Than Expected
Liver	Better Than Expected	Better Than Expected
Lung	Better Than Expected	As Expected
Pancreas	As Expected	As Expected
Jackson Memorial Hospital University of Miami School of Medicine		
Heart	Worse Than Expected	Worse Than Expected
Heart-Lung	Worse Than Expected	Worse Than Expected
Intestine	As Expected	Better Than Expected
Kidney	As Expected	Worse Than Expected
Kidney-Pancreas	Better Than Expected	Worse Than Expected
Liver	Better Than Expected	Worse Than Expected
Lung	Worse Than Expected	Worse Than Expected
Pancreas	As Expected	As Expected
Mayo Clinic Florida		
Heart	Worse Than Expected	Better Than Expected
Heart-Lung	Worse Than Expected	Better Than Expected
Kidney	As Expected	Worse Than Expected
Kidney-Pancreas	As Expected	As Expected
Liver	Better Than Expected	As Expected
Lung	As Expected	Better Than Expected
Pancreas	Better Than Expected	As Expected
Tampa General Hospital		
Heart	Better Than Expected	Worse Than Expected
Heart-Lung	As Expected	As Expected
Kidney	Better Than Expected	Better Than Expected
Kidney-Pancreas	Better Than Expected	As Expected
Liver	Better Than Expected	Better Than Expected
Lung	As Expected	As Expected
Pancreas	As Expected	As Expected
UF Health Shands Hospital		
Heart	Worse Than Expected	As Expected
Kidney	Worse Than Expected	Worse Than Expected
Kidney-Pancreas	As Expected	Better Than Expected
Liver	Worse Than Expected	Better Than Expected
Lung	Better Than Expected	Better Than Expected
Pancreas	Worse Than Expected	As Expected

[1] UF Health Shands has a heart-lung transplant program but did not perform any transplants in this period, so it does not have a tier assignment.

[2] SRTR cautions that it received feedback regarding its waitlist mortality measure for kidney transplant programs because many kidney transplant candidates are not cared for by the program at which they are listed. As a result, SRTR does not display the kidney waitlist mortality measure in its searchable database results for kidney transplant programs, even though SRTR provides this measure in its program-specific reports.

Source: OPPAGA analysis of SRTR outcome assessment data, July 1, 2017 through June 30, 2019, program-specific reports.

Transplant Centers With Two to Three Transplant Programs

The three transplant centers with two to three transplant programs are Cleveland Clinic Florida Weston, Largo Medical Center, and Memorial Regional Hospital. Among these programs, Cleveland Clinic Florida Weston and Memorial Regional Hospital were rated as better than expected or as expected for all of their programs on both metrics. Largo Medical Center was rated as better than expected for both of its transplant programs for adults getting a transplant faster. However, of these mid-sized transplant centers, Largo Medical Center was the only transplant hospital with a worse than expected rating, which it received for adult survival on its kidney program waitlist. (See Exhibit C-2.)

Exhibit C-2
SRTR Five-Tier Assessment Results for the Three Transplant Centers With Two to Three Adult Transplant Programs

Transplant Clinic/Organ Program	Adults Getting a Deceased Donor Transplant Faster	Adult Survival on the Waitlist[1]
Cleveland Clinic Florida Weston		
Heart	Better Than Expected	As Expected
Kidney	Better Than Expected	Better Than Expected
Liver	Better Than Expected	Better Than Expected
Largo Medical Center		
Kidney	Better Than Expected	Worse Than Expected
Liver	Better Than Expected	Better Than Expected
Memorial Regional Hospital		
Heart	As Expected	Better Than Expected
Kidney	Better Than Expected	As Expected

[1] SRTR cautions that it received feedback regarding its waitlist mortality measure for kidney transplant programs because many kidney transplant candidates are not cared for by the program at which they are listed. As a result, SRTR does not display the kidney waitlist mortality measure in its searchable database results for kidney transplant programs, even though SRTR provides this measure in its program-specific reports.

Source: OPPAGA analysis of SRTR outcome assessment data, July 1, 2017 through June 30, 2019, program-specific reports.

Transplant Centers With One Transplant Program

The four transplant centers with one transplant program are Broward Health Medical Center, Gulf Coast Medical Center, Halifax Medical Center, and Sacred Heart Hospital Pensacola. Among these programs, Broward Health Medical Center was rated as expected or better than expected for its liver program for both metrics. Gulf Coast Medical Center was rated as expected for its kidney program for both metrics. Halifax Medical Center and Sacred Heart Hospital had mixed results; both were rated as better than expected for their kidney programs for one measure but have the only two worse than expected ratings among the small programs. (See Exhibit C-3.)

Exhibit C-3
SRTR Five-Tier Assessment Results for the Four Transplant Centers With One Adult Transplant Programs

Transplant Center/Organ Program	Adults Getting a Deceased Donor Transplant Faster	Adult Survival on the Waitlist[1]
Broward Health Medical Center		
Liver	As Expected	Better Than Expected
Gulf Coast Medical Center[2]		
Kidney	As Expected	As Expected
Halifax Medical Center		
Kidney	Better Than Expected	Worse Than Expected
Sacred Heart Hospital Pensacola		
Kidney	Worse Than Expected	Better Than Expected

[1] SRTR cautions that it received feedback regarding its waitlist mortality measure for kidney transplant programs because many kidney transplant candidates are not cared for by the program at which they are listed. As a result, SRTR does not display the kidney waitlist mortality measure in its searchable database results for kidney transplant programs, even though SRTR provides this measure in its program-specific reports.

[2] Gulf Coast Medical Center had a transplant program during the time period of the assessment but the program ceased operation at the end of 2018.
Source: OPPAGA analysis of SRTR outcome assessment data, July 1, 2017 through June 30, 2019, program-specific reports.

Transplant Program-Level Results

Exhibit C-4 shows the five-tier assessment results organized by transplant program/organ type. Overall results by type of program are summarized below.

- Among the seven **heart transplant programs**, only Cleveland Clinic Florida Weston and Memorial Regional Hospital was rated as expected or better than expected across both metrics. Jackson Memorial Hospital University of Miami School of Medicine is the only heart program that was rated as worse than expected for both metrics.
- Among the three **heart-lung transplant programs**, only Tampa General Hospital was rated as expected or better than expected across both metrics. Jackson Memorial Hospital University of Miami School of Medicine was rated as worse than expected for both metrics.
- Jackson Memorial Hospital University of Miami School of Medicine had the only **intestine transplant program** and was rated as expected for adults getting a deceased donor transplant faster and better than expected for adult survival on the waitlist.
- Among the 11 **kidney transplant programs**, Cleveland Clinic Florida Weston and Tampa General Hospital had the only programs that were rated as better than expected for both metrics. Gulf Coast Medical Center and Memorial Regional Hospital were rated as expected or better than expected for both metrics. More than half of kidney programs overall (6 out of 11) were rated as worse than expected for adult survival on the waitlist.
- Among the five **kidney-pancreas programs**, AdventHealth Orlando had the only program that was rated as better than expected across both metrics. Jackson Memorial Hospital University of Miami School of Medicine had the only worse than expected rating, which was for adult survival on the waitlist. The other three programs (Mayo Clinic Florida, Tampa General Hospital, and UF Health Shands) were rated as expected or better than expected for both metrics.
- Florida's eight **liver transplant programs** did well overall. Out of the 16 ratings across the two metrics, 12 were better than expected, 2 were as expected, and only 2 were worse than expected. AdventHealth Orlando, Cleveland Clinic Florida Weston, Largo Medical Center, and Tampa General Hospital had programs that were rated as better than expected for both metrics.
- Among the five **lung transplant programs**, UF Health Shands Hospital is the only program that was rated as better than expected for both metrics. In addition to UF Health Shands

Hospital, AdventHealth Orlando, Mayo Clinic Florida, and Tampa General Hospital were rated as expected or better than expected for both metrics. Jackson Memorial Hospital University of Miami School of Medicine had the only clinic with a worse than expected rating, which it received for both metrics.

- The five **pancreas transplant programs** were rated as expected or better than expected for four out of five ratings for adults getting a deceased transplant faster, and as expected for all of their ratings for adult survival on the waitlist. UF Health Shands is the only center that was rated as worse than expected, which was for adults getting a transplant faster.

Exhibit C-4
SRTR Five-Tier Assessment Results by Organ for Florida Transplant Centers

Organ Program/Transplant Center[1]	Adults Getting a Deceased Donor Transplant Faster	Adult Survival on the Waitlist
Heart		
AdventHealth Orlando	Better Than Expected	Worse Than Expected
Cleveland Clinic Florida Weston	Better Than Expected	As Expected
Jackson Memorial Hospital University of Miami School of Medicine	Worse Than Expected	Worse Than Expected
Mayo Clinic Florida	Worse Than Expected	Better Than Expected
Memorial Regional Hospital	As Expected	Better Than Expected
Tampa General Hospital	Better Than Expected	Worse Than Expected
UF Health Shands Hospital	Worse Than Expected	As Expected
Heart-Lung		
Jackson Memorial Hospital University of Miami School of Medicine	Worse Than Expected	Worse Than Expected
Mayo Clinic Florida	Worse Than Expected	Better Than Expected
Tampa General Hospital	As Expected	As Expected
Intestine		
Jackson Memorial Hospital University of Miami School of Medicine	As Expected	Better Than Expected
Kidney[2]		
AdventHealth Orlando	Better Than Expected	Worse Than Expected
Cleveland Clinic Florida Weston	Better Than Expected	Better Than Expected
Gulf Coast Medical Center	As Expected	As Expected
Halifax Medical Center	Better Than Expected	Worse Than Expected
Jackson Memorial Hospital University of Miami School of Medicine	As Expected	Worse Than Expected
Largo Medical Center	Better Than Expected	Worse Than Expected
Mayo Clinic Florida	As Expected	Worse Than Expected
Memorial Regional Hospital	Better Than Expected	As Expected
Sacred Heart Hospital Pensacola	Worse Than Expected	Better Than Expected
Tampa General Hospital	Better Than Expected	Better Than Expected
UF Health Shands Hospital	Worse Than Expected	Worse Than Expected
Kidney-Pancreas		
AdventHealth Orlando	Better Than Expected	Better Than Expected
Jackson Memorial Hospital University of Miami School of Medicine	Better Than Expected	Worse Than Expected
Mayo Clinic Florida	As Expected	As Expected
Tampa General Hospital	Better Than Expected	As Expected
UF Health Shands Hospital	As Expected	Better Than Expected

Organ Program/Transplant Center[1]	Adults Getting a Deceased Donor Transplant Faster	Adult Survival on the Waitlist
Liver		
AdventHealth Orlando	Better Than Expected	Better Than Expected
Broward Health Medical Center	As Expected	Better Than Expected
Cleveland Clinic Florida Weston	Better Than Expected	Better Than Expected
Jackson Memorial Hospital University of Miami School of Medicine	Better Than Expected	Worse Than Expected
Largo Medical Center	Better Than Expected	Better Than Expected
Mayo Clinic Florida	Better Than Expected	As Expected
Tampa General Hospital	Better Than Expected	Better Than Expected
UF Health Shands Hospital	Worse Than Expected	Better Than Expected
Lung		
AdventHealth Orlando	Better Than Expected	As Expected
Jackson Memorial Hospital University of Miami School of Medicine	Worse Than Expected	Worse Than Expected
Mayo Clinic Florida	As Expected	Better Than Expected
Tampa General Hospital	As Expected	As Expected
UF Health Shands Hospital	Better Than Expected	Better than Expected
Pancreas		
AdventHealth Orlando	As Expected	As Expected
Jackson Memorial Hospital University of Miami School of Medicine	As Expected	As Expected
Mayo Clinic Florida	Better Than Expected	As Expected
Tampa General Hospital	As Expected	As Expected
UF Health Shands Hospital	Worse Than Expected	As Expected

[1] UF Health Shands has a heart-lung transplant program but did not perform any transplants in this period, so they do not have a tier assignment. Gulf Coast Medical Center had a transplant program during the time period of the assessment but the program ceased operation at the end of 2018.

[2] SRTR cautions that it received feedback regarding its waitlist mortality measure for kidney transplant programs because many kidney transplant candidates are not cared for by the program at which they are listed. As a result, SRTR does not display the kidney waitlist mortality measure in its searchable database results for kidney transplant programs, even though SRTR provides this measure in its program-specific reports.

Source: OPPAGA analysis of SRTR outcome assessment data, July 1, 2017 through June 30, 2019, program-specific reports.

APPENDIX D

Comparison of Florida to U.S. Kidney and Liver Transplant Program Waitlist Trends

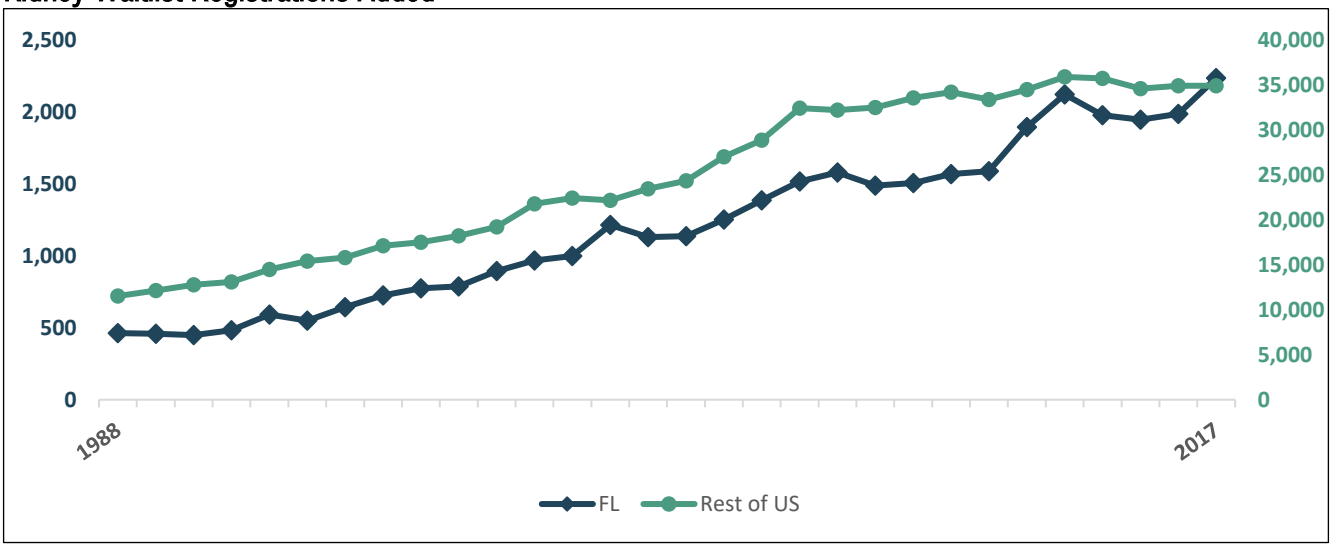
OPPAGA's analysis of data from UNOS shows that Florida compares similarly or favorably to the nation for kidney and liver waitlist trends.[83] UNOS provided data showing the outcomes of patients within three years of being placed on a transplant waitlist in Florida and in other states. While these results provide useful descriptive information, they should be viewed with caution, as they do not take into account differences in patient mixes over time or across states or differences in organ transplant quantity or quality. For example, if Florida transplant centers have older and sicker transplant patients on a waitlist, whether a result of waitlist acceptance and management practices or Florida's population characteristics, Florida's percentage of deaths on a waitlist would be worse than the rest of the nation's centers even if transplant success on comparable populations were identical. These results also do not take into account the mix of organs transplanted in Florida versus other states. For example, if Florida centers transplanted more organs that were less likely to be successful, either because of the type or quality of organ that the centers accept, their percentage of deaths on the waitlist would be higher than the rest of the nation's centers, even if transplants were similarly successful on equivalent organs.

Kidney Waitlist Trends

Florida's trend in new kidney waitlist registrations generally follows the same pattern of increase as the U.S. as a whole, with an increase in registrations over time. (See Exhibit D-1.) As registrations (demand for kidneys) grew rapidly, likely outstripping the growth in supply of kidneys, there was a decline in the percentage of new registrants who were able to receive a kidney. So despite the fact that there has been growth in the number of kidney recipients, there has been a decline in the percentage of registrants who received a kidney. (See Exhibit D-2.) However, Florida's percentage of patients who received a deceased donor transplant within three years of registering on the waitlist has remained better than the nation as a whole over time. In addition, Florida's percentage of patient deaths within three years of registering on the waitlist for a kidney has been similar to or slightly lower than the rest of the nation since 1988. (See Exhibit D-3.)

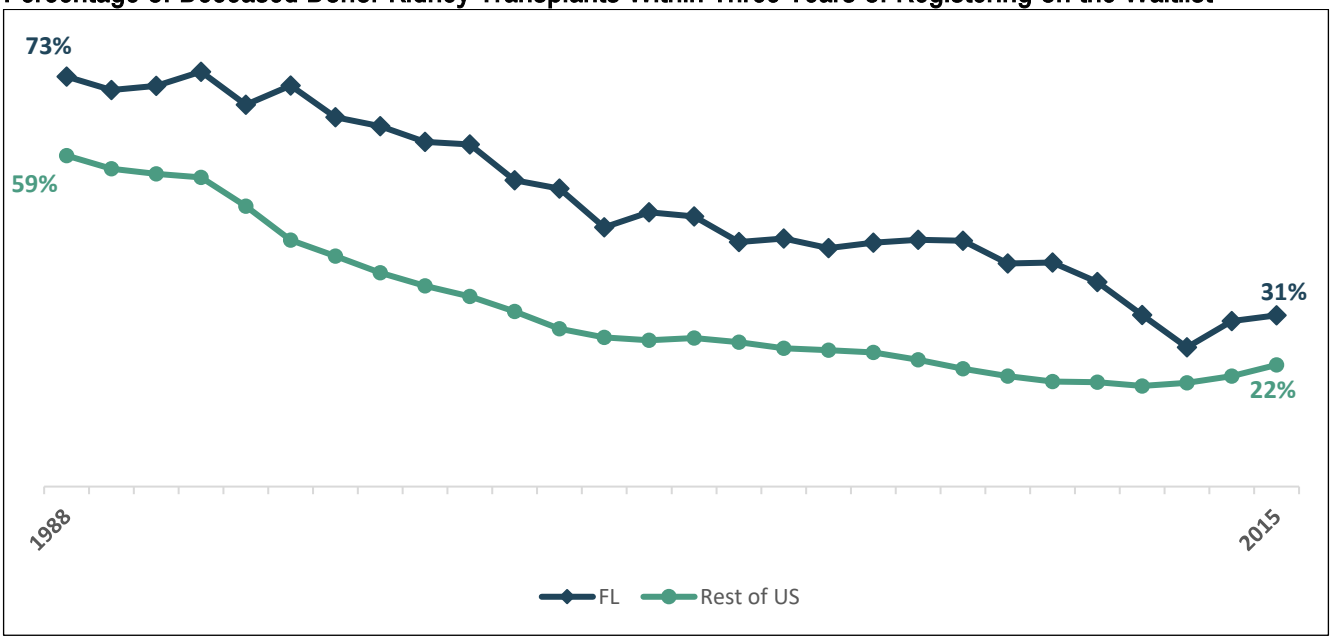
[83] For organs other than kidney and liver, the small number of organs showed a high degree of annual variability and made it difficult to draw conclusions about rates. We do not present a comparison of different organs because transplantation and death rates can be very different for different states. The mix and size of organ programs available in a state can change the apparent pooled relative outcomes for otherwise identical organ-by-organ performance.

Exhibit D-1
Kidney Waitlist Registrations Added



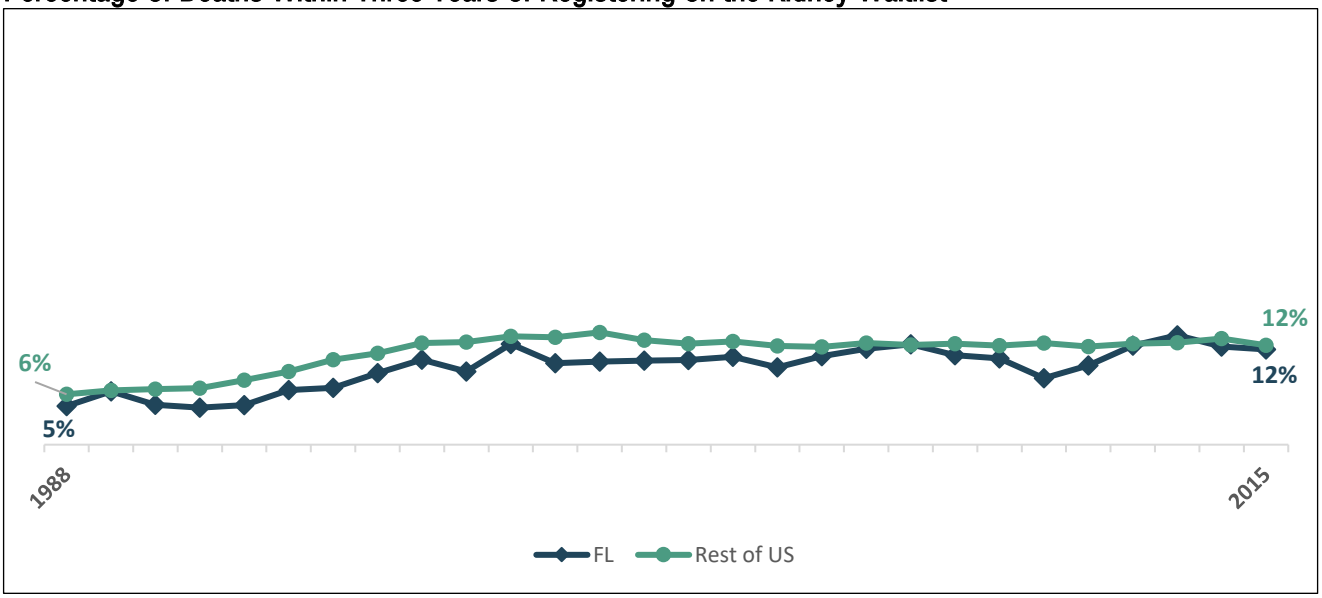
Source: OPPAGA analysis of UNOS data.

Exhibit D-2
Percentage of Deceased Donor Kidney Transplants Within Three Years of Registering on the Waitlist



Source: OPPAGA analysis of UNOS data

Exhibit D-3
Percentage of Deaths Within Three Years of Registering on the Kidney Waitlist[1]



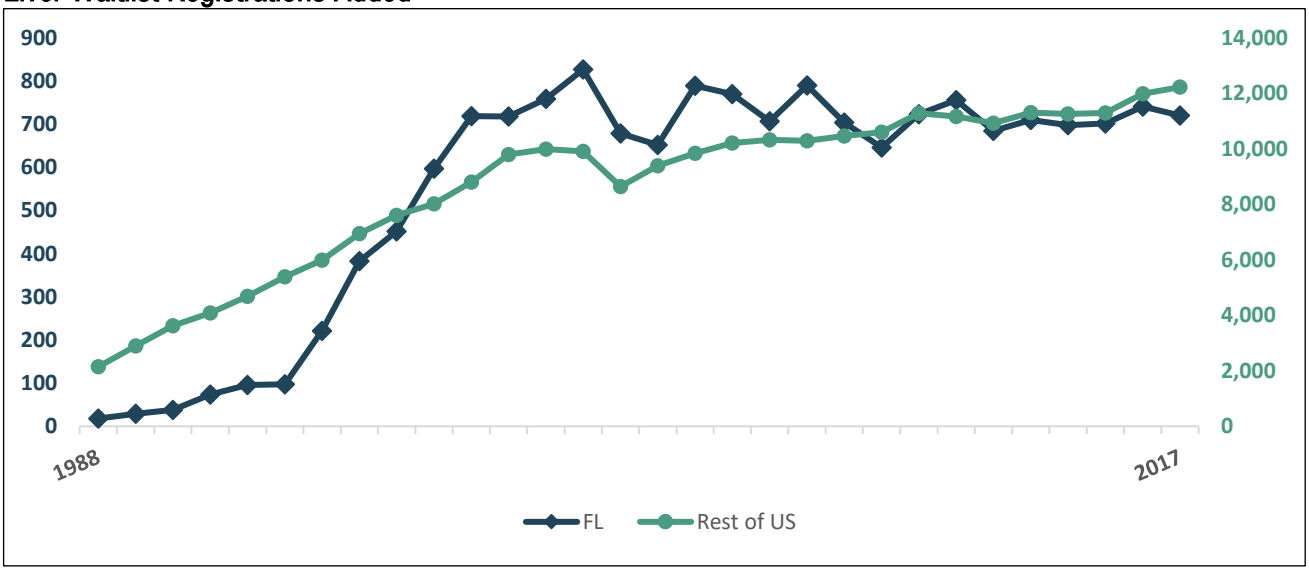
[1] The measure reflects the percentage of registrants who were removed from the waitlist due to death or being too sick to transplant, or who died after exiting the waitlist for other reasons.

Source: OPPAGA analysis of UNOS data.

Liver Waitlist Trends

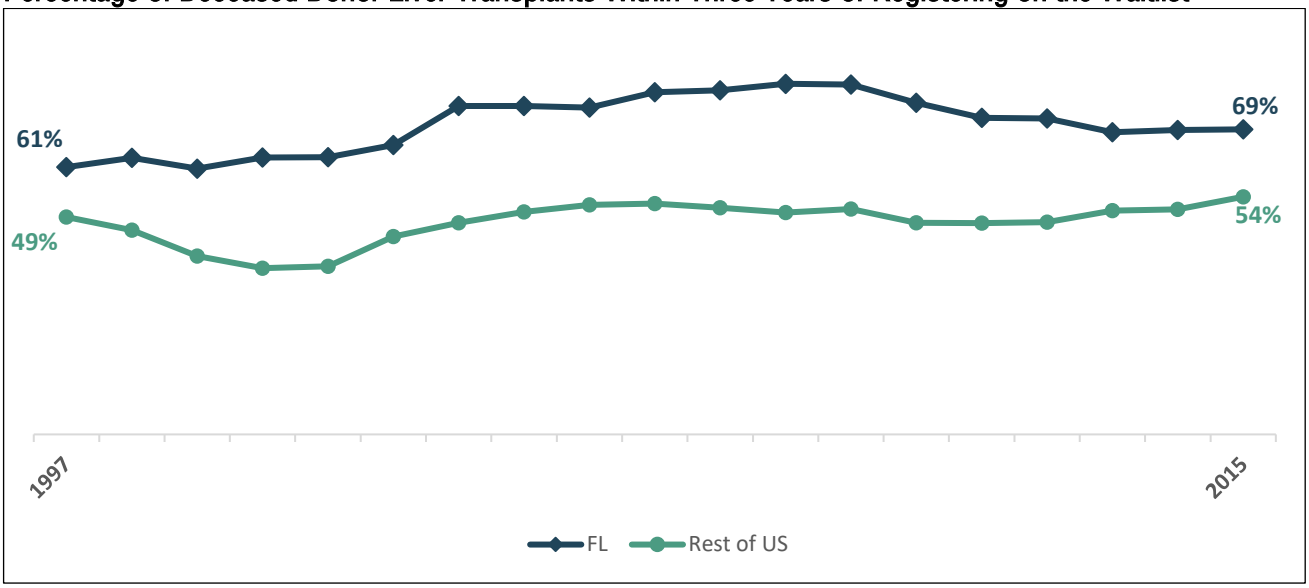
OPPAGA's analysis of UNOS data on liver waitlist trends yielded similar results as for kidney waitlist trends. Florida has increased the number of waitlist registrations for livers over time, a trend that roughly mirrors the pattern in the rest of the U.S. (See Exhibit D-4.) However, Florida has generally maintained relatively high transplantation rates for livers compared to the nation as a whole. These differences have been statistically significant in nearly all years of available data. (See Exhibit D-5.) Florida has also maintained a relatively low waitlist death rate for liver transplants compared to the nation as a whole. The differences have been statistically significant in nearly all years of available data. (See Exhibit D-6.)

Exhibit D-4
Liver Waitlist Registrations Added



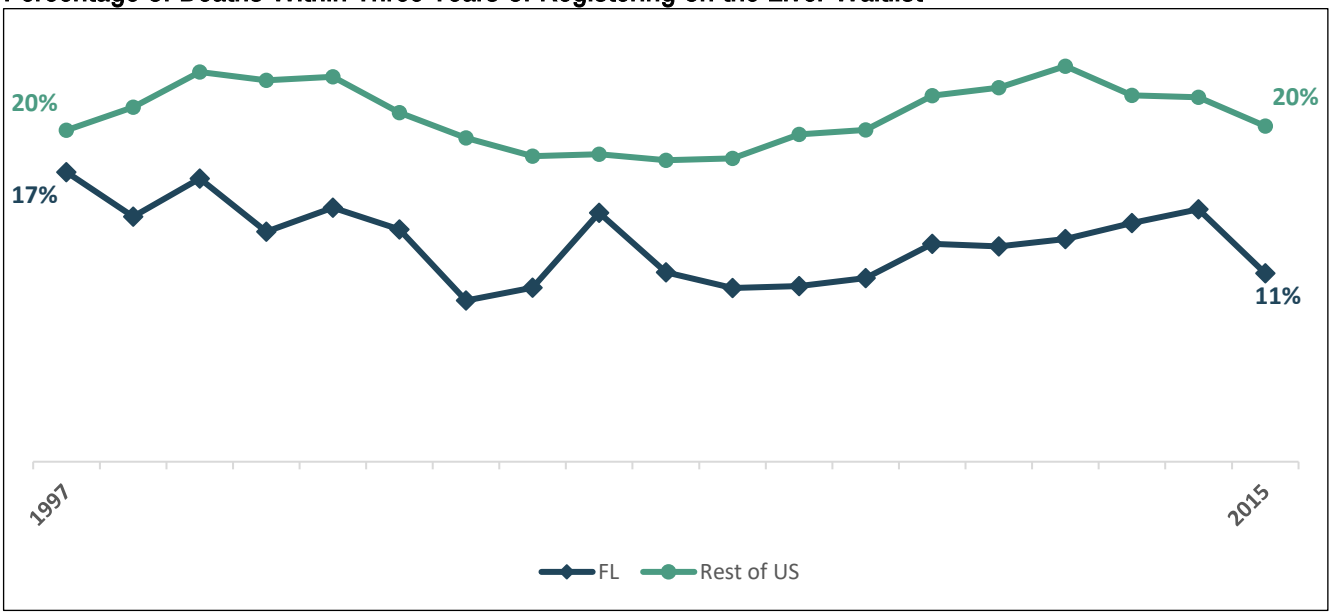
Source: OPPAGA analysis of UNOS data.

Exhibit D-5
Percentage of Deceased Donor Liver Transplants Within Three Years of Registering on the Waitlist



Source: OPPAGA analysis of UNOS data.

Exhibit D-6
Percentage of Deaths Within Three Years of Registering on the Liver Waitlist[1]



[1] The measure reflects the percentage of registrants who were removed from the waitlist due to death or being too sick to transplant, or who died after exiting the waitlist for other reasons.

Source: OPPAGA analysis of UNOS data.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 1516
INTRODUCER:	Health Policy Committee and Senator Harrell
SUBJECT:	Organ Donation
DATE:	January 29, 2020
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Fav/CS**
2.			JU	
3.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1516 amends multiple sections of law related to organ donations. The bill:

- Prohibits a health insurance policy from limiting or excluding coverage for a living organ donor under a preexisting condition provision.
- Prohibits an organ transplantation facility from charging an organ donor or his or her family any fee for services relating to the procurement or donation of the donor's organs.
- Adds a statement on the uniform donor card application form that neither the donor nor his or her family is responsible for the payment of any fees associated with services relating to the procurement or donation of the donor's organs, tissues, or eyes.
- Expands the organ donation education program to include federal laws and information on the organ donation and transplantation process.
- Requires the Organ and Tissue Procurement and Transplantation Advisory Board to submit specified recommendations to the Agency for Health Care Administration (AHCA) by September 1, 2021.
- Establishes additional requirements for the AHCA related to organ transplantation evaluation, reporting, and education.
- Expands the duties of the Organ Transplant Advisory Council (OTAC). The bill renames the OTAC as the Organ Transplant Technical Advisory Council (Council) and charges the Council with assisting the AHCA in developing standards for quality and outcomes at adult and pediatric organ transplant programs.
- Specifies that certificate of need (CON) rules for minimum volume standards for organ transplantation and neonatal intensive care unit (NICU) services remain in effect until the

AHCA has adopted corresponding licensure rules. The requirement to adopt rules expires upon the AHCA's adoption of such rules.

The bill has an effective date of July 1, 2020.

II. Present Situation:

Organ Transplant Advisory Council (OTAC)

Section 765.53, F.S., establishes the OTAC to consist of 12 physician[1] members who are appointed to represent the interests of the public and the clients of the Department of Health (DOH) or the AHCA. All members are appointed by the Secretary of the AHCA (a.k.a. the Secretary of Health Care Administration) and serve two-year terms. The OTAC is responsible for recommending indications for adult and pediatric organ transplants to the AHCA and formulating guidelines and standards for organ transplants and for the development of End Stage Organ Disease and Tissue/Organ Transplant programs. The OTAC's recommendations, guidelines, and standards are limited in applicability to only those health programs funded through the AHCA.

The OTAC met 22 times with its first meeting held on August 27, 2007 and its last meeting held on April 14, 2015. Most actions of the OTAC revolved around approving guidelines for organ transplantations and reviewing and approving hospital transplant program applications for recommendation to the AHCA.

Organ and Tissue Procurement and Transplantation Advisory Board (Board)

The Board is created by s. 765.543, F.S. The secretary of the AHCA appoints the 14 members of the Board who serve three-year terms. The Board is tasked with:

- Assisting the AHCA in the development of necessary professional qualifications, including, but not limited to, the education, training, and performance of persons engaged in the various facets of organ and tissue procurement, processing, preservation, and distribution for transplantation;
- Assisting the AHCA in monitoring the appropriate and legitimate expenses associated with organ and tissue procurement, processing, and distribution for transplantation and developing methodologies to assure the uniform statewide reporting of data to facilitate the accurate and timely evaluation of the organ and tissue procurement and transplantation system;
- Providing assistance to the Florida Medical Examiners Commission in the development of appropriate procedures and protocols to ensure the continued improvement in the approval and release of potential donors by the district medical examiners and associate medical examiners;
- Developing with and recommending to the AHCA the necessary procedures and protocols required to assure that all residents of this state have reasonable access to available organ and tissue transplantation therapy and that residents of this state can be reasonably assured that the statewide procurement transplantation system is able to fulfill their organ and tissue

[1] Licensed under chs. 458 and 459, F.S.

requirements within the limits of the available supply and according to the severity of their medical condition and need; and

- Developing with and recommend to the AHCA any changes to the laws of this state or administrative rules or procedures to ensure that the statewide organ and tissue procurement and transplantation system is able to function smoothly, effectively, and efficiently, in accordance with the Federal Anatomical Gift Act and in a manner that assures the residents of this state that no person or entity profits from the altruistic voluntary donation of organs or tissues.

The Board met five times between September of 2011 and January of 2014. The Board held its last meeting to conduct general business of the advisory board including review and discussion on recommendations for changes to the laws and administrative rules related to organ and tissue procurement activities in Florida.[2]

Licensure Requirements

Volume requirements (including NICU volume requirements):[3, 4]

Liver	5 transplants over two years
Kidneys	Adult – 15 transplants per year Pediatric – 5 transplants per year
Pediatric bone marrow	10 transplants per year of each type performed (allogenic or autologous)
Adult bone marrow	10 transplants per year of each type performed (allogenic or autologous)
Lung, Heart and Lung, Pancreas and Islet Cells, and Intestines	None
Proposed organ transplant volume requirements in 59A-3.246, F.A.R.	Each licensed organ transplant program must perform a minimum of 10 transplants per year averaged over 2 years. Hospitals providing adult and pediatric programs must meet the minimum volume requirement for each age group separately.

Level II NICU	10 beds and the hospital must have at least 1,000 live births per year.
Level III NICU	15 beds and the hospital must have at least 1,500 live births per year.
Proposed rule 59A-3.249	Same as above.

[2] See meeting notice 14072583 in the Florida Administrative Register. Additional meeting minutes and recommendations are available at https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Lab_HomeServ/OrganTissueBoard.shtml (last visited on Jan. 28, 2020).
[3] Projected prior to grant of licensure.
[4] Volume requirements for liver and kidney transplants are included in the CON portions of the rule.

Currently, standards for licensure for organ transplant programs in Florida can be found in AHCA Rule 59C-1.044, F.A.C.[5] These standards include:

- General staffing requirements:
  - A staff of physicians with expertise in caring for patients with end-stage disease requiring transplantation. The staff must have medical specialties or sub-specialties appropriate for the type of transplantation program to be established. A physician with one year of experience in the management of infectious diseases in the transplant patient must be a member of the transplant team. The program must employ a transplant physician, and a transplant surgeon, if applicable, as defined by the United Network for Organ Sharing (UNOS), June 1994.
  - A program director who has a minimum of one year of formal training and one year of experience at a transplantation program for the same type of organ transplantation program proposed.
  - A staff of practitioners with experience in the special needs of children if pediatric transplantations are performed;
  - A staff of nurses and nurse practitioners with experience in the care of chronically ill patients and their families;
  - Contractual agreements with consultants who have expertise in blood banking and are capable of meeting the unique needs of transplant patients on a long-term basis;
  - Nutritionists with expertise in the nutritional needs of transplant patients;
  - Respiratory therapists with expertise in the needs of transplant patients; and
  - Social workers, psychologists, psychiatrists, and other individuals skilled in performing comprehensive psychological assessments, counselling patients, and families of patients, providing assistance with financial arrangements, and making arrangements for use of community resources.
- Coordination of services:
  - Staff and other resources necessary to care for a patient's chronic illness prior to transplantation, during transplantation, and in the post-operative period. Services and facilities for inpatient and outpatient care must be available on a 24-hour basis.
  - If cadaveric transplantation will be part of the transplantation program, a written agreement with an organ acquisition center for organ procurement is required. A system by which 24-hour call can be maintained for assessment, management, and retrieval of all referred donors, cadaver donors or organs shared by other transplant or organ procurement agencies is mandatory. Applicants for a bone marrow transplantation program are exempt from this requirement.
  - An age-appropriate (adult or pediatric) intensive care unit which includes facilities for prolonged reverse isolation when required.
  - A clinical review committee for evaluation and decision-making regarding the suitability of a transplant candidate.
  - Written protocols for patient care for each type of organ transplantation program including, at a minimum, patient selection criteria for patient management and evaluation during the pre-hospital, in-hospital, and immediate post-discharge phases of the program.
  - Detailed therapeutic and evaluative procedures for the acute and long term management of each transplant program patient, including the management of commonly encountered complications.

[5] For a discussion of the licensure requirements in a CON rule versus a licensure rule, see the CON overview below.

- Equipment for cooling, flushing, and transporting organs. If cadaveric transplants are performed, equipment for organ preservation through mechanical perfusion is necessary. Applicants for a bone marrow transplantation program are exempt from this requirement. This requirement may be met through an agreement with an organ procurement agency.
- An onsite tissue-typing laboratory or a contractual arrangement with an outside laboratory within the state which meets the requirements of the American Society of Histocompatibility.
- Pathology services with the capability of studying and promptly reporting a patient's response to the organ transplantation surgery, and analyzing appropriate biopsy material.
- Blood banking facilities.
- A program for the education and training of staff regarding the special care of transplantation patients.
- Education programs for patients, their families, and a patient's primary care physician regarding after-care for transplantation patients.

- Specialized requirements:
  - <u>For heart transplant programs:</u>
    - A board-certified or board-eligible adult cardiologist, or, in the case of a pediatric heart transplantation program, a board-certified or board-eligible pediatric cardiologist;
    - An anesthesiologist experienced in both open heart surgery and heart transplantation; and
    - A one-bed isolation room in an age-appropriate intensive care unit.
  - <u>For liver transplant programs</u>:
    - A department of gastroenterology, including clinics, and adequately equipped procedure rooms;
    - Radiology services to provide complex biliary procedures, including transhepathic cholangiography, protal venography, and arteriography;
    - A laboratory with the capability of performing and promptly reporting the results of liver function tests as well as required chemistry, hematology, and virology tests; and
    - A patient convalescent unit for further monitoring of patient progress for approximately one month post-hospital discharge following liver transplantation.
    - In addition to the general staffing requirements for all transplantation programs, program staff for liver transplantation programs must be trained in the care of patients with hepatic diseases, and liver transplantation.
  - <u>For kidney transplant programs:</u>
    - Coordination of services requirements:
      - Inpatient services must be available and must include renal dialysis and pre- and post operative care. There must be 24-hour availability of onsite dialysis under the supervision of a board-certified or board-eligible nephrologist. If pediatric patients are served, a separate pediatric dialysis unit must be established.
      - Outpatient services must be available and must include renal dialysis services and ambulatory renal clinic services.
      - Ancillary services must include pre-dialysis, dialysis, and post transplantation nutritional services; bacteriologic, biochemical, and pathological services; radiologic services; and nursing services with the capability of monitoring and

support during dialysis and assisting with home care including vascular access and home dialysis management, when applicable.

- Staffing requirements for adult programs:
  - The kidney transplantation program must be under the direction of a physician with experience in physiology, immunology, and immuno-suppressive therapy relevant to kidney transplantation.
  - The transplant surgeon must be board-certified in surgery or a surgical subspecialty and must have a minimum of 18 months training in a transplant center.
  - The transplant team performing kidney transplantation must include physicians who are board-certified or board-eligible in the areas of anesthesiology, nephrology, psychiatry, vascular surgery, and urology.
  - Additional support personnel which must be available include a nephrology nurse with experience in nursing care of patients with permanent kidney failure, and a renal dietician.
  - A laboratory with the capability of performing and promptly reporting bacteriologic, biochemical, and pathologic analysis.
  - An anesthesiologist experienced in kidney transplantation.
- Staffing requirements for pediatric programs:
  - A medical director who is sub-board-certified or sub-board-eligible in pediatric nephrology.
  - A dialysis unit head nurse with special training and expertise in pediatric dialysis.
  - Nurse staffing at a nurse-to-patient ratio of one-to-one in the pediatric dialysis unit.
  - A registered dietician with expertise in nutritional needs of children with chronic renal disease.
  - A surgeon with experience in pediatric renal transplantation.
  - A radiology service with specialized equipment for obtaining X-rays on pediatric patients.
  - Education services to include home and hospital programs to ensure minimal interruption in school education.

- <u>For bone marrow transplant programs:</u>
  - Staffing Requirements:
    - A program director who is a board certified hematologist or oncologist with experience in the treatment and management of pediatric acute oncological cases involving high dose chemotherapy or high dose radiation therapy. The program director must have formal training in pediatric bone marrow transplantation;
    - Clinical nurses with experience in the care of critically ill immuno-suppressed patients. Nursing staff must be dedicated full time to the program;
    - An interdisciplinary transplantation team with expertise in hematology, oncology, immunologic diseases, neoplastic diseases, including hematopoietic and lymphopoietic malignancies, and non-neoplastic disorders. The team must direct permanent follow-up care of the bone marrow transplantation patients, including the maintenance of immunosuppressive therapy and treatment of complications;
    - A radiation therapy division onsite which is capable of sub-lethal x-irradiation, bone marrow ablation, and total lymphoid irradiation. The division must be under the direction of a board-certified radiation oncologist;

  - An ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation center operated by a teaching hospital. The program must include outcome monitoring and long-term patient follow-up; and;
  - An established research-oriented oncology program.
- Pediatric allogenic bone marrow transplant requirements:
  - A laboratory equipped to handle studies including the use of monoclonal antibodies, if this procedure is employed by the hospital, or T-cell depletion, separation of lymphocyte and hematological cell subpopulations and their removal for prevention of graft versus host disease. This requirement may be met through contractual arrangements;
  - An onsite laboratory equipped for the evaluation and cryopreservation of bone marrow;
  - An age-appropriate patient convalescent facility to provide a temporary residence setting for transplant patients during the prolonged convalescence; and
  - An age-appropriate outpatient unit for close supervision of discharged patients.
- Adult allogenic bone marrow transplant program requirements:
  - Inpatient transplantation units for post-transplant hospitalization. Post-transplantation care must be provided in a laminar air flow room; or in a private room with positive pressure, reverse isolation procedures, and terminal high efficiency particulate aerosol filtration on air blowers. The designated transplant unit must have a minimum of two beds. This unit can be part of a facility that also manages patients with leukemia or similar disorders;
  - A radiation therapy division onsite which is capable of sub-lethal x-irradiation, bone marrow ablation, and total lymphoid irradiation. The division must be under the direction of a board-certified radiation oncologist;
  - A laboratory equipped to handle studies including the use of monoclonal antibodies, if this procedure is employed by the hospital, or T-cell depletion, separation of lymphocyte and hematological cell subpopulations and their removal for prevention of graft versus host disease. This requirement may be met through contractual arrangements;
  - An onsite laboratory equipped for the evaluation and cryopreservation of bone marrow;
  - An ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation center operated by a teaching hospital. The program must include outcome monitoring and long-term patient follow-up;
  - An established research-oriented oncology program;
  - A patient convalescent facility to provide a temporary residence setting for transplant patients during the prolonged convalescence; and
  - An outpatient unit for close supervision of discharged patients.
- Adult autologous bone marrow transplant program requirements:
  - Inpatient transplantation units for post-transplant hospitalization. Post-transplantation care must be provided in a laminar air flow room; or in a private room with positive pressure, reverse isolation procedures, and terminal high efficiency particulate aerosol filtration on air blowers. The designated transplant

unit must have a minimum of two beds. This unit can be part of a facility that also manages patients with leukemia or similar disorders;
    - A radiation therapy division onsite which is capable of sub-lethal x-irradiation and total lymphoid irradiation. The division must be under the direction of a board-certified radiation oncologist;
    - An ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation center operated by a teaching hospital; or the applicant may enter into an agreement with an outpatient provider having a research program, as defined in this rule. Under the agreement, the outpatient research program may perform specified outpatient phases of adult autologous bone marrow transplantation, including blood screening tests, mobilization of stem cells, stem cell rescue, chemotherapy, and reinfusion of stem cells; and
    - An established research-oriented oncology program.
- Lung, Heart and Lung, Pancreas and Islet Cells, and Intestines transplant programs have no additional requirements.

CON 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, expedited, and exempt.[6] 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.[7] 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. The Legislature repealed Florida's CON program for most hospitals and tertiary services, including organ transplantation, in 2019 with the passage of HB 21.[8] However, HB 21 allowed the AHCA to continue to enforce the licensure portions of its CON rules for tertiary services until such time as the AHCA has adopted corresponding licensure rules.

Status of Certificate of Need Rules for Organ Transplant and Neonatal Intensive Care

Currently, licensure of organ transplantation programs in Florida is governed by Rule 59C-1.044, F.A.C., and licensure of NICUs is governed by Rule 59C-1.042, F.A.C. Although the CON program was repealed for tertiary services including organ transplantation and NICUs in 2019 (see CON Overview above), the AHCA was authorized to continue to enforce the licensure portions of its CON rules until such time as the AHCA has adopted corresponding licensure rules. As of January 23, 2020, the AHCA has proposed amending Rule 59A-3.246, F.A.C., to incorporate licensure requirements for organ transplant programs and has proposed creating Rule 59A-3.249, F.A.R.; however, these proposed changes have not yet been adopted.

[6] Section 408.036, F.S.
[7] Pub. Law No. 93-641, 42 U.S.C. s. 300k et seq.
[8] Chapter 2019-136, L.O.F.

III. Effect of Proposed Changes:

CS/SB 1516 substantially amends and creates several sections of law relating to organ donations.

Section 1 amends s. 408.0455, F.S., to specify that AHCA CON rules for minimum volume standards for organ transplantation and neonatal intensive care services remain in effect until the AHCA has adopted corresponding licensure rules.

Section 2 amends s. 627.6045 to prohibit a health insurance policy from limiting or excluding coverage for a living organ donor under a preexisting condition provision.

Sections 3 and 5 amend ss. 765.514 and 765.517, F.S., respectively, to prohibit an organ transplantation facility from charging an organ donor or his or her family any fee for services relating to the procurement or donation of the donor's organs and to add a statement on the uniform donor card form that neither the donor nor his or her family is responsible for the payment of any fees associated with services relating to the procurement or donation of the donor's organs, tissues, or eyes.

Section 4 amends s. 765.5155, F.S., to expand the organ donation education program to include federal laws and information on the organ donation and transplantation process.

Section 6 amends s. 765.522, F.S., to require that the AHCA establish rules and guidelines to require that individuals who request consent of an anatomical gift from a patient's health care surrogate or other representative, be required to clearly explain to patients and living organ donors the protocols of the hospital and the federal and state regulations regarding donation.

Section 7 revises s. 763.53, F.S., to expand the duties of the existing OTAC and rename it as the Organ Transplant Technical Advisory Council (Council).

The bill establishes the Council within the AHCA to develop standards for quality and outcomes at adult and pediatric organ transplant programs. The Council is also tasked with advising the AHCA and the Legislature regarding the cost savings, trends, research, and protocols and procedures relating to organ donation and transplantation, including the availability of organs for donation. The bill specifies that unless otherwise stated, the Council must operate in accordance with s. 20.052, F.S.

The bill establishes the membership of the council to include eight voting members appointed by the CEO of each of the following hospitals:

- Jackson Memorial Hospital in Miami.
- Tampa General Hospital in Tampa.
- University of Florida Health Shands Hospital in Gainesville.
- AdventHealth Orlando in Orlando.
- Mayo Clinic in Jacksonville.
- Cleveland Clinic Florida in Weston.
- Largo Medical Center in Largo.
- Broward Health Medical Center in Fort Lauderdale

Each such member must have technical expertise in adult or pediatric organ transplantation and must be an organ transplant surgeon licensed under chs. 458 or 459, F.S., or an organ transplant nurse coordinator licensed under ch. 464. Each such member's appointment is contingent upon the appointing hospital's compliance with ch. 395, F.S., and related rules. If the hospital is noncompliant, the member may serve only as a nonvoting member until the hospital comes into compliance.

Additionally, the Secretary of the AHCA must serve as the chair and a nonvoting member of the Council and must appoint the following to serve as voting members:

- The State Surgeon General or his or her designee.
- A parent of a child who has had an organ transplant.
- An adult who has had an organ transplant.
- An adult patient who is on an organ transplant waiting list.
- A licensed physician who practices in each of the following organ transplantation areas:
  - Kidneys.
  - Lungs.
  - Heart.
  - Liver.
  - Pancreas.

Voting members of the Council are required to reflect the ethnic and gender diversity of the state. Members serve without compensation but may be reimbursed for per diem and travel expenses. Members of the Council who are performing their duties in good faith are considered agents of the state for the purpose of sovereign immunity. Members may be reappointed and each vacancy may be filled in the same manner as it was originally filled.

The Council must meet at least twice annually and additionally upon call of the chair. The meetings may be held using any method of telecommunications.

The Council's duties include:

- Recommending to the AHCA and the Legislature standards for quality care of adult and pediatric organ transplant patients including:
  - Recommendations on minimum volume of transplants by organ type;
  - Personnel;
  - Physical plant;
  - Equipment;
  - Transportation; and
  - Data reporting for hospitals that perform organ transplants.
- Reporting its recommendations to the Governor, the President of the Senate, the Speaker of the House of Representatives, the Secretary of Health Care Administration, and the State Surgeon General by October 1, 2021.

Additionally, the Council may, but is not required to, further advise the AHCA and the Legislature regarding research focused on improving overall organ availability. Voting members may only vote on a specific recommendation if the hospital which the member represents has a transplant program for that type of organ.

Based on the recommendations of the Council, the AHCA must develop and adopt rules for organ transplant programs so that such rules include, at a minimum:

- Quality of care standards for adult and pediatric organ transplants, including minimum volume thresholds by organ type, personnel, physical plant, equipment, transportation, and data reporting.
- Outcome and survival rate standards that meet or exceed nationally established levels of performance in organ transplantation.
- Specific steps to be taken by the AHCA and licensed facilities when the facilities do not meet the volume, outcome, or survival rate standards within a specified timeframe that includes the time required for detailed case reviews and the development and implementation of corrective action plans.

This requirement to adopt or amend rules is repealed on July 1, 2030.

Section 8 amends s. 765.543, F.S., to require the Organ and Tissue Procurement and Transplantation Board to, by September 1, 2021, submit to the AHCA recommendations that address:

- The frequency of communication between patients and organ transplant coordinators.
- The monitoring of each organ transplantation facility and the annual reporting and publication of relevant information regarding the statewide number of patients placed on waiting lists and the number of patients who receive transplants, aggregated by the facility.
- The establishment of a coordinated communication system between organ transplantation facilities and living organ donors for the purpose of minimizing the cost and time required for duplicative lab tests, including the sharing of lab results between facilities.
- The potential incentives for organ transplantation facilities that may be necessary to increase organ donation in this state.
- The creation of a more efficient regional or statewide living organ donor process.
- The potential opportunities and incentives for organ transplantation research.
- The best practices for organ transplantation facilities and organ procurement organizations which promote the most efficient and effective outcomes for patients.
- The monitoring of organ procurement organizations.

Additionally, the bill specifies that the Board must collaborate with other relevant public or private entities in the development of necessary professional qualifications for persons engaged various facets of organ and tissue procurement.

Section 9 creates s. 765.548, F.S., to require the AHCA to:

- Monitor the operation of each organ transplantation facility and organ procurement organization located in this state.
- Develop uniform statewide rules regarding organ donations, which:
    - Must include the requirement that each hospital designate at least one employee or representative of the hospital who is educated on the protocols of the hospital and federal and state regulations regarding organ donation, to provide a clear explanation of such subjects to any patient, or a patient′s representative, who is considering posthumous or living organ donation; and

  - May include, but need not be limited to, procedures for maintaining a coordinated system of communication between organ transplantation facilities.
- Evaluate the current protocols and procedures used by organ transplantation facilities and make recommendations for improving such protocols and procedures.
- Establish annual reporting requirements for organ transplantation facilities and organ procurement organizations.
- In consultation with the state Board of Education and the contractor procured by the AHCA pursuant to s. 765.5155, F.S., develop a curriculum for educating high school students regarding the laws of this state relating to organ donation.
- Publish any data and other relevant information to adequately inform patients and potential donors about organ donation and organ transplantation by December 1, 2021, and each year thereafter.

Section 10 amends s. 409.815, F.S., to make a conforming change

Section 11 provides that the bill has an effective date of July 1, 2020.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

CS/SB 1516 may have an indeterminate negative fiscal impact on the AHCA due to the requirement to reimburse Council members for per diem and travel expenses.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends sections 408.0455 and 765.53 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on January 27, 2020:
The CS changes the title of the bill from "an act relating to organ transplant technical Advisory Council to "an act relating to organ donation" and amends and creates additional sections of law relating to organ donation as follows:

- Section 627.6045, F.S., is amended to prohibit a health insurance policy from limiting or excluding coverage for a living organ donor under a preexisting condition provision.
- Sections 765.517 and 765.514, F.S., are amended to prohibit an organ transplantation facility from charging an organ donor or his or her family any fee for services relating to the procurement or donation of the donor's organs and to add a statement on the uniform donor card form that neither the donor nor his or her family is responsible for the payment of any fees associated with services relating to the procurement or donation of the donor's organs, tissues, or eyes.
- Section 765.5155, F.S., is amended to expand the organ donation education program to include federal laws and information on the organ donation and transplantation process.
- Section 765.543, F.S., is amended to require the Organ and Tissue Procurement and Transplantation Board to, by September 1, 2021, submit to the AHCA recommendations that address:
  - The frequency of communication between patients and organ transplant coordinators.
  - The monitoring of each organ transplantation facility and the annual reporting and publication of relevant information regarding the statewide number of patients placed on waiting lists and the number of patients who receive transplants, aggregated by the facility.

  - The establishment of a coordinated communication system between organ transplantation facilities and living organ donors for the purpose of minimizing the cost and time required for duplicative lab tests, including the sharing of lab results between facilities.
  - The potential incentives for organ transplantation facilities that may be necessary to increase organ donation in this state.
  - The creation of a more efficient regional or statewide living organ donor process.
  - The potential opportunities and incentives for organ transplantation research.
  - The best practices for organ transplantation facilities and organ procurement organizations which promote the most efficient and effective outcomes for patients.
  - The monitoring of organ procurement organizations.
- Section 765.548, F.S., is created to require the AHCA to:
  - Monitor the operation of each organ transplantation facility and organ procurement organization located in this state.
  - Develop uniform statewide rules regarding organ donations, which must include the requirement that each hospital designate at least one employee or representative of the hospital who is educated on the protocols of the hospital and federal and state regulations regarding organ donation, to provide a clear explanation of such subjects to any patient, or a patient′s representative, who is considering posthumous or living organ donation; and may include, but need not be limited to, procedures for maintaining a coordinated system of communication between organ transplantation facilities.
  - Evaluate the current protocols and procedures used by organ transplantation facilities and make recommendations for improving such protocols and procedures.
  - Establish annual reporting requirements for organ transplantation facilities and organ procurement organizations.
  - In consultation with the state Board of Education and the contractor procured by the AHCA pursuant to s. 765.5155, F.S., develop a curriculum for educating high school students regarding the laws of this state relating to organ donation.
  - Publish any data and other relevant information to adequately inform patients and potential donors about organ donation and organ transplantation by December 1, 2021, and each year thereafter.

In addition, the CS amends requirements for the Council to:

- Require the Council to advise the AHCA and the Legislature regarding the cost savings, trends, research, and protocols and procedures relating to organ donation and transplantation, including the availability of organs for donation.
- Revise the membership of the Council to:
  - Allow the appointment of organ transplant nurses, in addition to physicians;
  - Reduce the members appointed by hospitals to eight;[9] and

[9] Memorial Regional hospital in Hollywood, Halifax Health Medical Center in Daytona Beach, Sacred Heart Hospital in Pensacola, H. Lee Moffitt cancer Center and Research Institute in Tampa, and the University of Miami Hospital in Fort Lauderdale are removed from the list while Broward Health Medical Center in Fort Lauderdale is added.

  - Grant voting rights to members of the Council appointed by the secretary of the AHCA and revise the list of members appointed by the secretary;[10] and
  - Require voting members to reflect the ethnic and gender diversity of the state;
- Revise the duties of the Council to:
  - Require recommendations be presented to the Legislature as well as the AHCA;
  - Eliminate the duty to develop recommendations for improving education, outreach, and communication between hospitals, patients, and the public, with an emphasis on potential and prospective donors, including recommendations for clear explanations to the public of relevant laws, rules, and regulations; requirements for coordinated communication between hospitals, between hospitals and patients, and between hospitals and prospective donors; and recommendations for providing education to the public on the organ donation process, with an emphasis on educating potential living donors; and
  - Allow the Council to advise the AHCA and the Legislature regarding research focused on improving overall organ availability.

The CS also revises the automatic repeal date of the requirement that the AHCA adopt rules based on the Councils recommendations from an automatic repeal when the AHCA adopts such rules to a repeal on the set date of July 1, 2030.

Amendments:

None.

[10] Representatives of the Florida Hospital Association, the Safety Net Hospital Alliance of Florida, and HCA Healthcare are removed from the underlying bill while an adult patient who is on an organ transplant waiting list and licensed physicians who specialize in organ transplantation of the kidneys, lungs, liver, heart, and pancreas are added.

By Senator Harrell

25-01544A-20 20201516__

A bill to be entitled

An act relating to the Organ Transplant Technical Advisory Council; amending s. 765.53, F.S.; requiring the Agency for Health Care Administration to establish the Organ Transplant Technical Advisory Council for a specified purpose; providing for membership, meetings, and duties of the council; requiring the council to submit a report to the Governor, the Legislature, the Secretary of Health Care Administration, and the State Surgeon General by a specified date; extending sovereign immunity to council members under certain circumstances; requiring the agency to amend or adopt specified rules based on the council's recommendations; providing for expiration of a certain provision; amending s. 408.0455, F.S.; revising a provision related to the operation of certain rules adopted by the agency; providing an effective date.

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

Section 1. Section 765.53, Florida Statutes, is amended to read:

(Substantial rewording of section. See s. 765.53, F.S., for present text.)

765.53 Organ Transplant Technical Advisory Council.—

(1) CREATION AND PURPOSE.—The Organ Transplant Technical Advisory Council, an advisory council as defined in s. 20.03, is created within the agency to assist the agency in developing standards for quality and outcomes at adult and pediatric organ

transplant programs. Unless expressly provided otherwise in this section, the council shall operate in a manner consistent with s. 20.052.

(2) MEMBERS.—

(a) Voting members of the council must have technical expertise in adult or pediatric organ transplantation. Each chief executive officer of the following hospitals shall appoint one representative, who must be an organ transplant surgeon licensed under chapter 458 or chapter 459, to serve as a voting member of the council:

1. Jackson Memorial Hospital in Miami.

2. Tampa General Hospital in Tampa.

3. University of Florida Health Shands Hospital in Gainesville.

4. AdventHealth Orlando in Orlando.

5. Mayo Clinic in Jacksonville.

6. Cleveland Clinic Florida in Weston.

7. Largo Medical Center in Largo.

8. Memorial Regional Hospital in Hollywood.

9. Halifax Health Medical Center in Daytona Beach.

10. Sacred Heart Hospital in Pensacola.

11. H. Lee Moffitt Cancer Center and Research Institute, Inc., in Tampa.

12. University of Miami Hospital in Miami.

(b) The Secretary of Health Care Administration shall serve as the chair and a nonvoting member of the council.

(c) The Secretary of Health Care Administration may appoint any of the following individuals to serve as a nonvoting member of the council:

1. The State Surgeon General.

2. A parent of a child who has had an organ transplant.

3. An adult who has had an organ transplant.

4. One representative from each of the following:

a. The Florida Hospital Association.

b. The Safety Net Hospital Alliance of Florida.

c. HCA Healthcare.

(d) Appointments made under paragraph (a) are contingent upon the hospital's compliance with chapter 395 and rules adopted thereunder. A member of the council appointed under paragraph (a) whose hospital fails to comply with such law and rules may serve only as a nonvoting member until the hospital comes into compliance.

(e) Any vacancy on the council must be filled in the same manner as the original appointment. Members are eligible for reappointment.

(f) Members of the council shall serve without compensation but may be reimbursed as provided in s. 112.061 for per diem and travel expenses incurred in the performance of their duties under this section.

(3) MEETINGS.—The council shall meet at least annually and upon the call of the chair. The council may use any method of telecommunications to conduct its meetings.

(4) DUTIES.—The council shall recommend to the agency standards for quality care of adult and pediatric organ transplant patients, including recommendations on minimum volume of transplants by organ type, personnel, physical plant, equipment, transportation, and data reporting for hospitals that perform organ transplants. The council shall also develop

recommendations for improving education, outreach, and communication between hospitals, patients, and the public, with an emphasis on potential and prospective donors, including recommendations for clear explanations to the public of relevant laws, rules, and regulations; requirements for coordinated communication between hospitals, between hospitals and patients, and between hospitals and prospective donors; and recommendations for providing education to the public on the organ donation process, with an emphasis on educating potential living donors. When developing its recommendations, the council shall review any relevant existing or proposed agency rules and may provide recommendations to the agency on amendments to such rules. A voting member may vote on standards related to a specific type of organ only if he or she represents a hospital that has a transplant program for that organ.

(5) REPORT.—By October 1, 2021, the council shall submit a report of its recommendations to the Governor, the President of the Senate, the Speaker of the House of Representatives, the Secretary of Health Care Administration, and the State Surgeon General.

(6) SOVEREIGN IMMUNITY.—Members of the council acting in good faith in the performance of their duties under this section are considered agents of the state for purposes of s. 768.28.

(7) AGENCY RULES.—

(a) Based on the recommendations of the council, the agency shall amend or adopt rules for organ transplant programs so that such rules include at least all of the following:

1. Quality of care standards for adult and pediatric organ transplants, including minimum volume thresholds by organ type,

personnel, physical plant, equipment, transportation, and data reporting.

2. Outcome and survival rate standards that meet or exceed nationally established levels of performance in organ transplantation.

3. Specific steps to be taken by the agency and licensed facilities when the facilities do not meet the volume, outcome, or survival rate standards within a specified timeframe that includes the time required for detailed case reviews and the development and implementation of corrective action plans.

(b) This subsection expires upon the agency's adoption of organ transplant program rules in accordance with paragraph (a).

Section 2. Section 408.0455, Florida Statutes, is amended to read:

408.0455 Rules; pending proceedings.—The rules of the agency in effect on June 30, 2004, ~~shall~~ remain in effect and are ~~shall be~~ enforceable by the agency with respect to ss. 408.031-408.045 until such rules are repealed or amended by the agency. Rules 59C-1.039 through 59C-1.044, Florida Administrative Code, including, but not limited to, the minimum volume standards for organ transplantation and neonatal intensive care services, remain in effect for the sole purpose of maintaining licensure requirements for the applicable services until the agency has adopted rules for the corresponding services pursuant to s. 395.1055(1)(i), Florida Statutes 2018.

Section 3. This act shall take effect July 1, 2020.

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/28/2020
Meeting Date

1516
Bill Number (if applicable)

705054
Amendment Barcode (if applicable)

Delete all amendment

Topic Organ transplant

Name Ron Watson

Job Title Lobbyist

Address 3738 Mundon Way
Street

Tallahassee FL 32309
City *State* *Zip*

Phone 850 567 1202

Email watson.strategies@comcast.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Renal Assoc.

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)

1/28/2020
Meeting Date

1516
Bill Number (if applicable)

705054
Amendment Barcode (if applicable)

Topic ORGAN TRANSPLANT

Name LAYNE Smith

Job Title Government Relations Director

Address 4500 San Pablo Road
Street

Jacksonville FL 32224
City *State* *Zip*

Phone 904-953-7334

Email smith.layne@mayo.edu

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Mayo Clinic

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)

28 JAN 2020
Meeting Date

SB 516
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic TRANSPLANT QUALITY STANDARDS

Name KIRAN DHANIREDDY MD

Job Title TAMPA GENERAL HOSPITAL FOR DIRECTOR OF TRANSPLANTATION

Address 1 TAMPA GENERAL CIRCLE
Street

Phone 813 660 6287

TAMPA FL 33606
City *State* *Zip*

Email KDHANIREDDY@TGH.ORG

Speaking: [X] For [ ] Against [X] Information

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

Representing

Appearing at request of Chair: [X] 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)

1/28/2020
Meeting Date

SB 1566
HB 1187
Bill Number (if applicable)

Topic ORGAN TRANSPLANTATION

Amendment Barcode (if applicable)

Name LAURENCE COCHRAN

Job Title ASSISTANT EXECUTIVE DIRECTOR - LIFEQUEST ORGAN RECOVERY

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Street

Phone 352.733.0350

GAINESVILLE FL 32606
City *State* *Zip*

Email COCHRL@LIFEQUEST.ORG EDU

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

1-28-2020 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) 1516

Meeting Date *Bill Number (if applicable)*

Topic Organ Transplant Tech Advisory Council *Amendment Barcode (if applicable)*

Name Louis Bedz

Job Title

Address PO Box 274108 Phone 8139632900

Street

Tmpa FL 33688 Email

City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against

(The Chair will read this information into the record.)

Representing MoveTransplants More Life PC

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)

1-28-20
Meeting Date

1516
Bill Number (if applicable)

Topic ~~SB1516~~ organ transplant

Amendment Barcode (if applicable)

Name Amy Kozsuch

Job Title Board President National Kidney Foundation of Florida

Address 3739 Flamingo St.
Street
St. Augustine FL 32080
City *State* *Zip*

Phone 904-599-2120

Email AmyKozsuch@me.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing National Kidney Foundation of Florida & Florida Renal 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

1/28/2020
Meeting Date

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

SB 1516
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Organ transplant

Name Ron Watson

Job Title Lobbyist

Address 3738 Mundon Way
Street

Tallahassee FL 32309
City *State* *Zip*

Phone 850 567-1202

Email Watson.Strategies@Comcast.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Renal Assoc

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)

28 Jan. 2020
Meeting Date

1516
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Lauren Whritenour

Job Title _____

Address 108 E. Jefferson St. Suite A
Street

Tallahassee FL 32301
City *State* *Zip*

Phone 850 509 3610

Email lauren.claire-henderson@gmail.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Lovis Betz & Associates

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)

1-28-2026
Meeting Date

1514
Bill Number (if applicable)

Topic Organ Transplant Tech Advisory Council

Amendment Barcode (if applicable)

Name Missy Timmins "Margaret"

Job Title

Address 2910 Henry Forest Pkwy D4-368
Street

Tall FL 32309
City *State* *Zip*

Phone 850-264-3775

Email missy@timminsconsulting.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Myself / More Transplants More Life PC

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

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 798
INTRODUCER:	Senator Rouson
SUBJECT:	Procurement of Human Organs and Tissue
DATE:	January 27, 2020
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Williams	Brown	HP	**Favorable**
2.			CJ	
3.			RC	

I. Summary:

SB 798 prohibits for-profit entities from obtaining certification as eye banks and from collecting any eye, cornea, eye tissue, or corneal tissue. The bill provides exceptions for specified entities.

The bill will result in the Agency for Health Care Administration (AHCA) collecting $4,000 less in annual assessment fees for the currently operating for-profit eye banks in Florida. The fiscal impact of the bill on private stakeholders is unknown.[1]

The effective date of the bill is July 1, 2020.

II. Present Situation:

Regulations and Standards for Tissue Processing

Tissue processing in the United States is governed by mandatory requirements enforced by federal and state regulatory authorities. The authorization of donated tissues is governed by the Uniform Anatomical Gift Act. Tissue banks in the United States are governed by the National Organ Transplantation Act (NOTA), which provides that tissue cannot be bought or sold. The law does allow for reimbursement of costs associated with the recovery, processing, and storing of tissue and the development of tissue processing technologies. Such activities can include research, screening and testing, sterilization processes, and precision-tooled shaping of allographs for transplantation.

Regardless of their status, all tissue banks must meet the same regulatory requirements and have the same goal of assisting in the process of making tissue safely available for transplants. Human tissue processed and distributed for transplantation by the American Association of Tissue Banks

[1] Agency for Health Care Administration, *Senate Bill 798 Analysis* (updated January 23, 2020) (on file with the Senate Committee on Health Policy).

(AATB)-accredited tissue banks is subject to federal Food and Drug Administration (FDA) regulation and AATB's standards.[2]

Statutory Provisions Specific to Eye Banks in Florida

Part V of ch. 765, F.S., contains provisions specific to the donation and procurement of human organs and tissues. Under this part, "procurement" is defined in s. 765.511(18), F.S., as "any retrieval, recovery, processing, storage, or distribution of human organs or tissues for transplantation, therapy, research, or education."

Section 765.542, F.S., provides requirements for the certification of procurement organizations in the state of Florida. Procurement organizations, as defined in subsection 765.511(19), F.S., include organ procurement organizations, eye banks, and tissue banks. Per s. 765.511(11), F.S., an eye bank is "an entity that is accredited by the Eye Bank Association of America or otherwise regulated under federal or state law to engage in the retrieval, screening, testing, processing, storage, or distribution of human eye tissue."

In accordance with s. 765.542(3), F.S., a person may not engage in the practice of eye procurement in the state of Florida without being appropriately certified as an eye bank by the AHCA. Funeral directors or direct disposers who retrieve eye tissue for a certified eye bank are exempt from being certified as eye banks.

All procurement organizations, including eye banks, are required to file an annual report and an annual assessment fee to the AHCA based on reported revenues from procurement and processing activities, as provided in s. 765.544, F.S. During State Fiscal Year 2018-2019, $3,500 in annual assessment fees were received by the AHCA from for-profit eye banks.[3]

Chapter 873, F.S., governs the sale of anatomical matter by a person or a for-profit entity and includes provisions related to the purchase, sale, and transfer of human organs and tissues, including, but not limited to: the eye, cornea, kidney, liver, heart, lung, pancreas, bone, and skin.[4]

Section 873.01(2), F.S., prohibits for-profit entities, or any employee of a for-profit entity, from transferring human organs and tissues or arranging for the transfer of human organs and tissues for valuable consideration. "Valuable consideration" does not include the reasonable costs associated with the removal, storage, and transportation of a human organ or tissue.

Procurement Organizations Regulated by the Agency for Health Care Administration

According to the AHCA, there are currently 155 procurement organizations certified in the state of Florida. Of these, four are certified as organ procurement organizations, 24 are certified as eye banks, and 127 are certified as tissue banks. Of the 24 certified eye banks, three are physically located in Florida, and the remaining 21 eye banks certified in Florida are out-of-state

[2] American Association of Tissue Banks, Regulation and Standards, *available at* https://www.aatb.org/regulatory (last visited on Jan. 23, 2020).
[3] *Supra* note 1.
[4] Section 873.01(3)(a), F.S.

organizations. The three eye banks located in Florida are not-for-profit corporations. The profit status of Florida's certified eye banks is as follows:

- Sixteen not-for-profit entities, and
- Eight for-profit entities.[5]

Corporate Trends in the Eye-Tissue Banking Industry

In recent years, the market for corneal tissue procurement, transport, and surgeon partnerships has experienced somewhat of a shift from local, community-based eye banks to larger companies. Some of these larger companies are represented by not-for-profit corporations affiliated with for-profit "daughter" companies, which, in partnership with each other, play defined roles in the process, with the non-profit organization recovering the tissue while the for-profit organization processes, evaluates, and distributes the tissues to cornea surgeons.[6]

The for-profit status of any participant in the process has drawn criticism. However, defenders of such partnerships respond by noting that such for-profit companies operate under the NOTA, which states that it is illegal to buy or sell organs and tissues while it *is* legal to obtain reasonable payment associated with the removal, transportation, processing, preservation, quality control, and storage of corneas and eye tissue. Similarly, local eye banks routinely obtain payment related to these actions. Some argue that the for-profit connection fundamentally alters the relationship between physicians, eye banks, and donors by rendering the gift of the tissue as a commodity. The resulting ethical debate may be crucial to the future of eye banks.[7]

III. Effect of Proposed Changes:

Section 1 amends s. 765.542, F.S., relating to requirements to engage in organ, tissue, or eye procurement, to specify that a for-profit entity may not engage, directly or indirectly, in the procurement of any eye, cornea, eye tissue, or corneal tissue. The bill stipulates that this new provision does not apply to any hospital or ambulatory surgical center licensed under ch. 395, F.S., or to a district medical examiner appointed under ch. 406, F.S.

Section 2 amends s. 873.01, F.S., relating to the prohibition on the purchase or sale of human organs and tissues, to specify that a for-profit entity may not engage, directly or indirectly, in the procurement, as defined in s. 765.511, F.S., of any eye, cornea, eye tissue, or corneal tissue. The bill stipulates that this new provision does not apply to any hospital or ambulatory surgical center licensed under ch. 395, F.S., or to a district medical examiner appointed under ch. 406, F.S.

Section 3 provides an effective date of July 1, 2020.

---

[5] *Supra* note 1.
[6] Majid Moshirfar, Jackson L. Goldberg, et al., *A paradigm shift in eye banking: how new models are challenging the status quo*, U.S. National Library of Medicine, National Institutes of Health (Dec. 27, 2018), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6311318/ (last visited Jan. 25, 2020)
[7] *Id.*

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:

According to the AHCA, SB 798 will result in the delicensing of eight for-profit eye banks that are currently certified to do business in Florida and will prohibit any for-profit entities from applying for and obtaining certification as eye banks in the future.[8]

C. Government Sector Impact:

The AHCA will collect $4,000 less in annual assessment fees for the currently operating for-profit eye banks doing business in Florida.[9]

VI. Technical Deficiencies:

None.

[8] *Supra* note 1.
[9] *Id.*

VII. Related Issues:

The statutory provisions proposed in the bill do not appear to conflict with applicable federal law relating to prohibition of organ purchases.[10]

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 765.542 and 873.01.

IX. Additional Information:

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

None.

B. Amendments:

None.

[10] *See* 42 U.S.C. 274e.

By Senator Rouson

19-00897A-20 2020798__

A bill to be entitled

An act relating to the procurement of human organs and tissue; amending s. 765.542, F.S.; prohibiting for-profit entities from procuring certain human organs and tissue, with certain exceptions; amending s. 873.01, F.S.; prohibiting for-profit entities from procuring certain human organs and tissue, with certain exceptions; providing an effective date.

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

Section 1. Present subsection (4) of section 765.542, Florida Statutes, is redesignated as subsection (5), and a new subsection (4) is added to that section, to read:

765.542 Requirements to engage in organ, tissue, or eye procurement.—

(4) A for-profit entity may not engage, directly or indirectly, in the procurement of any eye, cornea, eye tissue, or corneal tissue. This subsection does not apply to a hospital or an ambulatory surgical center licensed under chapter 395 or to a district medical examiner appointed under chapter 406.

Section 2. Present subsections (3) and (4) of section 873.01, Florida Statutes, are redesignated as subsections (4) and (5), respectively, a new subsection (3) is added to that section, and subsections (1) and (2) of that section are amended, to read:

873.01 Purchase or sale of human organs and tissue prohibited.—

(1) A ~~No~~ person may not ~~shall~~ knowingly offer to purchase

or sell, or purchase, sell, or otherwise transfer, any human organ or tissue for valuable consideration.

(2) A ~~No~~ for-profit corporation or any employee thereof may not ~~shall~~ transfer or arrange for the transfer of any human body part for valuable consideration.

(3) A for-profit entity may not engage, directly or indirectly, in the procurement, as defined in s. 765.511, of any eye, cornea, eye tissue, or corneal tissue. This subsection does not apply to a hospital or an ambulatory surgical center licensed under chapter 395 or to a district medical examiner appointed under chapter 406.

Section 3. This act shall take effect July 1, 2020.

The Florida Senate

Committee Agenda Request

To: Senator Gayle Harrell, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 15, 2020

I respectfully request that **Senate Bill # 798**, relating to Procurement of Human Organs and Tissue, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Senator Darryl Ervin Rouson
Florida Senate, District 19

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/28/20
Meeting Date

SB 798
Bill Number (if applicable)

Topic Procurement of Human Organs & Tissues

Amendment Barcode (if applicable)

Name Todd Tosko

Job Title Partner - Ballard Partners

Address 1726 E. 7th Ave Ste 13-15
Street

Phone

Tampa FL 33605
City *State* *Zip*

Email

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Lion's Eye Institute for Transplantation & Research

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)

2019 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

BILL INFORMATION	
BILL NUMBER:	SB 798
BILL TITLE:	Procurement of Human Organs and Tissue
BILL SPONSOR:	Senator Darryl Rouson
EFFECTIVE DATE:	July 1, 2020

COMMITTEES OF REFERENCE
1) Health Policy
2) Criminal Justice
3) Rules
4)
5)

CURRENT COMMITTEE

SIMILAR BILLS	
BILL NUMBER:	
SPONSOR:	

PREVIOUS LEGISLATION	
BILL NUMBER:	
SPONSOR:	
YEAR:	

IDENTICAL BILLS	
BILL NUMBER:	HB 563
SPONSOR:	Rep. Dan Daley

LAST ACTION:	

Is this bill part of an agency package?
Y ___ N _x_

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	
LEAD AGENCY ANALYST:	Ruby Grantham
ADDITIONAL ANALYST(S):	
LEGAL ANALYST:	Thomas M. Hoeler
FISCAL ANALYST:	

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

This legislation amends sections 765.542[1] and 873.01[2], Florida Statutes (F.S.) in order to prohibit for-profit entities from collecting eye, cornea, eye tissue or corneal tissue and obtaining certification as eye banks. The proposed bill creates exceptions for hospitals and ambulatory surgical centers licensed under chapter 395, F.S. and district medical examiners appointed under chapter 406, F.S.

The proposed bill would take effect July 1, 2020.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

There are currently 146 procurement organizations certified in the state of Florida, 24 of these procurement organizations are certified as eye banks. There are 2 eye banks located directly in Florida; the remaining 22 certified eye banks are out-of-state organizations. The eye banks located in Florida are both not-for-profit corporations.

The breakdown of certified eye banks is as follows:

16 – not-for-profit corporations
1 – not-for-profit hospital district
7 – for-profit corporations

Chapter 765, Part V[3], F.S. contains provisions for the donation and procurement of human organs and tissues. Procurement is defined in section 765.511,[4] F.S. as "any retrieval, recovery, processing, storage, or distribution of human organs or tissues for transplantation, therapy, research, or education." Chapter 873,[5] F.S. governs the sale of anatomical matter by a person or a for-profit entity and includes explanations related to the purchase, sale and transfer of human organs and tissues including but not limited to: the eye, cornea, kidney, liver, heart, lung, pancreas, bone, and skin.

Section 765.542, F.S. provides requirements for the certification of procurement organizations in the state of Florida. Procurement organizations, as defined in subsection 765.511(19), F.S. include organ procurement organizations, eye banks, and tissue banks. Per subsection 765.511(11), F.S. an eye bank is "an entity that is accredited by the Eye Bank Association of America or otherwise regulated under federal or state law to engage in the retrieval, screening, testing, processing, storage, or distribution of human eye tissue."

In accordance with subsection 765.542(3), F.S., a person may not currently engage in the practice of eye procurement in the state of Florida without being appropriately certified as an eye bank by the Agency for Health Care Administration (Agency). Funeral directors or direct disposers who retrieve eye tissue for a certified eye bank are exempt from being certified as eye banks.

All procurement organizations, including eye banks, are required to file an annual report and an annual assessment fee based on reported revenues from procurement and processing activities, as provided in section 765.544, F.S. During the fiscal year 2018-19, $3,500.00 in annual assessment fees were received from for-profit eye banks.

Subsection 873.01(2), F.S. currently prohibits for-profit entities, or any employee of a for-profit entity, from transferring human organs and tissues or arranging human organs and tissues for transfer for more than the reasonable costs associated with the removal, storage, and transportation of these organs and tissues.

2. EFFECT OF THE BILL:

The bill amends sections 765.542, F.S. and 873.01, F.S. in order to prohibit for-profit entities from engaging in the procurement of eye, cornea, eye tissue or corneal tissue. The proposed bill creates exceptions for hospitals and ambulatory surgical centers licensed under chapter 395, F.S. and district medical examiners appointed under chapter 406, F.S.

[1] 765.542 Requirements to engage in organ, tissue, or eye procurement, F.S.
[2] 873.01 Purchase or sale of human organs and tissue prohibited, F.S.
[3] Chapter 795, Part V, Anatomical Gifts
[4] Chapter 795.511, Definitions
[5] Chapter 873, Sale of Anatomical Matter

The creation of subsection 765.542(4), F.S. would result in the delicensing of 7 eye banks that are currently certified, and would prohibit any for-profit entities from applying for and obtaining certification as eye banks in the future.

Section 873.01, F.S. is also expanded to prohibit for-profit entities from engaging in any procurement activities of any eye, cornea, eye tissue, or corneal tissue, not just the transfer or arrangement for transfer of human eye tissue.

The delicensing of the for-profit eye banks would result in an estimated loss of $3,500 in annual assessment fees per year to the Agency.

For-profit eye banks account for less than 5% of all of the procurement organizations currently certified. The Agency anticipates no impact from this bill based on the representation of for-profit eye banks currently certified within the state of Florida.

The proposed changes do not conflict with Title 42 USC 274e[6] relating to prohibition of organ purchases.

The impact on private stakeholders is unknown.

3. DOES THE BILL DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES? Y ___ N _X_

If yes, explain:	
Is the change consistent with the agency's core mission?	Y ___ N ___
Rule(s) impacted (provide references to F.A.C., etc.):	

4. WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?

Proponents and summary of position:	Unknown
Opponents and summary of position:	Unknown

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y ___ N _X_

If yes, provide a description:	
Date Due:	
Bill Section Number(s):	

6. ARE THERE ANY GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSION, ETC.? REQUIRED BY THIS BILL? Y ___ N __X_

Board:	
Board Purpose:	
Who Appointments:	
Appointee Term:	
Changes:	

[6] 42 USC 274e: Prohibition of organ purchases

Bill Section Number(s):	

FISCAL ANALYSIS

1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT? Y ___ N _X__

Revenues:	
Expenditures:	
Does the legislation increase local taxes or fees? If yes, explain.	
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	

2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT? Y _X__ N ___

Revenues:	The delicensure of the for-profit eye banks would result in an estimated loss in revenue of $3,500 per year to the Agency, which is minimal when looking at the revenue collected from the entire licensure program.
Expenditures:	
Does the legislation contain a State Government appropriation?	No
If yes, was this appropriated last year?	

3. DOES THE BILL HAVE A THE FISCAL IMPACT TO THE PRIVATE SECTOR? Y _X__ N ___

Revenues:	Unknown – for-profit eye banks that can no longer be licensed
Expenditures:	Unknown – for-profit eye banks that can no longer be licensed
Other:	

4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y _X__ N ___

If yes, explain impact.	Decrease in AHCA revenue from annual assessment fees
Bill Section Number:	N/A

TECHNOLOGY IMPACT

1. DOES THE BILL IMPACT THE AGENCY'S TECHNOLOGY SYSTEMS (I.E. IT SUPPORT, LICENSING SOFTWARE, DATA STORAGE, ETC.)? Y ___ N __X_

If yes, describe the anticipated impact to the agency including any fiscal impact.	

FEDERAL IMPACT

1. DOES THE BILL HAVE A FEDERAL IMPACT (I.E. FEDERAL COMPLIANCE, FEDERAL FUNDING, FEDERAL AGENCY INVOLVEMENT, ETC.)? Y ___ N _X__

If yes, describe the anticipated impact including any fiscal impact.	

ADDITIONAL COMMENTS

LEGAL – GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	None.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 1556
INTRODUCER:	Senator Bean
SUBJECT:	Nondiscrimination in Organ Transplants
DATE:	January 27, 2020
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Favorable**
2.			BI	
3.			AP	

I. Summary:

SB 1556 prohibits specified entities from denying, refusing to allocate, or lowering an individual's priority for organ transplant medical services solely on the basis of an individual's disability. The bill:

- Defines certain terms and entities;
- Specifies when certain entities may consider an individual's disability and when they may not;
- Requires certain entities to take steps to ensure that an individual with a disability is not denied services, with exceptions;
- Requires certain entities to make reasonable modifications to transplant policies, practices, and procedures to accommodate individuals with a disability, with an exception;
- Prohibits certain entities from denying transplant services due to individual's lack of auxiliary aids and services, with an exception;
- Permits a civil action for injunctive or other equitable relief for violations;
- Prohibits insurers, nonprofit health care service plans, and health maintenance organizations that provide transplant coverage, from denying coverage solely on the basis of an individual's disability; and
- Does not authorize transplants that are not medically necessary.

The bill has an effective date of July 1, 2020.

II. Present Situation:

Tissue Donation and Organ Transplantation

Organ and tissue donation and transplantation is the process of surgically removing an organ or tissue from one person (the donor) and transplanting it into another person (the recipient).

Transplantation may be necessary because the recipient's organ or tissue has failed or has been damaged by disease or injury. Transplantable organs include the kidneys, liver, heart, lungs, pancreas, and intestine.[1] Transplantable tissue includes:

- Skin, which can be used as a temporary dressing for burns, serious abrasions, and other exposed areas;
- Heart valves used to replace defective valves;
- Tendons used to repair torn ligaments in knees or other joints;
- Veins used in cardiac bypass surgery;
- Corneas used to restore sight; and
- Bone used in orthopedic surgery to facilitate healing of fractures or to prevent amputation.[2]

The Organ Procurement and Transplantation Network (OPTN)

The National Organ Transplant Act (NOTA) established the Organ Procurement and Transplantation Network (OPTN) in 1984.[3] In 2000, The U.S. Department of Health and Human Services (HHS) implemented a final rule establishing a regulatory framework for the structure and operations of the OPTN.[4] HHS implemented the final rule that established the regulatory framework for the structure and operations of the OPTN.[5]

The OPTN policies are rules that govern the operation of all member transplant hospitals, organ procurement organizations (OPOs) and histocompatibility labs in the U.S.[6] Currently, every transplant hospital program, OPO, and transplant histocompatibility laboratory in the U.S. is an OPTN member. Membership means that an institution meets OPTN requirements and that it plays an active role in forming the policies that govern the transplant community.[7]

The OPTN is a unique public-private partnership that links all professionals involved in the U.S. donation and transplantation system. Also crucial to the system are individuals who sign organ donor cards, people who comment on policy proposals, and countless volunteers who support donation and transplantation, among many others. The OPTN regulates how donor organs are matched and allocated to patients on the waiting list.[8] On average, 95 transplants take place each day in the U.S.[9]

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[1] Donate Life Florida, *Frequently Asked Questions*, https://www.donatelifeflorida.org/categories/donation/ (last visited Jan. 27, 2018).
[2] *Id*.
[3] 42 U.S.C. 274.
[4] U.S. Department of Health & Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, *About the OPTN* https://optn.transplant.hrsa.gov/governance/about-the-optn/ (last visited Jan. 22, 2020).
[5] Id.
[6] U.S. Department of Health & Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, *Policies* https://optn.transplant.hrsa.gov/governance/policies/ (last visited Jan. 24, 2020).
[7] U.S. Department of Health & Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, *Members* https://optn.transplant.hrsa.gov/members/ (last visited Jan. 22, 2020).
[8] U.S. Department of Health & Human Services, Health Resources & Services Administration, U.S. Government Information on Organ Donation and Transplantation, *The Organ Transplant Process* https://organdonor.gov/about/process/transplant-process.html (last visited Jan. 22, 2020).
[9] U.S. Department of Health & Human Services, Health Resources & Services Administration, U.S. Government Information on Organ Donation and Transplantation, *Organ Donation and Transplantation Can Save Lives* https://optn.transplant.hrsa.gov/ (last visited Jan. 22, 2020).

United Network for Organ Sharing (UNOS)

The United Network for Organ Sharing (UNOS) serves as the OPTN under contract with the Health Resources and Services Administration (HRSA) of HHS. UNOS is a private, non-profit organization based in Richmond, Virginia.[10]

Organ Procurement Organizations (OPOs) Serving Florida

In Florida, four non-profit, federally designated OPOs work closely with hospitals and transplant centers to facilitate the organ donation and transplantation process:[11]

- Life Alliance Organ Recovery Agency;[12]
- LifeLink Florida;[13]
- LifeQuest Organ Recovery Services;[14] and
- Our Legacy.[15]

Organ Transplant Centers (OTCs)

There are currently 252 organ transplant centers (OCTs) in the United States.[16] Florida has 11 transplant centers to serve its citizens requiring organ transplants:

- The Miami Transplant Institute at the University of Miami/Jackson Memorial Medical Center;
- Broward General Medical Center/JMH Liver Transplant Program;
- Cleveland Clinic Florida;
- Memorial Healthcare System;
- Tampa General Hospital;
- Largo Medical Center;
- All Children's Hospital;
- Gulf Coast Medical Center, a Division of Lee Memorial Health System;
- University of Florida Health, Shands Transplant Center;
- Transplant Program at Mayo Clinic Hospital;

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[10] Id.

[11] Donate Life Florida, Organ Procurement Organizations and Transplant Centers, Organ Procurement Organizations (OPOs) Serving Florida https://www.donatelifeflorida.org/local-resources/transplant-centers/ (last visited Jan. 23, 2020).

[12] University of Miami, Miller College of Medicine, *Life Alliance Organ Recovery Agency* http://surgery.med.miami.edu/laora (last visited Jan. 22, 2020).

[13] The LifeLink Foundation, *Our Mission* https://www.lifelinkfoundation.org/ (last visited Jan. 22, 2020). The LifeLink Foundation is a non-profit community service organization dedicated to the recovery of life-saving and life-enhancing organs and tissue for transplantation therapy. The Foundation works in a sensitive, diligent, and compassionate manner to facilitate the donation of desperately needed organs and tissues for waiting patients, support research efforts to enhance the available supply of organs and tissue for transplant patients, improve clinical outcomes of patients post transplantation and work closely with the United Network For Organ Sharing (UNOS) to support its goals.

[14] LifeQuest Organ Recovery Services, *Mission* https://lifequestfla.org/about/ (last visited Jan. 22, 2020). The mission of LifeQuest is to honor individuals' donor designations, to ensure families' opportunities to donate and to maximize the Gift of Life through organ and tissue donation.

[15] OurLegacy, *Mission* https://www.ourlegacyfl.org/mission(last visited Jan. 22, 2020). The mission of OurLegacy is dedicated to saving and improving lives through organ and tissue donation and public education, while honoring all donors and their loved ones whose generosity makes the gift of life possible.

[16] U.S. Department of Health & Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, *Members* https://optn.transplant.hrsa.gov/members (last visited Jan. 23, 2020).

- Sacred Heart Health System, Pensacola;
- AdventHealth Transplant Institute; and
- Halifax Health Center for Transplant Services.

The Organ Transplant Advisory Council (OTAC)

The Florida Legislature established the Organ Transplant Advisory Council (OTAC) in 1985 to recommend indications for adult and pediatric organ transplants to Florida's Agency for Health Care Administration (AHCA). The council consists of twelve members who are physicians.[17] The OTAC has met 22 times, with its first meeting held August 27, 2007; and its most recent meeting held on April 14, 2015.

The responsibilities of the council are to:
- Recommend to the AHCA indications for adult and pediatric organ transplants;
- Formulate guidelines and standards for organ transplants; and
- Development of End Stage Organ Disease and Tissue/Organ Transplant programs.

The recommendations, guidelines, and standards developed by the council are applicable only to those health programs funded through the AHCA.[18]

Oversight and Implementation of Florida's Organ Donation and Transplantation System

The organ donation and transplantation system consists of an extensive network of federal, state, and local entities, as well as individual organ donors, recipients, and individuals on organ transplant waitlists. The process of organ donation relies on coordination among these entities to match organs from donors to individuals on organ transplant waitlists. The Legislature's Office of Program Policy Analysis and Government Accountability's (OPPAGA) January 22, 2020, research memo, *Reviewing Florida Organ Donation and Transplantation System*, lists the participants in Florida's organ transplantation system as follows:[19]

Entity	Level	Role Within the Organ Donation and Transplantation System
U.S. Department of Health and Human Services	Federal	Oversees the two federal agencies responsible for organ procurement and transplantation regulation
Federal Centers for Medicare & Medicaid Services (CMS)	Federal	Monitors procurement and transplant program success and quality
Health Resources and Services Administration (HRSA)	Federal	Oversees the Organ Procurement and Transplantation Network and contractors (United Network for Organ Sharing and Scientific Registry of Transplant Recipients)

[17] Agency for Health Care Administration, *Organ Transplant Advisory Council*, available at https://ahca.myflorida.com/medicaid/organ_transplant/index.shtml (last visited Jan. 23, 2020).
[18] Section 765.53, F.S.
[19] Office of Program Policy Analysis and Government Accountability, Research Memo, *OPPAGA Review of Florida's Organ Donation and Transplant System*, (Jan. 22, 2020) (on file with the Senate Committee on Health Policy).

Entity	Level	Role Within the Organ Donation and Transplantation System
Scientific Registry of Transplant Recipients	Private/ Nonprofit	Provides statistical and other analytic support to OPTN for the formulation and evaluation of organ allocation
Organ Procurement and Transplantation Network (OPTN)	Private/ Nonprofit	Maintains a national registry for organ matching and carries out numerous other responsibilities relating to organ procurement and transplantation
United Network for Organ Sharing (UNOS)	Private/ Nonprofit	Operates OPTN under contract with HRSA
Agency for Health Care Administration	State	Contracts with Donate Life Florida for online donor registration and education system; coordinates with DHSMV to obtain donor registry funding; certifies and monitors organ procurement organizations for compliance and collects fees
Donate Life Florida	Private/ Nonprofit	Contracts with AHCA to operate a statewide online donor registry and to provide donor education
Department of Highway Safety and Motor Vehicles	State	Coordinates with county tax collector offices where donor education and registration occur when issuing driver licenses and identification cards; encourages and registers organ donors when issuing identification cards and driver licenses; provides donor educational materials; collects voluntary financial contributions to donor registry
County Tax Collector Offices	Local	Encourage and register organ donors when issuing identification cards and driver licenses; may provide donor educational materials; collect voluntary financial contributions to donor registry
Organ Procurement Organizations (Certified by CMS)	Regional within the State	Follow policies set by CMS and OPTN; primarily responsible for procuring organs and matching donor organs to patients on waitlists and coordinating with hospital transplant centers for transport of matched organs
Transplant Centers	Local/Private/ Nonprofit	Evaluate patients to determine eligibility to be placed on waitlists and suitability of and procuring organs at donor hospitals after being contacted by an OPO; perform transplant surgeries and conduct pre- and post-transplant care
Donor Hospitals	Local/ Private/ Nonprofit	Responsible for timely notification of OPO in their region of death or imminent death of a patient who is a viable organ donor [20]

[20] Id.

The Organ Transplant Process

Step 1- Get a physician referral or contact the transplant center directly as a self-referral to be evaluated by a transplant program as a potential transplant candidate.

Step 2- Select a Transplant Center. The OPTN has a list of member transplant centers. While a transplant candidate may be referred to a transplant center or program, he or she may want to make sure that it meets his or her need. Factors to consider are:

- Location;
- Compatibility with insurance;
- Financial arrangements; and
- Support group availability.

Step 3- Contact the transplant hospital to schedule an evaluation to find out if the candidate is a good candidate for transplant. The standard transplant evaluation usually includes the following tests and assessments:

- Blood typing;
- Tissue typing;
- Dental exam;
- Chest X-ray;
- Cardiac work-up;
- Pulmonary work-up;
- Infectious disease testing;
- Cancer screening;
- Gender-specific testing;
- Psychological evaluation to determine emotional preparedness;
- Evaluation of social and financial supports; and
- Ability to care for oneself and the new organ after transplant.

Other testing may be required depending on the needed organ and the individual's health history.[21]

The exact process varies among transplant centers, as each center determines its own criteria for evaluating patients. Each organ transplant center is required by law to provide its specific guidelines and criteria for inclusion and exclusion of patients as candidates for transplant.

Step 4- If the transplant team members determine that a candidate is suitable for a transplant, they will add him or her to the OPTN national waiting list of all people waiting for a transplant. The transplant team will contact the candidate in writing about ten days after he or she is listed to let the patient know the date and time his or her name was added to the national list.[22]

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[21] United Network for Organ Sharing, Talking About Transplantation, *What Every Patient Needs to Know*, 2019, p. 11, *available at* https://www.unos.org/wp-content/uploads/unos/WEPNTK.pdf (last visited Jan. 23, 2020).

[22] U.S. Department of Health and Human Services, Health Resources & Services Administration, Organdonor.gov, *The Organ Transplant Process* https://www.organdonor.gov/about/process/transplant-process.html (last visited Jan. 22, 2020).

Organ Allocation

More than 120,000 people in the U.S. are waiting to receive an organ transplant. There are not enough donated organs to transplant everyone in need, so a balance of the following is sought:

- Justice (fair consideration of candidates' circumstances and medical needs); and
- Medical utility (trying to increase the number of transplants performed and the length of time patients and organs survive).[23]

Many factors are used to match organs with patients in need. Some are the same for all organs, but the system must accommodate some unique differences for each organ.[24]

Before an organ is allocated, all transplant candidates on the waiting list that are incompatible with the donor are automatically screened out from any potential match. Then the system determines the order in which the compatible candidates will receive offers, according to national policies.

There are 58 local Donation Service Areas, and 11 regions, that are used for United States organ allocation. Hearts and lungs have less time to be transplanted, so the OPTN uses a radius from the donor hospital, instead of regions, when allocating those organs.

Factors in Organ Allocation

Each organ has different criteria for allocation, but wealth, social status, citizenship, residency, political influence, national origin, ethnicity, sex, or religion are never factors.[25] Blood type and other medical factors weigh into the allocation of every donated organ, and other factors are unique to each organ-type. For example, to receive a kidney, the following additional medical factors weigh heavily in the allocation process:

- Waiting time;
- Donor/recipient immune system compatibility;
- Pediatric status;
- Prior living donor;
- How far the candidate lives from donor hospital; and
- Survival benefit.

For a heart or a liver transplant, the following medical factors weigh heavily in the allocation process:

- Medical need; and
- How far the candidate lives from donor hospital.

For a lung transplant, the following medical factors weigh heavily in the allocation process:

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[23] U.S. Department of Health and Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, *How Organ Allocation Works* https://optn.transplant.hrsa.gov/learn/about-transplantation/how-organ-allocation-works/ (last visited Jan. 22, 2020).
[24] Id.
[25] U.S. Department of Health and Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, *Policies, 5.4 Organ Offers* (Jan. 9, 2020), p. 92, *available at* https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf (last visited Jan. 23, 2020).

- Survival benefit;
- Medical urgency;
- Waiting time; and
- How far the candidate lives from donor hospital.

Wait Times for Organ Transplants

Candidate wait times vary widely for many reasons. The shortage of organs causes most patients to wait for a transplant. Some patients are more ill than others when they are put on the transplant waiting list. Some patients get sick more quickly than other patients or respond differently to treatments. Patients may have medical conditions that make it more difficult to find a good match.[26]

How long a patient waits depends on many factors. These can include:
- Blood type;
- Tissue type;
- Height and weight of transplant candidate;
- Size of donated organ;
- Medical urgency;
- Time on the waiting list;
- The distance between the donor's hospital and the potential donor organ;
- How many donors there are in the local area over a period of time; and
- The transplant center's criteria for accepting organ offers.[27]

Depending on the kind of organ needed, some factors are more important than others.

The Donor Matching System

The OPTN has policies that regulate how donor organs are matched and allocated to patients on the waiting list. There are some common factors in how organs are matched, such as blood type and how severe the patient's illness is. However, depending on the organ, some factors become more important than others, so there is a different policy for each organ.[28] The OPTN operates the national database of all patients in the U.S. waiting for a transplant. OPTN's computer system matches the donor's organs to potential recipients.[29]

When transplant hospitals accept patients onto the waiting list, the patients are registered in a centralized, national computer network that links all donors and transplant candidates. The UNOS center is staffed 24 hours a day throughout the year, and it assists with the matching, sharing, and transportation of organs via this computer network.

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[26] U.S. Department of Health & Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network Transplant Process, *Wait Times* https://optn.transplant.hrsa.gov/learn/about-transplantation/transplant-process/ (last visited Jan. 22, 2020).
[27] Id.
[28] U.S. Department of Health & Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, *Donor Matching System* https://optn.transplant.hrsa.gov/learn/about-transplantation/donor-matching-system/ (last visited Jan. 22, 2020).
[29] Id.

Transplant centers, tissue typing laboratories, and OPOs are involved in the organ sharing process. When donor organs are identified, the procuring organization typically accesses the computerized organ matching system, enters information about the donor organs, and runs the match program. At times, when requested or when there is a need to identify perfectly matched kidney donors to recipients, the matching process is handled by organ center personnel at UNOS headquarters in Richmond, Virginia.

For each organ that becomes available, the computer program generates a list of potential recipients ranked according to objective criteria (i.e. blood type, tissue type, size of the organ, medical urgency of the patient, time on the waiting list, and distance between donor and recipient). After printing the list of potential recipients, the procurement coordinator contacts the transplant surgeon caring for the top-ranked patient (i.e. patient whose organ characteristics best match the donor organ and whose time on the waiting list, urgency status, and distance from the donor organ adhere to allocation policy) to offer the organ. Depending on various factors, such as the donor's medical history and the current health of the potential recipient, the transplant surgeon determines if the organ is suitable for the patient. If the organ is turned down, the next listed individual's transplant center is contacted, and so on, until the organ is placed.

Once the organ is accepted for a potential recipient, transportation arrangements are made for the surgical teams to come to the donor hospital, and surgery is scheduled. For heart, lung, or liver transplantation, the recipient of the organ is identified prior to the organ recovery and called into the hospital where the transplant will occur to prepare for the surgery.

The recovered organs are stored in a cold organ preservation solution and transported from the donor to the recipient hospital. For heart and lung recipients, it is best to transplant the organ within six hours of organ recovery. Livers can be preserved up to 24 hours after recovery. For kidneys and typically the pancreas, laboratory tests designed to measure the compatibility between the donor organ and recipient are performed. A surgeon will not accept the organ if these tests show that the patient's immune system will reject the organ. Therefore, the recipient is usually not identified until after these organs are recovered.

For example, some organs can survive outside the body longer than others. So the distance between the donor's hospital and the potential recipient's hospital must be taken into consideration. How long individual organs can stay alive outside of the body is approximately the following:

- Hearts and Lungs: 4-6 hours;
- Livers: 8-12 hours;
- Pancreas: 12-18 hours;
- Kidney: 24-36 hours; and
- Intestines: 8-16 hours.

When matching organs from deceased donors to patients on the waiting list, many of the factors taken into consideration are the same for all organs. These usually include:

- Blood type;
- Body size;
- Severity of patient's medical condition;

- Distance between the donor's hospital and the patient's hospital;
- The patient's waiting time; and
- Whether the patient is available (for example, whether the patient can be contacted and has no current infection or other temporary reason that transplantation cannot take place).

Allocation Calculators

The Calculated Panel Reactive Antibody (CPRA) calculator is used to evaluate candidates for kidney, pancreas, and kidney/pancreas transplants. This calculator uses the same formula as the UNet[SM] computer system. UNet is the computer system used by the transplant center to calculate kidney, pancreas, and kidney/pancreas allocation scores for candidates in need of a transplant. This calculator produces a value based on the unacceptable antigens.[30]

Estimated Post Transplant Survival (EPTS) score is assigned to all adult candidates on the kidney waiting list, as part of the new kidney allocation system. An EPTS score is assigned to all adult candidates on the kidney waiting list and is based on four factors:

- Candidate time on dialysis;
- Current diagnosis of diabetes;
- Prior solid organ transplants; and
- Candidate age.

A candidate's EPTS score can range from 0 percent to 100 percent. An EPTS score of 20 percent or less will receive offers for kidneys from donors with KDPI scores of 20 percent or less before other candidates at the local, regional, and national levels of distribution. The EPTS score is not used in allocation of kidneys from donors with KDPI scores greater than 20 percent.

The Kidney Donor Profile Index (KDPI) calculator summarizes the risk of graft failure after kidney transplant. The Kidney Donor Risk Index (KDRI) combines a variety of donor factors to summarize the risk of graft failure after kidney transplant into a single number. The KDRI expresses the relative risk of kidney graft failure for a given donor compared to the median kidney donor from last year.

The KDPI and KDRI are combined and put on a cumulative percentage scale. A donor with a KDPI of 80 percent or higher has a greater expected risk of graft failure. If diabetes or hypertension statuses are unknown, the calculator will assume the donor has the same chance as a randomly selected donor having the condition. If Hepatitis C Virus (HCV) status is unknown, the calculator will assume the donor is negative for HCV.

The Lung Allocation Score (LAS) is a numerical calculation used for allocating lungs to candidates age 12 and older to calculate lung allocation scores for patients in need of a lung transplant.[31]

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[30] *See* https://unos.org/technology/unet/ (last visited Jan. 25, 2020)

[31] U.S. Department of Health & Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, Transplant Process, *Allocation Calculators* https://optn.transplant.hrsa.gov/resources/allocation-calculators/ (last visited Jan. 22, 2020).

Organ Transplant Costs

The cost of transplantation and follow-up care varies across the country and by organ. Even before a transplantation, these costs can add up quickly. These costs may include:

- Medical costs
  - Pre-transplant evaluation and testing;
  - Hospital stay and surgery;
  - Additional hospital stays for complications;
  - Follow-up care and testing;
  - Anti-rejection and other drugs, which can cost more than $10,000 per year;
  - Fees for surgeons, physicians, radiologist and anesthesiologist;
  - Fees for the surgical recovery (procurement) of the organ from the donor;
  - Physical, occupational, and vocational rehabilitation; and
  - Insurance deductibles and co-payments.
- Nonmedical costs
  - Transportation to and from the transplant center, before and after transplantation;
  - Food, lodging, long distance phone calls for the patient and his or her family;
  - Child care; and
    Lost wages if the patient's employer does not pay for the patient's time away from work.[32]

The most common funding sources for organ transplants are:

- Insurance;
- Extending insurance coverage through COBRA;
- Medicare and Medicaid;
- TRICARE;
- Charitable organizations;
- Advocacy organizations;
- Fundraising campaigns; and
- Other sources of insurance.[33]

Organ Transplants and Medicare

Medicare Part B covers doctor services for certain organ transplants. Medicare Part A covers heart, lung, kidney, pancreas, intestine, and liver transplants under certain conditions at Medicare-certified facilities. Part A also covers some stem cell transplants under certain conditions. Part B covers cornea transplants, under some conditions. Stem cell and cornea transplants are not limited to Medicare-approved transplant centers. Organ transplant coverage under Medicare includes:

- Medically necessary tests, labs, and exams before surgery;
- Transplant immunosuppressive drugs (under certain conditions);
- Follow-up care, and

[32] U.S. Department Of Health And Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation, *Partnering With Your Transplant Team: The Patient's Guide to Transplantation* (2008), p. 22, *available at* https://www.unos.org/wp-content/uploads/unos/PartneringWithTransplantTeam.pdf (last visited Jan. 23, 2020).
[33] Id.

- Procurement of organs.[34]

A Medicare recipient's out-of-pocket costs may include:
- Twenty percent of the Medicare-approved amount for doctors' services;
- The Part B deductible; and
- Various amounts for organ transplant facility charges.

Medicare does not pay for a living donor for a kidney transplant.[35]

Organ Transplants and Florida Medicaid

Florida Medicaid coverage for organ transplants is restricted to those transplants currently accepted as therapeutic modalities and do not include experimental procedures. For children under 21, Florida Medicaid covers kidney, liver, cornea, heart, lung pancreas, intestines, bone marrow, and multivisceral[36]transplants that are medically necessary and appropriate.[37] The following are samples of the AHCA's Medicaid fee-for-service reimbursement rates for specific transplant surgery:
- Adult Heart: Facility $135,000; physician $27,000;
- Adult Liver: Facility $95,600; physician $27,000;
- Adult Lung: Facility $205,000; physician $33,000;
- Pediatric Lung: Facility $280,000.00; physician $40,800; and
- Adult and Pediatric Intestinel/Multivisceral: Facility $450,000; physician: $50,000.[38]

Discrimination in Access to Anatomical Gifts and Organ Transplants

On September 25, 2019, the National Council on Disability (NCD) submitted a report to the President and Congress entitled, *Organ Transplant Discrimination Against People with Disabilities.*[39] The report found, among other things, that people with disabilities are frequently denied access to organ transplants based on a transplant center's written and unwritten policies excluding people with disabilities as candidates for a transplant, and even refusing to evaluate a particular person's medical suitability for an organ transplant because of the person's disability.

The NCD is an independent federal agency charged with advising the President, Congress, and other federal agencies on disability policy to advance the goals of the federal Americans with

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[34] Medicare.gov., The Official U.S. Government Site for Medicare; *Open Enrollment Is Over - Get Ready for A New Year of Coverage*, available at https://www.medicare.gov/ (last visited Jan. 23, 2020).
[35] Id.
[36] A multivisceral transplant is the transplantation of three or more abdominal organs all at once, namely the liver together with the pancreatoduodenal complex, the stomach as well as the small bowel with/without the right hemicolon. Medical Dictionary by Farlex, *available at* https://medical-dictionary.thefreedictionary.com/Multivisceral+Transplantation (last visited Jan. 23, 2020).
[37] Agency for Health Care Administration, *Florida Standards for the Coverage of Organ Transplant Services*, (effective April 1, 2015), p. 1, *available at* https://ahca.myflorida.com/medicaid/organ_transplant/pdfs/state_plan_standards_for_coverage_updated_2015.pdf, (last visited Jan. 23, 2020).
[38] Id.
[39] National Council on Disability, Bioethics and Disability Series, *Organ Transplant Discrimination Against People with Disabilities*, *available at* https://ncd.gov/sites/default/files/NCD_Organ_Transplant_508.pdf, (last visited Jan. 23, 2020).

Disabilities Act (ADA): equal opportunity, full participation, independent living, and economic self-sufficiency for persons with disabilities.[40]

The American's with Disabilities Act & The Rehabilitation Act of 1973

The ADA[41] and section 504 of the Rehabilitation Act of 1973[42] prohibit discrimination on the basis of disability. The Rehabilitation Act specifically prohibits discrimination against otherwise qualified individuals on the basis of disability in:

- Programs and activities receiving financial assistance from HHS;[43] and
- Programs or activities conducted by HHS.[44]

According to the NCD, while there are few empirical studies analyzing how organ transplant centers actually evaluate patients for transplantation, particularly with respect to how any particular disability influences which patients are selected, the primary forms of disability discrimination occurring at organ transplant centers are:

- Refusal to evaluate a person with a disability as a candidate for transplant; and
- Refusal to place a person with a disability on the national organ transplant waiting list.

The ADA defines "disability" as:

- A physical or mental impairment that substantially limits one or more of the major life activities;
- A record of such an impairment; or
- Being regarded as having such an impairment.[45]

The ADA specifies the meaning of the phrase "physical or mental impairment" to mean:

- Any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems:
  - Neurological;
  - Musculoskeletal;
  - Special sense organs;
  - Respiratory (including speech organs);
  - Cardiovascular;
  - Reproductive;
  - Digestive;
  - Genitourinary;
  - Hemic and lymphatic;
  - Skin;
  - Endocrine; or
- Any mental or psychological disorder such as:
  - Mental retardation;

[40] National Council on Disabilities, Letter to UNOS, OPTN, HRSA Regarding Organ Transplants (Sept. 25, 2019), *available at* https://ncd.gov/publications/2019/ncd-letter-unos-optn-hrsa-regarding-organ-transplants (last visited Jan. 23, 2020).
[41] 28 C.F.R. Part 35 and 36.
[42] 29 U.S.C. s. 794.
[43] 45 C.F.R. 84.
[44] 45 C.F.R. 85.
[45] 28 C.F.R., s. 35.104.

- Organic brain syndrome;
- Emotional or mental illness; or
- Specific learning disabilities.[46]

The phrase "physical or mental impairment" specifically includes, but is not limited to:

- Contagious and noncontagious diseases and conditions as orthopedic, visual, speech and hearing impairments;
- Cerebral palsy;
- Epilepsy;
- Muscular dystrophy;
- Multiple sclerosis;
- Cancer;
- Heart disease;
- Diabetes;
- Emotional illness;
- HIV disease (whether symptomatic or asymptomatic);
- Tuberculosis;
- Drug addiction; and
- Alcoholism.

The ADA also specifies the meaning of the phrase "major life activities" to include functions such as:

- Caring for oneself;
- Performing manual tasks;
- Walking;
- Seeing;
- Hearing;
- Speaking;
- Breathing;
- Learning; and
- Working.

Enforcement of the ADA and the Rehabilitation Act of 1973

An individual who believes that he or she has been subjected to discrimination on the basis of his or her disability, by a public entity, may file a complaint with the Department of Justice (DOJ) no later than 180 days from the date of the alleged discrimination, unless the time for filing is extended by the designated agency for good cause shown.[47] The DOJ, or designated agency, will then investigation, and if discrimination on the basis of disability is found, issue a non-compliance letter of findings to the Assistant Attorney General and initiate negotiations with the public entity to secure compliance by voluntary means.[48] If the public entity declines to enter into voluntary compliance negotiations, or if negotiations are unsuccessful, the designated agency shall refer the matter to the Attorney General with a recommendation for appropriate

[46] Id.
[47] 28 C.F.R. s. 35.170.
[48] 28 C.F.R. s. 35.173.

action.[49] If the complainant prevails, he or she may be awarded a reasonable attorney's fee, including litigation expenses and costs.[50]

A Cause of Action Under the Florida Civil Rights Act of 1992

The general purposes of the Florida Civil Rights Act of 1992 (Act) were set out by the Legislature as follows:

- To secure for all individuals within the state freedom from discrimination because of race, color, religion, sex, pregnancy, national origin, age, handicap, or marital status and thereby to protect their interest in personal dignity;
- To make available to the state their full productive capacities;
- To secure the state against domestic strife and unrest;
- To preserve the public safety, health, and general welfare; and
- To promote the interests, rights, and privileges of individuals within the state.[51]

The Act creates both a state and individual cause of action for any violation of a Florida statute making unlawful discrimination because of race, color, religion, gender, pregnancy, national origin, age, *handicap*, or marital status in the areas of education, employment, housing, or public accommodations for relief and damages under s. 760.11(5), F.S., unless greater damages are expressly provided for.[52] [emphasis added]

Section 760.22(12), F.S., as created by the Florida Fair Housing Act defines "handicap" to mean:

- A person has a physical or mental impairment which substantially limits one or more major life activities, or he or she has a record of having, or is regarded as having, such physical or mental impairment; or
- A person has a developmental disability under s. 393.063, F.S.,[53] which manifests itself before the age of 18 and constitutes a substantial handicap that can reasonably be expected to continue indefinitely, including:
  - A disorder or syndrome that is attributable to intellectual disability;
  - Cerebral palsy;
  - Autism;
  - Spina bifida;
  - Down syndrome;
  - Phelan-McDermid syndrome;[54] or

[49] 28 C.F.R. s. 35.174.
[50] 28 C.F.R. s. 35.175.
[51] Section 760.01, F.S.
[52] Section 760.07, F.S.
[53] Section 760.22(7), F.S.
[54] U.S. Department of Health and Human Services, National Institutes of Health, Genetic and Rare Disease Information Center, *22q13.3 deletion syndrome* https://rarediseases.info.nih.gov/diseases/10130/phelan-mcdermid-syndrome (last visited Jan. 23, 2020). 22q13.3 deletion syndrome, also known as Phelan-McDermid syndrome, is a chromosome disorder caused by the loss (deletion) of a small piece of chromosome 22. The deletion occurs near the end of the long arm (or q arm) of the chromosome at a location designated as q13.3. Not everyone with 22q13.3 deletion syndrome will have the same medical, developmental, or behavioral problems (features). Common problems include low muscle tone (hypotonia), intellectual disability, developmental delays especially delayed or absent speech, and tendency to overheat. Children may be tall and thin.

- Prader-Willi syndrome.[55, 56]

A Florida Civil Rights cause of action for discrimination based on a disability may apply to a violation of s. 501.2077(2), F.S., within the "Florida Deceptive and Unfair Trade Practices Act," which creates civil liability and a penalty of not more than $15,000 for each violation if a person willfully uses a method, act, or practice which victimized or attempted to victimize a person who has a disability, and if he or she knew that his or her conduct was unfair or deceptive.[57] If members of a transplant team intentionally discriminated against an otherwise qualified disabled person in a transplant decision, this may create a civil rights violation under the Florida Civil Rights Act.

III. Effect of Proposed Changes:

SB 1556 creates sections 765.523, 627.64197, 627.65736, and 641.31075, F.S. The bill prohibits specified covered entities from denying, refusing to allocate, or lowering an individual's priority for organ transplant medical services solely on the basis of an individual's disability.

The bill defines the following:
- Auxiliary aids and services;
- Covered entity;
- Disability;
- Organ transplant; and
- Qualified individual.

Under the bill, "covered entity" means any of the following:
- A licensed health care practitioner.
- A hospital, skilled nursing facility, hospice, or intermediate care facility for the developmentally disabled.
- A facility providing room and board and personal care for persons who have developmental disabilities.
- An institutional medical unit in a correctional facility.
- Any other entity responsible for potential recipients of an anatomical gift.

The bill mandates that a covered entity may not do any of the following, solely on the basis of an individual's disability:
- Consider a qualified individual ineligible for a transplant;
- Deny medical or other organ transplant services, including:

[55] U.S. Department of Health and Human Services, National Institutes of Health, U.S. National Library of Medicine, P*rader-Willi Syndrome* https://ghr.nlm.nih.gov/condition/prader-willi-syndrome (last visited Jan 23, 2020). Prader-Willi syndrome is a complex genetic condition. In infancy, this condition is characterized by weak muscle tone (hypotonia), feeding difficulties, poor growth, and delayed development. Beginning in childhood, affected individuals develop an insatiable appetite, which leads to chronic overeating (hyperphagia) and obesity. People with Prader-Willi syndrome typically have mild to moderate intellectual impairment and learning disabilities. Behavioral problems include temper outbursts, stubbornness, and compulsive behavior such as picking at the skin. Sleep abnormalities can also occur. Both affected males and females have underdeveloped genitals. Puberty is delayed or incomplete, and most affected individuals are infertile.
[56] Section 393.063(12), F.S.
[57] *See* ss. 501.2077(2), and 760.07, F.S.

  - Evaluations;
  - Surgery;
  - Counseling; and
  - Post-transplant treatment and services;
- Refuse to refer the individual to an organ procurement organization or specialist for evaluation for an organ transplant;
- Refuse to place a qualified individual on an organ transplant waiting list;
- Place a qualified individual at a lower priority on an organ transplant waiting list; or
- Consider the individual's inability to independently comply with the post-transplant medical requirements if the individual has the necessary support system to assist him or her with such compliance.

The bill also mandates that, unless the covered entity can demonstrate that making modifications to its policies, practices, or procedures to allow an individual with a disability access to services would fundamentally alter the nature of the services, a covered entity must:
- Make reasonable modifications to its policies, practices, or procedures to allow an individual with a disability access to services, including:
  - Transplant-related counseling;
  - Information;
  - Coverage; or
  - Treatment.

The bill requires that, unless a covered entity can demonstrate that taking affirmative steps to ensure that an individual with a disability is not denied services due to the absence of auxiliary aids and services, would fundamentally alter the nature of the services being offered, or would result in an undue burden on the covered entity, a covered entity must to take additional steps to ensure that an individual with a disability is not denied services due to the absence of auxiliary aids and services.

The bill provides that a covered entity may consider an individual's disability, following an evaluation, if a physician finds the person's disability to be medically significant to the life of the transplant but only to the extent that the covered entity is making treatment or coverage recommendations or decisions for the individual.

If a person has the necessary support system to assist him or her in complying with post-transplant medical requirements, a covered entity may not consider the individual's inability to independently comply with the post-transplant medical requirements to be medically significant.

The bill allows a person with a disability to file a civil action for injunctive or other equitable relief for violations.

The bill prohibits insurers, nonprofit health care service plans, and health maintenance organizations that provide transplant coverage from denying coverage solely on the basis of an individual's disability.

The bill has an effective date of July 1, 2020.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill could be interpreted to conflict with federal law. The federal National Organ Transplant Act (NOTA) established the OPTN. The OPTN policies and procedures are rules that govern and control the operation of all member transplant hospitals, OPOs, and histocompatibility labs in the U.S. The OPTN rules have supremacy over any state law regarding transplant candidate selection and allocation criteria.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 765.523, 627.64197, 627.65736, and 641.31075.

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

None.

B. Amendments:

None.

By Senator Bean

4-01472B-20 20201556__

A bill to be entitled

An act relating to nondiscrimination in organ transplants; creating s. 765.523, F.S.; defining terms; prohibiting certain entities from making certain determinations or engaging in certain actions related to organ transplants solely on the basis of an individual's disability; specifying an instance where certain entities may consider an individual's disability, with an exception; requiring certain entities to make reasonable modifications in their policies, practices, and procedures under certain circumstances, with an exception; requiring certain entities to take certain necessary steps to ensure an individual with a disability is not denied services, with exceptions; providing a cause of action for injunctive and other relief; providing construction; creating ss. 627.64197, 627.65736, and 641.31075, F.S.; prohibiting insurers, nonprofit health care service plans, and health maintenance organizations that provide coverage for organ transplants from denying coverage solely on the basis of an individual's disability under certain circumstances; providing construction; defining the term "organ transplant"; providing an effective date.

WHEREAS, the Americans with Disabilities Act prohibits discrimination against individuals with disabilities, yet many individuals with disabilities still experience discrimination in accessing critical health care services, and

WHEREAS, in other states nationwide, individuals with mental or physical disabilities have historically been denied lifesaving organ transplants based on assumptions that their lives are less worthy, that they are incapable of complying with posttransplant medical requirements, or that they lack adequate support systems to ensure compliance with posttransplant medical requirements, and

WHEREAS, although organ procurement organizations must consider medical and psychosocial criteria when determining if a patient is suitable to receive an organ transplant, organ procurement organizations that participate in Medicare and other federally funded programs are required to use patient selection criteria that result in a fair and nondiscriminatory distribution of organs, and

WHEREAS, residents of this state in need of organ transplants are entitled to assurances that they will not encounter discrimination on the basis of a disability, NOW, THEREFORE,

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

Section 1. Section 765.523, Florida Statutes, is created to read:

765.523 Discrimination in access to anatomical gifts and organ transplants prohibited.—

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

(a) "Auxiliary aids and services" means:

1. Qualified interpreters or other effective methods of making aurally delivered materials available to individuals with

hearing impairments.

2. Qualified readers, recorded texts, texts in an accessible electronic format, or other effective methods of making visually delivered materials available to individuals with visual impairments.

3. Supported decisionmaking services, including any of the following:

a. The use of a support person to assist an individual in making medical decisions, communicating information to the individual, or ascertaining his or her wishes.

b. The provision of information to a person designated by the individual, consistent with the Health Insurance Portability and Accountability Act and other applicable laws and rules governing the disclosure of health information.

c. If an individual has a court-appointed guardian or other legal representative authorized to make health care decisions on his or her behalf, any measures used to ensure that the guardian or legal representative is included in decisions involving the individual's health care and that medical decisions are in accordance with the individual's own expressed interests.

d. Any other aid or service that is used to provide information in a format that is readily understandable and accessible to individuals with cognitive, neurological, developmental, or intellectual disabilities.

(b) "Covered entity" means any of the following:

1. A licensed health care practitioner as defined in s. 456.001.

2. A health care facility as defined in s. 408.07.

3. A residential facility licensed under chapter 393.

4. An institutional medical unit in a correctional facility.

5. Any other entity responsible for potential recipients of an anatomical gift.

(c) "Disability" means, with respect to an individual, a physical or mental impairment that substantially limits one or more major life activities of the individual, a record of the individual having such impairment, or the individual being regarded as having such impairment.

(d) "Organ transplant" means the transplantation or transfusion of a part of a human body into the body of another individual for the purpose of treating or curing a medical condition.

(e) "Qualified individual" means an individual who has a disability and meets the eligibility requirements for the receipt of an anatomical gift, regardless of:

1. The support networks available to the individual;

2. The provision of auxiliary aids and services; or

3. Reasonable modifications to the policies or practices of a covered entity, including modifications to allow:

a. Communication with the persons responsible for supporting the individual with his or her postsurgical and posttransplant care, including medication; and

b. The consideration of support networks available to the individual, including family, friends, and home and community-based services funded through Medicare, the state's Medicaid managed medical assistance program, or another health plan in which the individual is enrolled or any program or source of funding available to the individual, in determining whether the

individual is able to comply with posttransplant medical requirements.

(2) A covered entity may not do any of the following solely on the basis of an individual's disability:

(a) Consider a qualified individual ineligible to receive an anatomical gift or organ transplant.

(b) Deny medical or other services related to an organ transplant, including evaluation, surgery, counseling, and posttransplant treatment and services.

(c) Refuse to refer the individual to an organ procurement organization or a related specialist for the purpose of evaluation or receipt of an organ transplant.

(d) Refuse to place a qualified individual on an organ transplant waiting list.

(e) Place a qualified individual at a lower priority position on an organ transplant waiting list than the position at which the qualified individual would have been placed if not for the disability.

(3)(a) A covered entity may take an individual's disability into account if, following an individualized evaluation of him or her, a physician finds the individual's disability to be medically significant to the provision of the anatomical gift, but only to the extent that the covered entity is making treatment or coverage recommendations or decisions for the individual.

(b) If an individual has the necessary support system to assist him or her in complying with posttransplant medical requirements, a covered entity may not consider the individual's inability to independently comply with the posttransplant

medical requirements to be medically significant for the purposes of paragraph (a).

(4) A covered entity shall make reasonable modifications in policies, practices, or procedures when the modifications are necessary to allow an individual with a disability access to services, including transplant-related counseling, information, coverage, or treatment, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the services.

(5) A covered entity shall take such steps as may be necessary to ensure that an individual with a disability is not denied services, including transplant-related counseling, information, coverage, or treatment, due to the absence of auxiliary aids and services, unless the covered entity can demonstrate that taking the steps would fundamentally alter the nature of the services being offered or would result in an undue burden on the covered entity.

(6) If a covered entity violates this section, the qualified individual who is affected by the violation may bring an action in the appropriate circuit court for injunctive or other equitable relief.

(7) This section may not be construed to require a covered entity to make a referral or recommendation for or perform a medically inappropriate organ transplant.

Section 2. Section 627.64197, Florida Statutes, is created to read:

627.64197 Nondiscrimination of coverage for organ transplants.—A health insurance policy issued, delivered, or renewed on or after July 1, 2020, in this state by an insurer

which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

Section 3. Section 627.65736, Florida Statutes, is created to read:

627.65736 Nondiscrimination of coverage for organ transplants.—A group health insurance policy delivered, issued, or renewed on or after July 1, 2020, in this state by an insurer or nonprofit health care services plan which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer or nonprofit health care service plan to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

Section 4. Section 641.31075, Florida Statutes, is created to read:

641.31075 Nondiscrimination of coverage for organ transplants.—A health maintenance contract issued or renewed on or after July 1, 2020, in this state by a health maintenance organization which provides coverage for organ transplants may not deny coverage for an organ transplant solely on the basis of a subscriber's disability. This section may not be construed to require such health maintenance organization to provide coverage

for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

Section 5. This act shall take effect July 1, 2020.

The Florida Senate

Committee Agenda Request

To: Senator Gayle Harrell, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 16, 2020

I respectfully request that **Senate Bill # 1556**, relating to Nondiscrimination in Organ Transplants, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Aaron Bean

Senator Aaron Bean
Florida Senate, District 4

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/28/2020
Meeting Date

SB 1556
Bill Number (if applicable)

Topic Nondiscrimination in Organ Transplants

Amendment Barcode (if applicable)

Name Olivia Babis

Job Title Public Policy Analyst

Address 2473 Care Dr Ste 200
Street

Phone 850-617-9718

Tallahassee FL 32308
City *State* *Zip*

Email oliviab@disabilityrightsflorida.org

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Disability Rights 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)

THE FLORIDA SENATE

APPEARANCE RECORD

1/28/2020
Meeting Date

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

1556
Bill Number (if applicable)

Topic Organ transplant nondiscrimination

Amendment Barcode (if applicable)

Name Ron Watson

Job Title Lobbyist

Address 3738 Mundy Way
Street

Tallahassee FL 32309
City *State* *Zip*

Phone 850 567-1202

Email watson.strategies@comcast.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Renal Assoc

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)

1-28-2020
Meeting Date

1556
Bill Number (if applicable)

Topic Nondiscrimination of Organ Transplants

Amendment Barcode (if applicable)

Name Missy Timmins "Margaret"

Job Title

Address 2910 Kerry Forest Pky D4-368
Street

Phone 850-264-3225

TLH FL 32309
City *State* *Zip*

Email missy@timminsconsltg.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Myself

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)

OPPAGA
Office of Program Policy Analysis and Government Accountability
Research Memorandum

January 22, 2020

OPPAGA Review of Florida's Organ Donation and Transplantation System

SCOPE

As directed by the Legislature, OPPAGA examined Florida's organ donation and transplantation system, including its performance, challenges, and opportunities for improvement. This research memorandum provides background information on the system, federal and state policy changes, and stakeholder revenues and costs. The memo addresses seven questions.

1. How does the organ donation and transplantation system function and what are the roles of its key players?
2. How have federal and state organ donation and transplantation policies changed over the past 25 years?
3. What are the projected impacts on Florida of changes to OPTN national organ allocation policies?
4. How has Florida's organ donation and transplantation system performed over time and in comparison to other states?
5. What factors enhance transplant success and what challenges are associated with organ donation and transplantation?
6. What policies have other states and countries pursued to improve organ availability?
7. What options could the Legislature consider to improve organ availability in Florida?

SUMMARY

The organ donation and transplantation system consists of an extensive network of federal, state, and local entities, as well as individual organ donors, recipients, and individuals on organ transplant waitlists. The process of organ donation relies on coordination among these entities to match organs from donors to individuals on organ transplant waitlists.

Two federal agencies oversee all organ transplant programs across the U.S. At the state level, the Agency for Health Care Administration (AHCA), the Department of Highway Safety and Motor Vehicles (DHSMV), county tax collectors, four Organ Procurement Organizations (OPOs), 12 transplant centers, and donor hospitals comprise the state's organ donation and transplantation system. (See Exhibit 1.)

Exhibit 1
Multiple Entities at the Federal, State, Regional, Local, and Private Levels Participate in the Oversight and Implementation of Florida's Organ Donation and Transplantation System

Entity	Level	Role Within the Organ Donation and Transplantation System
U.S. Department of Health and Human Services	Federal	Oversees the two federal agencies responsible for organ procurement and transplantation regulation
Centers for Medicare and Medicaid Services (CMS)	Federal	Monitors procurement and transplant program success and quality
Health Resources and Services Administration (HRSA)	Federal	Oversees the Organ Procurement and Transplantation Network and contractors (United Network for Organ Sharing and Scientific Registry of Transplant Recipients)
Scientific Registry of Transplant Recipients	Private/Nonprofit	Provides statistical and other analytic support to OPTN for the formulation and evaluation of organ allocation
Organ Procurement and Transplantation Network (OPTN)	Private/Nonprofit	Maintains a national registry for organ matching and carries out numerous other responsibilities relating to organ procurement and transplantation
United Network for Organ Sharing (UNOS)	Private/Nonprofit	Operates OPTN under contract with HRSA
Agency for Health Care Administration	State	Contracts with Donate Life Florida for online donor registration and education system; coordinates with DHSMV to obtain donor registry funding; certifies and monitors organ procurement organizations for compliance and collects fees
Donate Life Florida	Private/Nonprofit	Contracts with AHCA to operate a statewide online donor registry and to provide donor education
Department of Highway Safety and Motor Vehicles	State	Coordinates with county tax collector offices where donor education and registration occur when issuing driver licenses and identification cards; encourages and registers organ donors when issuing identification cards and driver licenses; provides donor educational materials; collects voluntary financial contributions to donor registry
County Tax Collector Offices	Local	Encourage and register organ donors when issuing identification cards and driver licenses; may provide donor educational materials; collect voluntary financial contributions to donor registry
Organ Procurement Organizations (Certified by CMS)	Regional Within the State	Follow policies set by CMS and OPTN; primarily responsible for procuring organs and matching donor organs to patients on waitlists and coordinating with hospital transplant centers for transport of matched organs
Transplant Centers	Local/Private/ Nonprofit	Evaluate patients to determine eligibility to be placed on waitlists and suitability of and procuring organs at donor hospitals after being contacted by an OPO; perform transplant surgeries and conduct pre- and post-transplant care
Donor Hospitals	Local/ Private/ Nonprofit	Responsible for timely notification of OPO in their region of death or imminent death of a patient who is a viable organ donor

Source: OPPAGA analysis of state and federal laws and rules and stakeholder interviews.

Florida has improved its rate of donor registration over time, and the number of organ transplants performed has increased. The state compares favorably to the rest of the nation in how quickly people on waitlists receive transplants but fares similarly or worse in mortality rates. Federal and state policies related to the organ donation and transplantation system have been modified over the years, and recent federal policy changes have potential positive and negative impacts for Florida. Since 2017, OPTN committees have made or adopted proposals to change allocation policies for lungs, livers, hearts, kidneys, and pancreases. UNOS projections indicate that these changes would have positive impacts on Florida for lung, heart, and kidney-pancreas transplants, but the changes would have

negative impacts for kidney and liver transplants.[1] These policy changes are particularly important for Florida due to the fact that kidney and liver transplants are the most common types of transplants in the state. In addition, Florida's population age 65 and above is projected to continue to increase, and individuals in this age group in Florida have a higher rate of kidney transplants than the U.S. as a whole.[2]

Factors that may lead to higher transplant success rates include multidisciplinary teams, volume, patient demographics and hospital and center characteristics, post-transplant care, and regulation of the organ transplantation system. Our research also identified some of the challenges regarding organ donation and transplantation. These challenges include misunderstanding or lack of support for organ donation; need for financial support to cover the costs incurred by living donors; and hospital personnel mishandling communication with families. Other states have considered or adopted legislation to increase organ donor availability through policies to increase both the number of living donors and registered organ donors. Other countries have implemented policies that aim to increase organ donation and availability rates and decrease the time patients spend on waitlists. We present options for the Legislature's consideration to improve organ availability in Florida by increasing the rate of living donation and increasing organ donor registration.

QUESTIONS AND ANSWERS

How Does the Organ Donation and Transplantation System Function and What Are the Roles of Its Key Players?

Federal Entities' Roles

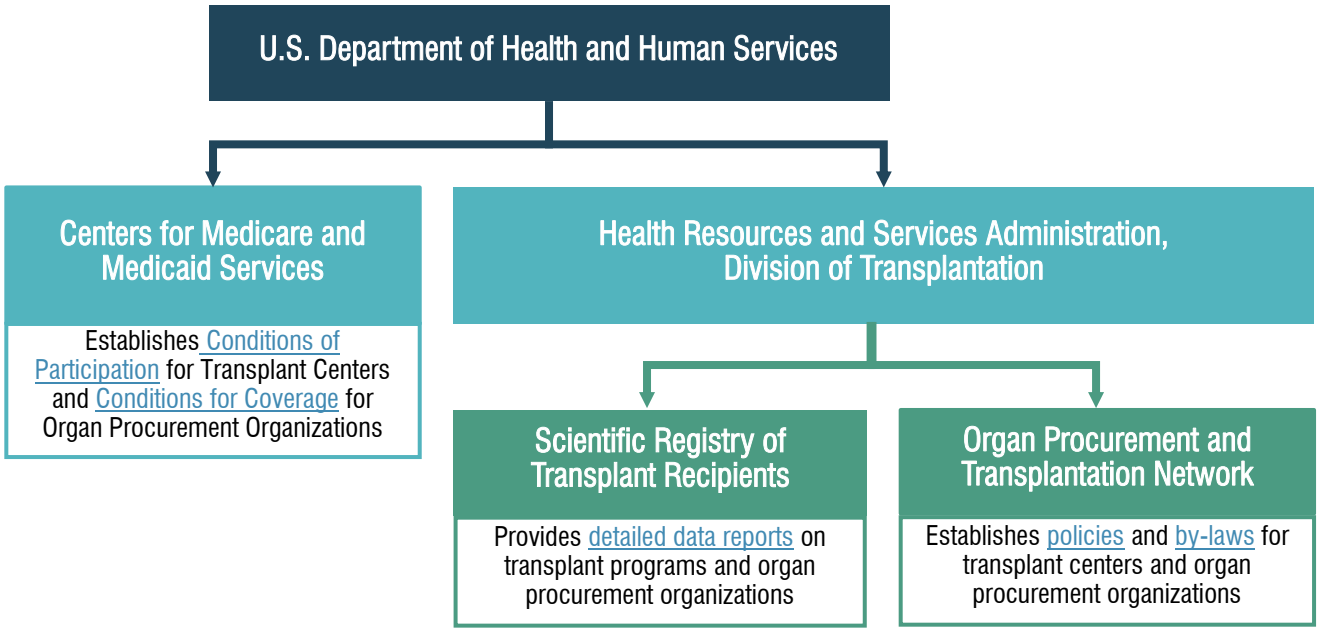
The Centers for Medicare and Medicaid Services and the Organ Procurement and Transplantation Network are the primary federal agencies with oversight of organ transplantation policies and practices. At the federal level, two agencies in the U.S. Department of Health and Human Services (HHS) oversee organ transplant programs: the Centers for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA). CMS monitors transplant program success and quality, holds transplant centers accountable through its published Medicare Conditions of Participation, and requires all transplant centers to develop, implement, and maintain a written, comprehensive, data-driven quality assessment and performance improvement program designed to monitor and evaluate performance of all of their transplantation services. CMS has also established extensive requirements for organ procurement organizations (OPOs). There are 58 OPOs in the U.S. that are responsible for working with donor hospitals to help place donor organs for transplant. CMS requirements for OPOs are designed to ensure quality as a condition of Medicare and Medicaid coverage and recertification every four years.[3] (See Exhibit 2.)

[1] UNOS also provided data for the impact of changes in the pancreas allocation process. However, there were too few transplants to show a meaningful difference.

[2] In 2018, 20.9% of kidney transplants nationwide were for the age group 65 and above, compared to 26.8% of kidney transplants in Florida. (The nationwide figure is from UNOS, which provided data for all states combined, including Florida.)

[3] These requirements include standards for donation outcome measures; participation in OPTN; relationships with hospitals, critical access hospitals, and tissue banks; administration and governing body; human resources; data reporting; information management; requesting consent; evaluation and management of potential donors and organ placement and recovery; organ preparation and transport; quality assessment and performance improvement; and emergency preparedness. See CFR Title 42 §486.301 to 486.360.

Exhibit 2
Federal Oversight of the Organ Donation and Transplantation System



Source: OPPAGA analysis of HHS and HRSA organizational charts and documents.

The Organ Procurement and Transplantation Network (OPTN) is the private nonprofit established in 1984 by the National Organ Transplant Act.[4] The act directed the HHS secretary to contract for the establishment and operation of OPTN. Federal law gives OPTN numerous responsibilities, including establishing a national list of individuals who need organs, a national system to match organs and individuals, membership criteria, and medical criteria for allocating organs and providing the public an opportunity to comment with respect to such criteria.[5] OPTN is also required to maintain a 24-hour telephone service to facilitate matching organs with individuals included in the list, assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients, and adopt and use standards of quality for the acquisition and transportation of donated organs. Among its other responsibilities, OPTN is also required to coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers; provide information to physicians and other health professionals regarding organ donation; collect, analyze, and publish data concerning organ donation and transplants; carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation; and work actively to increase the supply of donated organs.

In 2000, HHS established a final rule that provided a regulatory framework for the structure and operations of OPTN.[6] The rule includes making the OPTN board of directors responsible for developing, with the advice of the OPTN membership and other interested parties, policies within the mission of OPTN as set forth in the act and the secretary's contract for operation of OPTN, including policies for equitable allocation of cadaveric organs. The allocation policies must meet several

[4] 1984 Public Law 98-507.
[5] Title 42 USC 274.
[6] CFR Title 42 Part 121.

provisions, including being based on sound medical judgment, seeking to achieve the best use of donated organs, preserving the ability of a transplant program to decline an offer of an organ, being specific to each organ type or combination of types, and not being based on a candidate's place of residence or place of listing, with exceptions.[7] The final rule requires that the board of directors shall provide opportunities for OPTN membership and other interested parties to comment on proposed policies and take their comments into account.[8] Compliance with the policies is voluntary, but the OPTN board can recommend that the secretary make the policy enforceable.[9] However, OPTN has never asked for enforcement of one of its policies.

OPTN has established operational rules that include transplant policies and membership requirements with by-laws for transplant centers and organ procurement organizations.[10] The United Network for Organ Sharing (UNOS), a private, non-profit organization under contract with HRSA, manages OPTN and develops the requirements for its operation. Under contract with HHS, the Scientific Registry of Transplant Recipients (SRTR) is responsible for providing statistical and other analytic support to OPTN for the formulation and evaluation of organ allocation. OPTN also uses SRTR data to evaluate transplant center performance.

OPTN establishes OPO performance requirements and reviews an OPO whose observed organ yield rates fall below the expected rates by more than a specified threshold. OPTN has additional OPO membership requirements for quality assessment and performance improvement, the relationship with transplant hospitals, laboratory testing services, tissue bank services, education plans, organ allocation plans, personnel, patient confidentiality, and donation after circulatory death protocols.

OPTN's Membership and Professional Standard Committee (MPSC) evaluates transplant program compliance through medical peer review and by monitoring the SRTR's analyses of transplant programs' one-year patient and graft survival rates. In addition to transplant program quality, OPTN also monitors programs' waitlist data integrity, and organ allocation policy compliance, and conducts on-site surveys, desk reviews, and patient safety investigations.

The MPSC plays a large role in the accountability of OPOs and transplant programs and can take action against them by issuing warning letters or letters of reprimand, requiring corrective action plans, or recommending that the OPTN board of directors place the transplant program/member on probation or declare the member to be not in good standing. Based on review and hearing of the MPSC's recommendations, the OPTN board of directors can notify the HHS secretary, who can take further action such as removing one or more of the member's designated transplant programs or terminating the member's ability to receive Medicare or Medicaid funding.

UNOS also assists with the regulation and oversight of the U.S. organ transplantation system. UNOS's Department of Member Quality works with the OPTN MPSC to monitor transplant member performance and ensure that all transplant programs are in compliance with transplant standards. Like the MPSC, UNOS member quality staff conduct various ongoing reviews to evaluate OPTN member compliance with OPTN bylaws and policies. When reviews identify non-compliance, the UNOS member quality staff compile information on the cases for the MPSC to make decisions on the

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[7] CFR Title 42 §121.8.

[8] See Making OPTN Policy for a description of the OPTN policy making process.

[9] Per CFR Title 42 §121.4. To make a policy enforceable, the OPTN board must provide the secretary with the proposed policy at least 60 days before implementation. If OPTN does refer the policy for enforcement, per CFR Title 42 §121.4, the secretary sends significant proposed policies to the Advisory Committee on Organ Transplantation established under CFR Title 42 §121.12, and otherwise follows the process outlined in the CFR.

[10] See the OPTN *Organ Procurement and Transplantation Network Policies* and *Organ Procurement and Transplantation Network Bylaws*.

appropriate monitoring or action. Overall, the role that UNOS staff plays in the regulatory process varies based on the type of review (e.g., peer visits, transplant program activity, transplant program outcomes, patient safety compliance check, and member compliance).

State, Regional, and Local Entities' Roles

The primary state agencies involved in the organ donation and transplantation system in Florida are the Agency for Health Care Administration and the Department of Highway Safety and Motor Vehicles, with assistance from county tax collectors. AHCA is required by statute to contract for a statewide organ donor registry coupled with a program for donor education.[11] Accordingly, the agency contracts with Donate Life Florida for an online donor registration and education system. AHCA also coordinates with DHSMV in obtaining funding for the donor registry. Recently, CMS gave AHCA and similar agencies in other states responsibility for conducting on-site surveys of transplant centers for compliance with CMS regulations. In addition, AHCA is required by statutes to establish a program for the certification of organizations that procure organs, tissue, and eyes for transplantation, to set forth appropriate standards and guidelines for these organizations, and to monitor them for compliance.[12,13] AHCA is also responsible for collecting fees from organ procurement organizations and tissue and eye banks to support the cost of the certification program, an advisory board, the donor registry, and organ and tissue donation education.[14,15]

Several Non-Federal Entities Play Important Roles in Florida's Organ Donation and Transplantation System

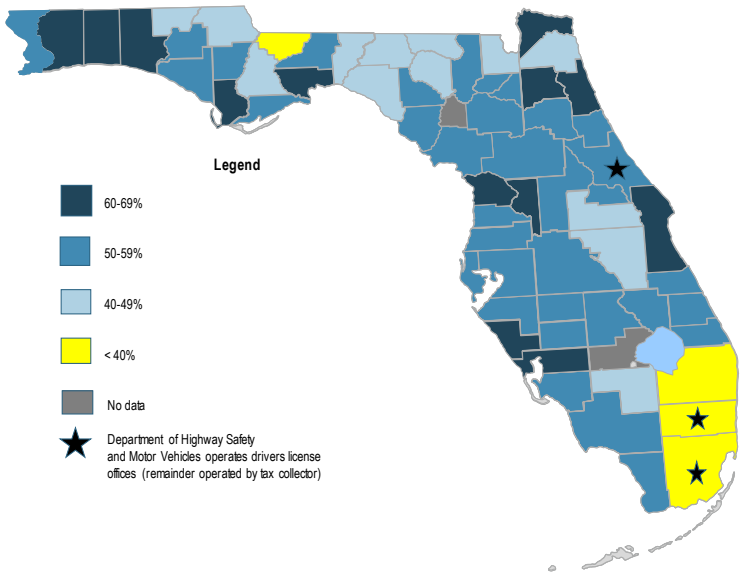
- Agency for Health Care Administration
- Department of Highway Safety and Motor Vehicles
- County Tax Collectors
- Donate Life Florida
- Organ Procurement Organizations
- Donor Hospitals
- Transplant Centers

Driver license offices operated by DHSMV and county tax collectors encourage and register organ donors when issuing identification cards and driver licenses. Driver license employees ask applicants if they want to be an organ donor and, if so, to enter their information into the state's driver license data system, which sends a nightly download of this information to Donate Life Florida. DHSMV also collects voluntary contributions to the donor registry that citizens submit when paying for an identification card, driver license, or motor vehicle registration. Nearly 90% of Florida's registrations are via driver license offices. (See Appendix A for details on the demographic characteristics of donor registrants.)

[11] Section 765.5155, *F.S.*
[12] Section 765.541, *F.S.*
[13] OPPAGA excluded tissue and eye banks from the scope of this review.
[14] Section 765.544, *F.S.*
[15] Section 765.543, *F.S.*, creates an Organ and Tissue Procurement and Transplantation Advisory Board to assist AHCA and the Florida Medical Examiners Commission, but AHCA reports that the board has not been active since 2015.

Several other entities play a significant role in Florida's organ donation and transplantation system. Donate Life Florida contracts with AHCA to operate a statewide online donor registry and to provide a donor education program. Donate Life Florida is a non-profit organization established in 1997 from a coalition of organ, tissue, and eye recovery programs in Florida and other individuals and organizations. Funding for Donate Life Florida is provided by the organ procurement organizations and voluntary contributions made by Floridians during license or motor vehicle transactions, and other fund-raising initiatives or private donations. As of December 31, 2018, over 10 million people were enrolled in the Joshua Abbott Organ and Tissue Donor Registry that Donate Life Florida operates. There is some regional variation in donor registration rates across Florida. Florida's three largest counties by population (Miami-Dade, Broward, and Palm Beach) have the three lowest donor registration rates at 35%, 31%, and 36%, respectively, with the exception of Gadsden County, which has a 35% registration rate.[16] (See Exhibit 3.)

Exhibit 3
Organ Donor Registration Rates by County, December 2018



Source: OPPAGA analysis of data from the *Donate Life Florida 2018 Annual Report.*

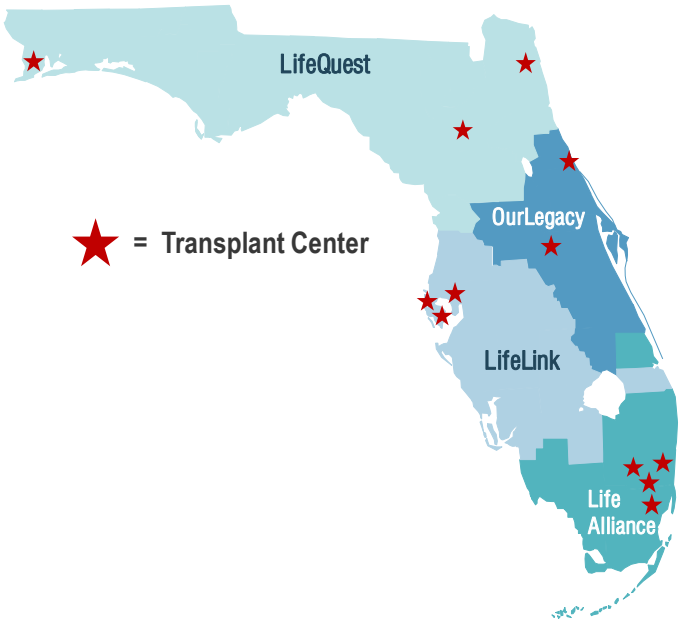
The state has four Organ Procurement Organizations (OPOs), each of which is responsible for a donation service area. (See Exhibit 4.) OPOs must be certified by the Centers for Medicare and Medicaid Services and abide by CMS regulations as well as be members of OPTN and follow OPTN's policies. OPOs are primarily responsible for procuring organs from deceased donors, using a national database to match donor organs to patients on waiting lists, and coordinating with hospital transplant centers for transport of matched organs. To increase donor registration, they provide education on organ donation to employees of driver license offices and place educational materials in these offices. OPOs offer opportunities for volunteering to raise awareness about the importance of registering as a donor.

Any of the state's Class I or Class II hospitals can act as a donor hospital for organ donation. Hospitals are responsible for timely notification of the applicable OPO in their area of a death or imminent death of a patient who is a viable organ donor. The state has 12 hospital transplant centers with responsibilities that include evaluating patients to determine waiting list eligibility and suitability and procurement of organs at donor hospitals.[17] They perform transplant surgeries and conduct pre- and post-transplant care.

[16] Donor registration rates are the percentage of customers who say "yes" when asked, "Do you want to be a donor?" during a driver license transaction; the registration rate for Florida overall is 49%.
[17] This excludes transplant centers that only perform bone marrow transplants. It also excludes Gulf Coast Medical Center, which had a transplant program that ceased operation at the end of 2018.

The organ donation system includes both living and deceased donors; hospitals, OPOs, and transplant centers work together to procure organs from deceased donors. Living donors may donate one kidney, one lung, or a portion of the liver, pancreas, or intestine. From 1988 through October 2019, 30% of Florida donors were living donors, compared to about 43% nationally.[18] Most living donations are from family members or friends. Potential living donors are evaluated by the transplant center where they intend to make the donation to determine their suitability to donate. Generally, living donors should be physically fit, in good health, between the ages of 18 and 60, and should not have (or have had) diabetes, cancer, high blood pressure, kidney disease, or heart disease.

Exhibit 4
Florida Has Four OPOs and 12 Transplant Centers



Source: Donate Life Florida and the Agency for Health Care Administration.

Deceased individuals may donate kidneys, livers, lungs, hearts, pancreases, and intestines.[19] Deceased donation is limited to very specific circumstances, and nationally, less than 1% of all U.S. deaths are candidates for organ donation. The typical process of deceased donation occurs after a patient comes to a hospital because of illness or accident. The medical team puts the patient on mechanical support, which keeps blood flowing to the organs. To be medically eligible for donation, the potential donor must

- be declared brain dead and be on a ventilator to maintain heart function and blood flow to organs; or after circulatory death, have an irreversible loss of function of the heart and lungs and be taken off of ventilated support until their heart stops beating;
- not have cancer or certain infections or diseases; and
- be in good health.[20]

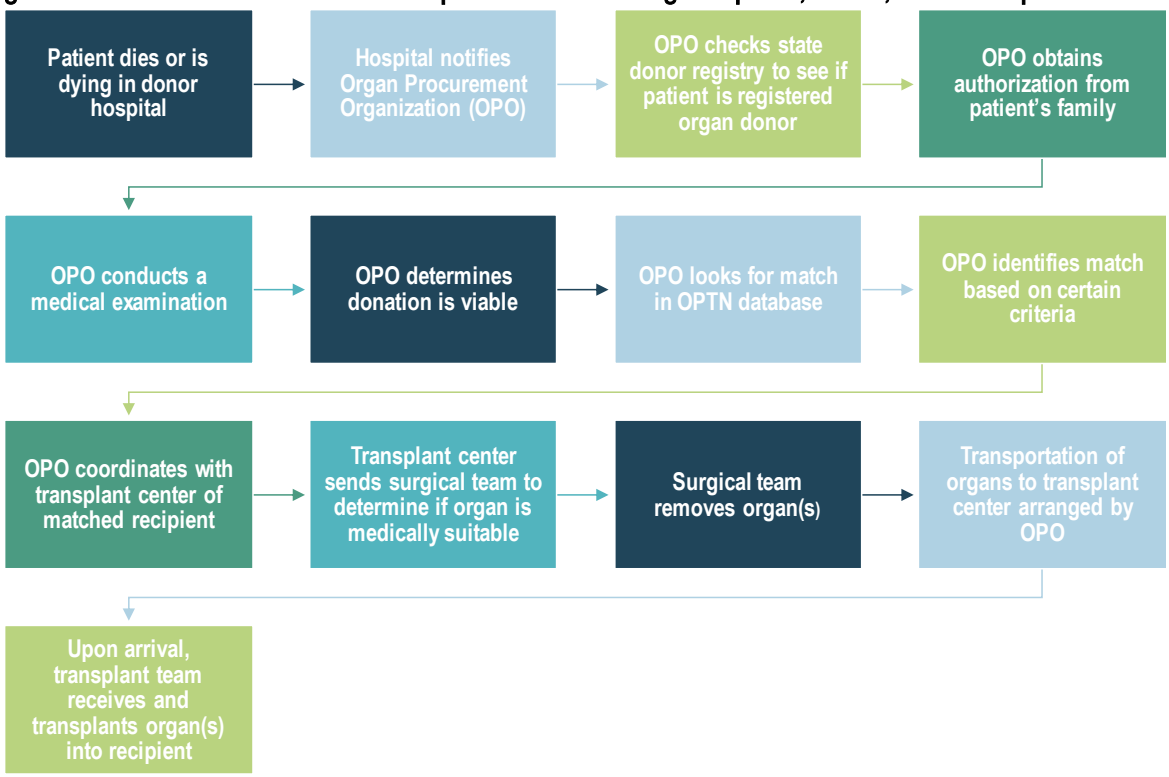
When a patient is near death or has died and is a viable organ donor, Florida hospitals are required to contact their regional OPO. The hospital gives the OPO information about the deceased patient to confirm whether they have the potential to be a donor; if they have the potential, an OPO representative travels immediately to the hospital. Once notified, the OPO checks the state donor registry to determine if the deceased is a registered organ donor. If not, the OPO representative will ask the next of kin for authorization to donate the organs.[21]

[18] The nationwide figure is from UNOS, which provided data for all states combined, including Florida.
[19] In 2014, hands and faces were added to the organ transplant list.
[20] The potential organs procured from circulatory death are lungs, livers, pancreases, and kidneys. Hearts and intestines cannot be recovered after circulatory death.
[21] Although the 2006 Revised Uniform Anatomical Gift Act and s. 765.512(1)(b), *F.S.*, established that next-of-kin cannot override a donor's decision to donate organs, two of Florida's OPOs nonetheless described a process wherein they would honor the family's wishes if the family is vehemently opposed to donation, even if it contradicted the deceased person's donor registry status.

If the OPO's evaluation indicates donation is viable, the OPO representative will find a match for the organs by entering information into the UNOS national database of all patients in the U.S. waiting for a transplant. The database generates a list of patients who match the donor, and the OPO then offers each available organ to the transplant team of each matched patient by contacting hospitals in sequence. Once a match is identified, the OPO coordinates with the transplant center that accepts an organ. Transplant centers at certain hospitals around the state send surgical teams to the donor hospitals to procure their assigned organs or rely on a surgical team that is at the donor hospital to procure another organ. The OPO representative will arrange for the transport of the organ via ambulance, helicopter, or commercial airline, depending on the organ and the distance. The transplant team and the recipient will be waiting at the hospital to transplant the organ as soon as it arrives. (See Exhibit 5.)

Exhibit 5

The Organ Donation Process Is a Multi-Step Process Involving Hospitals, OPOs, and Transplant Centers



Source: OPPAGA analysis of the Health Resources and Services Administration's "The Deceased Donation Process" and interviews.

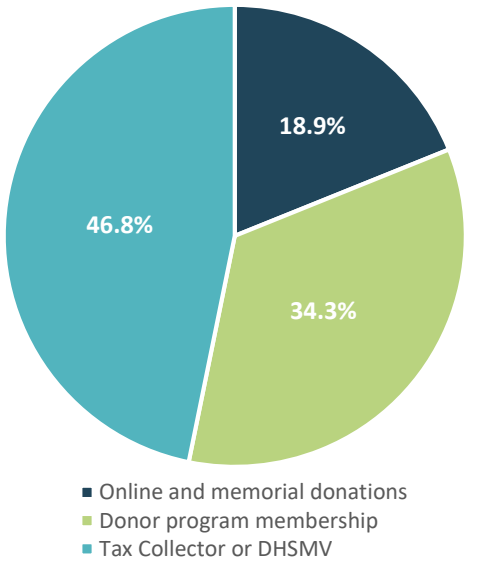
In Florida, multiple entities collect and expend funds associated with organ donation and transplantation. AHCA pays Donate Life Florida from voluntary contributions collected by the Department of Highway Safety and Motor Vehicles. AHCA reports that its five-year contract with Donate Life Florida is for up to $320,000; the agency allots the organization approximately $64,000 per calendar year and makes quarterly payments based on historical accounts of voluntary donations. AHCA receives a quarterly invoice from Donate Life Florida with a DHSMV file listing donations. DHSMV pays the amount to AHCA, which then pays Donate Life Florida. (See Exhibit 6.)

Exhibit 6
AHCA Pays Donate Life Florida Quarterly From Donations Collected by the Department of Highway Safety and Motor Vehicles

	Fiscal Year			
Quarter	2015-16	2016-17	2017-18	2018-19
July-September	$6,063.93[1]	$4,560.72	$7,452.49	$7,082.93
October-December	4,621.71	5.344.78	6,866.88	5,131.43
January-March	5,817.11	8,175.99	7,016.58	7,715.33
April-June[2]	34,298.44	33,101.31	19,669.33	62,060.01
Total	**$50,801.09**	**$51,182.80**	**$41,005.28**	**$81,989.70**

[1] AHCA reports that it paid Donate Life Florida for the first quarter of Fiscal Year 2015-16 under a prior contract.
[2] AHCA reports that April is National Donate Life Month and Donate Life Florida members work with driver license office employees and management to help increase donor awareness and registrations through an annual campaign, which may result in increased donations during this time period.
Source: Agency for Health Care Administration.

Exhibit 7
Donate Life Florida Revenues, Calendar Year 2018



Source: OPPAGA analysis of data from the *Donate Life Florida 2018 Annual Report*.

Donate Life Florida collects additional revenues from donations and OPO member dues. Donate Life Florida reports collecting $105,233 in calendar year 2018 in voluntary contributions from the public (from online and memorial donations or driver license offices), and another $55,025 from member dues paid by OPOs, for a total of $160,258. (See Exhibit 7.)

Fees paid by OPOs, tissue banks, and eye banks exceed AHCA's costs, but AHCA has not used the remaining revenues for donation education. We asked AHCA how much it collected in fees from OPOs, tissue banks, and eye banks in Fiscal Year 2018-19, and how it used these revenues. AHCA is required by statute to spend fee revenues for the implementation, administration, and operation of a certification program for OPOs and tissue and eye banks, an advisory board, donor registry maintenance, and organ and tissue donor education.[22] AHCA provided data showing it collected $670,039 in fees from OPOs, tissue banks, and eye banks in Fiscal Year 2018-19. However, the agency reports that it only spent $78,228 on the certification program and left the remainder in the Health Care Trust Fund rather than spending it on organ and tissue donor education.[23,24] (See Exhibit 8.) In addition, AHCA reports that the advisory board has not been active since 2015.

[22] Section 765.544, *F.S.*
[23] As discussed earlier, AHCA is required by s. 765.541, *F.S.*, to establish a program for the certification of organizations that procure organs, tissue, and eyes for transplantation, to set forth appropriate standards and guidelines for these organizations, and to monitor them for compliance.
[24] The Health Care Trust Fund was established in s. 408.16, *F.S.*

Exhibit 8
AHCA Spent Approximately $78,000 on the Certification Program in Fiscal Year 2018-19

Expense Category	Total Expenditures
Salary	$70,588
Expenses	7,278
Contracted Services	247
Leased Equipment	115
Total Expenditures	**$78,228**

Source: Agency for Health Care Administration.

OPO annual reports show that three of Florida's four OPOs report greater revenues than expenditures in Fiscal Year 2017-18. During organ procurement, OPOs pay fees to hospitals that are a percentage of the charges involved in the procurement process. They obtain revenues by charging transplant centers for organs. The Life Alliance Organ Recovery Agency's (LAORA) annual report showed that its expenditures exceeded its revenues. LAORA administrators reported that in Fiscal Year 2017-18, they were in the initial stages of implementing and negotiating a new case rate with hospitals. The OPO also added staff during this time, contributing to higher expenses. (See Exhibit 9.)

Exhibit 9
Three of Four Florida OPOs Reported Higher Revenues Than Expenditures for Fiscal Year 2017-18

OPO	Life Alliance	Life Link	Life Quest	Our Legacy
Total Revenue	$19,297,045	$22,344,900	$14,892,963	$19,329,030
Total Expenditures	20,962,176	19,882,958	13,120,243	19,068,059
Difference	**($1,665,131)**	**$2,461,942**	**$1,772,720**	**$260,971**

Source: Organ Procurement Agency annual reports to the Agency for Health Care Administration.

Transplant centers report a wide range of charges for transplants. Hospitals report charges for organ transplantation surgical stays to AHCA's Florida Center for Health Information and Transparency. Data for 2017 show that average charges for organ transplants ranged from a high of $1.3 million for a heart transplant to a low of $252,000 for a kidney transplant. (See Exhibit 10.) These reported charges are the raw charges and do not reflect rate negotiations with payers and also do not include physician charges.[25]

[25] The payer for the transplant may be the recipient's insurance, Medicare, or Medicaid.

Exhibit 10
Hospitals Report Varying Charges for Transplants[1,2]

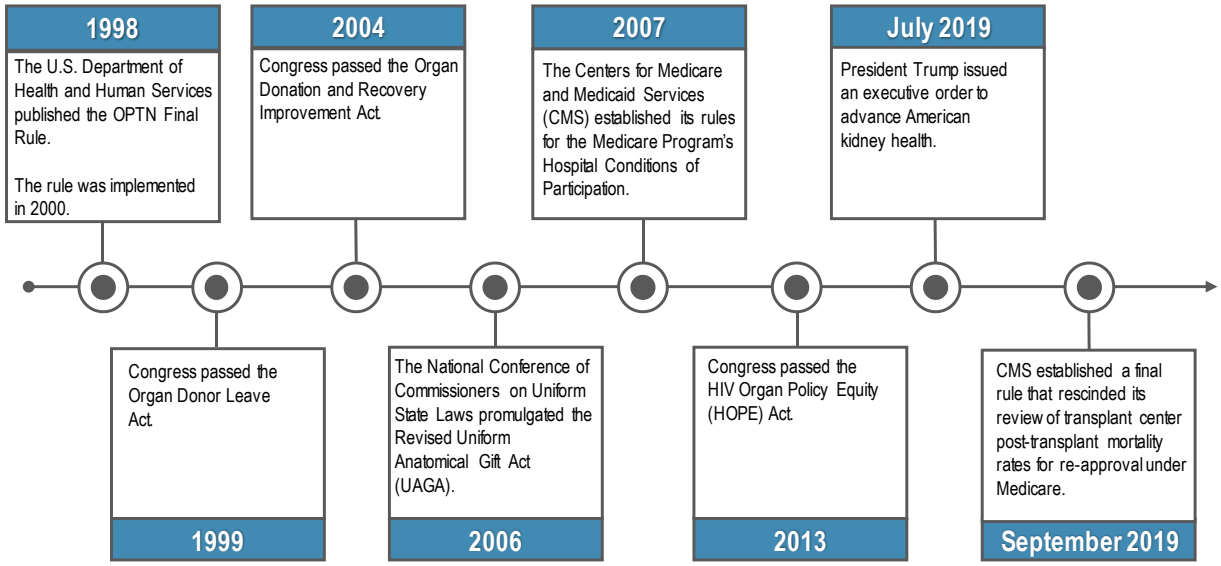
Medicare Severity Diagnosis Related Group (MS-DRG)	Number of Hospital Discharges	Hospital Reported Charges	Average Charges
Heart Transplant or Implant of Heart Assist System, With Major Complication or Co-Morbidity	426	$533,953,848	$1,253,413
Heart Transplant or Implant of Heart Assist System	53	39,147,691	738,636
Lung Transplant	78	51,430,044	659,360
Allogeneic Bone Marrow Transplant	511	317,290,325	620,920
Liver Transplant, With Major Complication or Co-Morbidity or Intestinal Transplant	345	182,654,247	529,433
Simultaneous Pancreas/Kidney Transplant	57	24,545,970	430,631
Autologous Bone Marrow Transplant	47	19,507,922	415,062
Liver Transplant	136	47,851,968	351,853
Autologous Bone Marrow Transplant, With Complications or Co-Morbidity, or Major Complications or Co-Morbidity	504	168,372,045	334,072
Kidney Transplant	1,054	265,580,847	251,974
Total/Average	**3,211**	**$1,650,334,907**	**$513,963**

[1] AHCA states that charges shown are the raw charges, and that patients rarely are required to pay the full charges, so the charge comparison may not be the most meaningful indicator of what you can expect to pay. Actual amounts paid may be significantly less due to rate negotiations with payers. Physician charges are not included.
[2] AHCA's data inquiry tool excludes results from those with fewer than 30 records.
Source: OPPAGA analysis of data from AHCA's Florida Center for Health Information and Transparency.

How Have Federal and State Organ Donation and Transplantation Policies Changed Over the Past 25 Years?

Over the past 25 years, the U.S. Congress, various federal agencies, and the President have made several key policy changes that have affected the organ donation and transplantation system. (See Exhibit 11.)

Exhibit 11
Major Federal Policy Changes to the Organ Transplantation and Donation System



Source: OPPAGA analysis of federal legislation.

In the 1990s, new transplant techniques were developed and the country's transplant system grew rapidly, with the demand for organ transplants exceeding the supply of organs. In an attempt to improve the system, in 1998, the U.S. Department of Health and Human Services published what OPTN refers to as the "final rule," which governs OPTN operations. The OPTN final rule was intended to improve the effectiveness and equity of the organ transplantation system, further the development of a nationwide organ allocation system, and encourage organ donation. HHS implemented the rule in March 2000.

Around the same time, Congress passed two laws to aid in living organ donation. The 1999 Organ Donor Leave Act entitles an employee in or under an executive agency to leave without loss of or reduction in pay to serve as a bone marrow or organ donor. In 2004, Congress passed the Organ Donation and Recovery Improvement Act, which allows the HHS secretary to award grants to states, transplant centers, or OPOs; grants are for the reimbursement of travel and subsistence expenses for living organ donors and for organ donor awareness and education efforts. Both of these grant programs are still offered through HHS's Division of Transplantation.

In 2006, the National Conference of Commissioners on Uniform State Laws promulgated the Revised Uniform Anatomical Gift Act. The original act was promulgated in 1968 to address a critical organ shortage by providing additional ways for making organ, eye, and tissue donations, and it was enacted by all states. The national conference made revisions in 1987 and again in 2006 to address changes in the field of transplantation. The 2006 changes include

- strengthening the language barring others from overriding a donor's decision to donate organs;
- facilitating donations by expanding the list of those who may make an anatomical gift for another individual during that individual's lifetime to include health care agents and, under certain circumstances, parents or guardians;
- enabling procurement organizations to gain access to documents of gifts in donor registries, medical records, and the records of a state motor vehicle department; and
- updating the act to allow for electronic records and signatures.

In 2007, CMS established its rules for the Medicare Program's Hospital Conditions of Participation, requiring all transplant programs to comply with these requirements. The requirements are meant to protect the health and safety of both transplant recipients and living donors, and they focus on a transplant program's ability to perform successful transplants and deliver quality care as evidenced through outcomes, policies, and procedures.

More recently, the 2013 Congress passed the HIV Organ Policy Equity Act, which permits donated, HIV-positive organs to be used for transplantation in HIV-positive patients. This shortens the waitlist for organs by allowing for greater use of HIV-negative organs in HIV-negative patients.

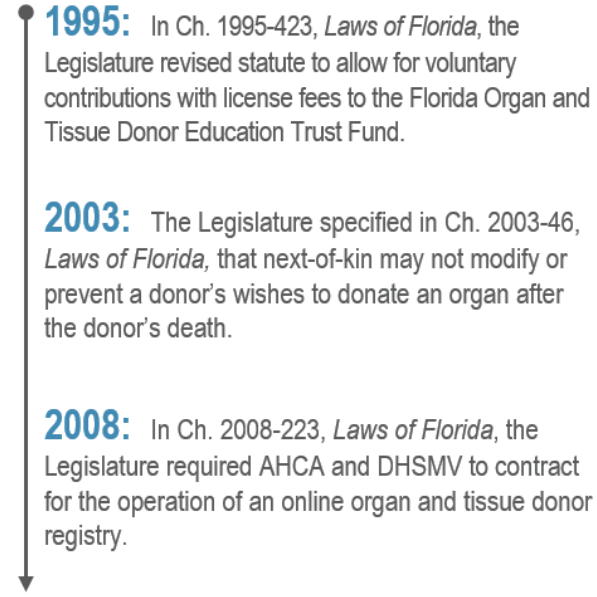
In July 2019, President Trump issued an executive order to advance American kidney health, as kidney disease is the ninth-leading cause of death in the U.S. The executive order requires the HHS secretary to

- select a payment model to test innovations in compensation for providers of kidney care services based on kidney patient cost and quality outcomes;
- select a payment model to encourage greater use of home dialysis and kidney transplants for Medicare beneficiaries on dialysis;
- encourage the development of an artificial kidney;

- increase utilization of available organs through establishing better metrics to evaluate OPO performance and streamlining the kidney matching process; and
- propose a regulation to remove financial barriers to living organ donation.

Finally, in September 2019, CMS established a final rule that rescinded its review of transplant center post-transplant mortality rates for re-approval under Medicare. CMS cited stakeholder input and research studies that concluded that CMS's assessment was causing some transplant centers to be more conservative than they would be otherwise regarding the patients and organs they will take because of concern over losing their Medicare funding. CMS expressed concern that as a result, fewer patients had access to life-saving transplants and that viable organs were being discarded. The expected outcome of this final rule is an increase in organ transplants and a decrease in discarded organs. As part of this final rule, CMS also rescinded review of transplant center clinical experience (volume) for re-approval. CMS retained review of mortality rates and clinical experience only for initial Medicare approval of transplant centers.

Exhibit 12
Major State Policy Changes to Florida's Organ Transplantation and Donation System



Source: OPPAGA analysis of Florida legislation.

While many changes affecting Florida's organ donation and transplantation system have occurred at the federal level, the Florida Legislature has passed a few key policy changes in the last 25 years. (See Exhibit 12.)

In Ch. 1995-423, *Laws of Florida*, the Legislature revised statutes to allow people to make a voluntary contribution with their license fees to the Florida Organ and Tissue Donor Education Trust Fund for organ and tissue donor education. This same law clarified that an anatomical gift made by an adult and not revoked by the donor does not require the consent of any person after the donor's death. It also charged AHCA and DHSMV with developing and implementing a statewide, electronic donor registry.

Several years later, in Ch. 2003-46, *Laws of Florida*, the Legislature specified that next-of-kin may not modify or prevent a donor's wishes to donate an organ after the donor's death.[26] It also clarified that organ and tissue donor cards, living wills and advance directives, driver licenses, and other written forms serve as evidence of legally sufficient informed consent to donate an organ. In Ch. 2008-223, *Laws of Florida*, the Legislature further amended the list of items that can serve as evidence of a decedent's informed consent to donate to include entry in the organ and tissue registry.[27] This law required AHCA and DHSMV to contract for the operation of an online organ and tissue donor registry, designated as the Joshua Abbott Organ and Tissue Registry, and an education program regarding the laws surrounding organ donation and the need for organs in Florida.

[26] Chapter 2003-46, *Laws of Florida*.
[27] Chapter 2008-223, *Laws of Florida*.

What Are the Projected Impacts on Florida of Changes to OPTN National Organ Allocation Policies?

In the past few years, Organ Procurement and Transplantation Network committees have attempted to address a perceived equity issue in the allocation of organs, which has traditionally been based on organ procurement organization donation service areas (DSAs) or OPTN regions. A DSA is the geographic area designated by CMS that is served by one OPO, one or more transplant centers, and one or more donor hospitals. A region is 1 of 11 geographic areas in the country used for the administration of organ allocation and appropriate geographic representation within the OPTN policy structure. The stated rationale for changing the current allocation methodology that uses DSAs and regions is that this methodology is contrary to the OPTN final rule, which states that policies regarding organ allocation shall not be based on a candidate's place of residence or place of listing.

To this end, in 2018, the OPTN/UNOS Ad Hoc Geography Committee was formed to establish principles and a framework to guide how OPTN policies should address future geographic distribution of organs. The OPTN/UNOS board of directors adopted a set of principles developed by the Geography Committee to guide future organ transplant policy relating to geographic aspects of organ distribution. The adopted statement of principle states that deceased donor organs are a national resource to be distributed as broadly as feasible. Any geographic constraints pertaining to the principles of organ distribution must be rationally determined and consistently applied. Using this principle statement, OPTN has proposed and, in some cases, implemented organ-specific allocation policy changes over time. Since 2017, OPTN committees have made or adopted proposals to change allocation policies for lungs, livers, hearts, kidneys, and pancreases.[28]

Lung Allocation Policy Change

In 2017, OPTN implemented a policy change for lung allocation that removed the DSA method of allocation for deceased donor lungs and replaced it with a 250 nautical mile circle around the donor hospital. This policy change was in response to a lawsuit filed by a transplant candidate in New York that argued that the use of DSAs as the first unit of allocation for lungs from deceased adult donors under the OPTN Lung Allocation Policy was in direct conflict with the OPTN final rule. The complaint further argued that the allocation policy discriminated against people such as the plaintiff based on geography and not on medical priority. The plaintiff sought an injunction to require the acting HHS secretary to enjoin HHS and OPTN from applying the aspect of the Lung Allocation Policy that used the DSA as a primary unit of allocation for deceased adult lungs. The Administrator of the Health Resources and Services Administration directed OPTN to review the lung allocation policy and determine whether any changes needed to be made. OPTN subsequently implemented a new lung allocation policy that has gone into effect.

Liver Allocation Policy Change and Current Lawsuit

In 2018, OPTN proposed a policy change for liver allocation that eliminates the use of DSAs for organ allocation and replaces it with a broader framework with the stated intent to decrease waitlist mortality rates and allow for more equity in access for liver transplant candidates. Prior to this policy proposal, liver organ distribution policies used DSAs and OPTN regions as geographic units. Under the

[28] The proposed liver allocation policy also includes intestine distribution.

new policy, livers will first be offered to the most urgent liver transplant candidates listed at transplant hospitals within a radius of 500 nautical miles of the donor hospital. Livers would next be offered to candidates at hospitals within distances of 150, 250, and 500 nautical miles of the donor hospital, based on medical urgency. The revised policy was implemented briefly but has been on hold due to a lawsuit. A group of hospitals and individual patients filed suit, arguing that HHS and UNOS violated the Administrative Procedures Act (APA) by failing to follow established procedures during the policy's development and that these actions were arbitrary, capricious, and unlawful.[29,30] The group also claimed that HHS and UNOS actions constituted a violation of the Due Process Clause of the Fifth Amendment.[31] In a separate motion, the plaintiffs asked the district court to issue a temporary restraining order to prevent the new policy from taking effect.[32]

While plaintiffs made three arguments, the district court denied the group's motion based solely on an analysis of the initial claim that the policy failed to follow proper rule making procedures during the policy's development. The new policy went into effect briefly until the plaintiffs filed an appeal and asked the district court for an injunction pending appeal. The injunction was granted and placed the previous liver allocation policy in effect. The appellate court determined that the district court correctly decided that HHS and UNOS's interpretation of the rule making procedure was the more reasonable one but remanded the case to the district court to decide the remaining two claims.[33] At the time of our review, the parties were in discovery, with the district court determining what, if any, additional information will be exchanged. Implementation of the policy is still on hold.

Heart Allocation Policy Change

In 2019, OPTN approved a policy change for heart allocation that replaced the DSA-level of allocation for deceased donor hearts with a 250 nautical mile circle around the donor hospital. The goal of this change is to make heart allocation policy more consistent with the final rule and provide more equity in access to transplantation regardless of a candidate's place of listing. This policy is expected to go into effect in January 2020.

Kidney and Pancreas Allocation Policy Change

Also in 2019, OPTN proposed additional policy changes for both kidney and pancreas allocation that would remove the DSA and regional boundaries used in the current organ allocation system and allocate using a 500 nautical mile circle around the donor hospital. The goal of these proposals is to provide consistent distribution units and promote patient access to transplant. Both proposals were open for public comment until October 2019 and were pending further action at the time of our review.

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[29] The plaintiffs argue that because the liver-allocation policy is a significant policy, the defendants violated the law by neither referring the policy or publishing the policy in accordance with 42 CFR §121.4(b), which states that "[t]he Secretary will refer significant proposed policies to the Advisory Committee on Organ Transplantation established under § 121.12, and publish them in the Federal Register for public comment." HHS and UNOS disagree and claim that the provision only applies when the policy at issue is one that OPTN's board recommends to be enforceable or when the policy at issue is one that relates to such other matters as the secretary directs in accordance with the opening provisions of the statute.

[30] In Count II, the plaintiffs assert that HHS and UNOS's decision to approve the April 2019 policy in a limited time frame was arbitrary and capricious.

[31] In Count III, the plaintiffs contend that they were not given notice or meaningful opportunity to be heard before the policy was adopted in violation of the Fifth Amendment, which provides individuals with the right to be heard regarding "governmental decisions which deprive individuals of ['life,'] liberty' or 'property' interests." *Mathews v. Elderidge*, 424 US 319, 332 (1971).

[32] To determine if the court should issue injunctive relief, the court must decide, among other things, that the party requesting relief has a substantial likelihood of success on the merits. The standard for obtaining preliminary injunctive relief is "(1) substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest." *McDonalds' Corp. v. Robertson*, 147 F.3d 1301, 1306 (11th Cir. 1998).

[33] The appellate court indicated that the remaining issues to be decided by the district court are context intensive and fact dependent and will hinge on whether UNOS is an agency under the APA.

Exhibit 13 summarizes the actual and projected effects on Florida of the federal organ allocation policy changes based on data provided by UNOS. The most significant negative effect results from the kidney and liver allocation proposals. The number of transplants for both organs would decrease under the new policies, with an 11% decrease for livers and a 24% decrease for kidneys.

Exhibit 13
UNOS Projects That Changes in Organ Allocation Policies Will Have Both Positive and Negative Effects on Florida[1,2]

Organ	Annual Number of Transplants Pre-Change	Annual Number of Transplants Post-Change	Difference	Percentage Difference
Lung—Actual Volume over 1.5 Years	248	302	+54	+22%
—Projected Average	245	262	+17	+7%
Liver—Projected Average	459	408	**-51**	**-11%**
Heart—Projected Average	273	294	+21	+8%
Kidney—Projected Average	738	558	**-180**	**-24%**
Kidney-Pancreas—Projected Average	46	64	+18	+39%

[1] For the projected averages, UNOS provided data showing what happened in 2017 under the distribution model in use at that time and what would have happened in 2017 under the revised distribution model.
[2] UNOS also provided data for the impact of changes in the pancreas allocation process. However, there were too few transplants to show a meaningful difference.
Source: United Network for Organ Sharing.

How Has Florida's Organ Donation and Transplantation System Performed Over Time and in Comparison to Other States?

Florida's Donor Registry Trend

Florida has improved its rate of donor registration over time. Donor registries are an important tool in increasing the availability of organs for transplant. Florida has improved its rate of donor registration over time, both in whole numbers and as a percentage of the population. In 2009, Florida had 5,275,904 registered donors, compared to 10,674,300 in 2018. As a percentage, Florida increased its donor registration rate of adults 18 and older from 36% in 2009 to 59% in 2017. (See Appendix B for more information on the trends in donor registration.) In 2018 (the most recent data available), 38% of eligible deaths were registered donors.[34]

Exhibit 14
Florida Performs Better Than Its Peer States in National Rank for Donor Registrations

State	National Rank for Donor Registrations
Florida	33
Texas	41
California	44
Pennsylvania	45
New York	50

Source: OPPAGA analysis of data from *Donate Life America, 2018 Annual Update.*

Florida also compares favorably to peer states in its rate of donor registration. Florida is the third most populous state, after California and Texas, followed by New York and Pennsylvania. It ranks higher than these states in the percentage of adults registered as donors. (See Exhibit 14).

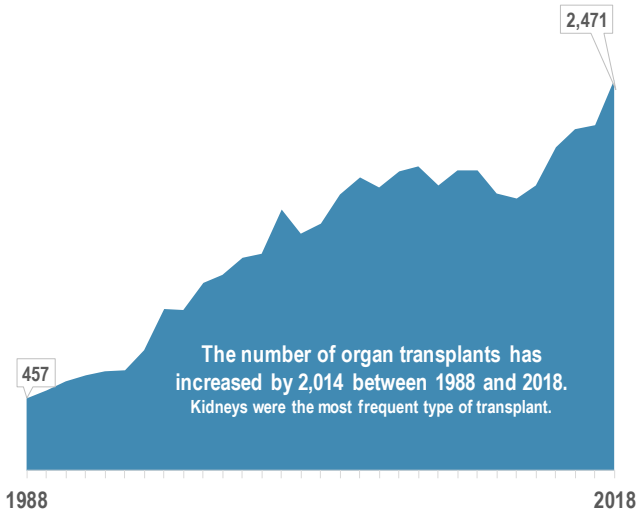
[34] Nationally, 33% of eligible deaths were registered donors.

Florida's Trend for Organ Transplants and Actual Number of Donors

Florida is similar to the rest of the nation with an upward trend in organ transplants performed in 2018. (See Exhibit 15.) Nationally, the number of organ transplants from deceased and living donors increased 5% from 2017 to 2018. In Florida, the number of organ transplants from deceased and living donors increased about 7% from 2017 to 2018; transplants from living donations increased by 14% and transplants from deceased donation increased by 4%.

Nationally, some of the increase in deceased donation is due to the increased usage of donors with medical criteria that would have excluded them from donation previously. Nearly 20% of donors in 2018 donated after circulatory death as opposed to brain death, 9% involved organs with a kidney donor profile index of 86% or higher, and more donors were 50 or older or identified as having increased risk for blood-borne disease.[35,36]

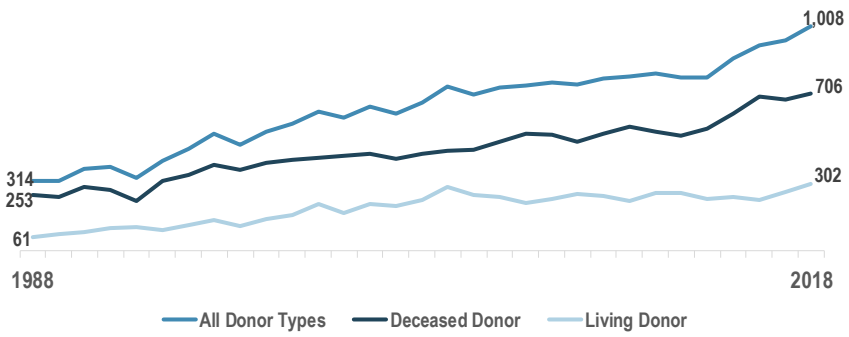
Exhibit 15
The Number of Florida Transplants Has Increased



Source: OPPAGA analysis of OPTN data.

There are many factors determining whether a potential deceased donor becomes an actual donor. For deceased donations, an OPO needs to gain consent from the deceased person's family, the transplant hospital needs to accept the organ, and the organ must be successfully and quickly delivered to the donor hospital. Florida has increased its numbers of actual organ donors over time, including deceased donors and living donors. (See Exhibit 16). Nationally, in 2018, about 81% of the transplants involved organs from deceased donors, while in Florida, 70% of transplants were from deceased donors, which has remained roughly consistent over time.

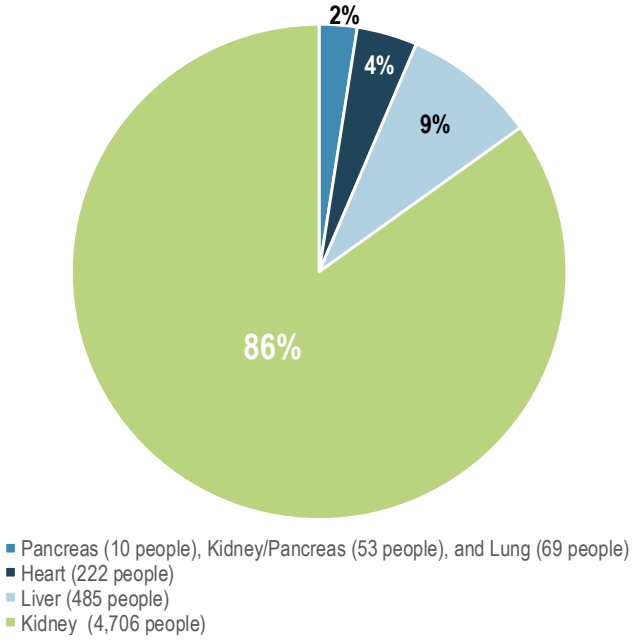
Exhibit 16
The Number of Florida Organ Donors Has Increased Over Time



Source: OPPAGA analysis of OPTN data.

[35] Organ Transplants in United States Set Sixth Consecutive Record in 2018 (2019).
[36] Higher scores are associated with shorter expected functioning of the kidney relative to all the kidneys recovered in the U.S. during the last year. A kidney with a score of 86% is expected to have shorter longevity than 86% of all recovered kidneys.

Exhibit 17
The Vast Majority of People on Florida's Transplant Waitlist Are Waiting for a Kidney[1]



[1] An additional 13 people were waiting for other types of transplants: 3 for a heart-lung transplant, 8 for an intestine transplant, and 2 for an abdominal wall transplant.
Source: OPPAGA analysis of OPTN data, June 4, 2019.

Florida's Waitlist Outcomes

Florida compares favorably to the rest of the nation in how quickly people on waitlists receive transplants but fares similarly or worse in mortality rates. Each year, the number of people on a waitlist for organ donation grows and continues to outpace both the number of donors and organ transplants. As of June 4, 2019, Florida had 5,461 people on an organ transplant waitlist. Of those, 86% were waiting for a kidney. (See Exhibit 17.) Nationally, this compares to almost 84% of people on an organ waitlist who are waiting for a kidney.

The Scientific Registry of Transplant Recipients produces outcome assessments for all transplant programs in the U.S. using a five-tier metric for *getting a deceased donor transplant faster*.[37] This metric assesses how quickly those on the waitlist get a transplant during the two-year period evaluated relative to how quickly they would be expected to get a transplant based on national data. The metric provides a measure of the rate at which the program finds deceased donor organs for its candidates.[38,39] Tiers 1 and 2 indicate that the center is performing worse than expected, Tier 3 that the center is performing roughly as expected, and Tiers 4 and 5 that the center is performing better than expected.[40]

Florida's organ transplant programs generally do better than the rest of the nation based on SRTR's measure for getting adults a deceased donor transplant faster after controlling for the characteristics of the population served. As of July 2019, 47% of Florida's 45 rated transplant programs were in the top two of five performance tiers for getting a deceased donor transplant faster, compared to just 27% of the programs in the rest of the U.S.[41] (See Exhibit 18.)

[37] A transplant program is organ specific within a single transplant center. Transplant centers that conduct transplants for more than one organ would thus have more than one transplant program, and multiple rankings.
[38] The strength of the tier-rating system is that it controls for the characteristics of the patients served, the organs used, and the volume of transplants conducted. The tiers are based on the ratio of how many on the waitlist actually received a transplant relative to how many would be expected to receive a transplant given their age, how sick they are, and how many transplants are conducted at the program. If Florida's transplant centers had older and sicker transplant patients, the tier ranking they received would not penalize them for these factors; rather, it should reflect their performance. The tier ranking also takes into account the likelihood of getting an especially high or low tier score due to a small volume of transplants.
[39] SRTR excludes individuals who undergo living donor transplants from the analysis.
[40] Ratings are based on a probabilistic estimate, thus a specific rating represents a range of outcomes that are driven by both performance relative to expected performance as well as the volume of transplants in a program. For details about the computation of the rating tiers, see SRTR's *Calculating the 5-tier Assessments: A Guide for Pre-and Posttransplant Metrics*.
[41] Two programs in Florida and 106 programs elsewhere had no rating.

Exhibit 18
Florida Had a Higher Percentage of Programs That SRTR Assessed as Better Than Expected for Adults Getting a Deceased Donor Transplant Faster Than the Rest of the U.S.[1]

Adults Getting a Transplant Faster Tier Rating: Higher Score Is Better	Percentage of Florida's Transplant Programs Within Tier (n=45)	Percentage of Rest of U.S. Within Tier (n=785)
1	7%	8%
2	16%	34%
3	31%	31%
4	22%	19%
5	24%	8%
Better Than Expected (Tiers 4 and 5)	**47%**	**27%**
Worse Than Expected (Tiers 1 and 2)	22%	42%

[1] Numbers are rounded; totals are rounded only after summing original unrounded numbers.

Source: OPPAGA analysis of SRTR outcome assessment data, July 1, 2017 to June 30, 2019, program-specific reports.

SRTR also assesses all transplant programs in the U.S. using a five-tier system for survival on the waiting list, where higher tiers show better outcomes.[42] The five-tier assessment for survival on the waiting list is based on a measure of how many patients die compared to how many are expected to die while waiting for an organ transplant. Tiers 1 and 2 indicate that the center is performing worse than expected, Tier 3 that the center is performing roughly as expected, and Tiers 4 and 5 that the center is performing better than expected.

Compared to the rest of the nation, Florida's programs perform similarly or worse than would be expected based on SRTR's measure for mortality while on the waiting list. (See Exhibit 19.) While Florida had a similar percentage of programs rated in the top two performance tiers for adult survival on the waiting list, the state had 29% of transplant programs in the bottom two tiers, or worse than expected, compared to 21% for the rest of the nation. (See Appendix C for the performance of individual Florida transplant centers and programs.)

Exhibit 19
Florida Had a Higher Percentage of Programs That SRTR Assessed as Worse Than Expected For Adult Waitlist Mortality Than the Rest of the U.S.[1]

Adult Waitlist Mortality Tier Rating: Higher Score Is Better	Percentage of Florida's Transplant Programs Within Tier (n=45)	Percentage of Rest of U.S. Within Tier (n=785)
1	9%	5%
2	20%	16%
3	33%	44%
4	31%	27%
5	7%	8%
Better Than Expected (Tiers 4 and 5)	38%	35%
Worse Than Expected (Tiers 1 and 2)	**29%**	**21%**

[1] Numbers are rounded; totals are rounded only after summing original unrounded numbers.
Source: OPPAGA analysis of SRTR outcome assessment data, July 1, 2017 to June 30, 2019, program-specific reports.

[42] The tiers are based on the ratio of how many actually died on the waitlist relative to how many would be expected to die given the ages of people on the waitlist, how sick they are, and how many transplants are conducted at the program.

OPPAGA's analysis of data from UNOS shows that Florida compares similarly or favorably to the nation for kidney and liver waitlist trends.[43] OPPAGA analyzed UNOS data showing outcomes of patients within three years of being placed on a transplant waitlist in Florida and in other states between 1988 and 2015. Florida's trend in waitlist registrations added for kidneys generally follows the same pattern of increase as the U.S. as a whole, with an increase in registrations over time. As registrations (demand for kidneys) grew rapidly, likely outstripping the growth in supply of kidneys, there was a decline in the percentage of new registrants who were able to receive a kidney. However, Florida's percentage of patients who received a deceased donor transplant within three years of registering on the waitlist has remained better than the nation as a whole over time. In addition, Florida's percentage of patient deaths within three years of registering on the waitlist for a kidney has been similar to or slightly lower than the rest of the nation since 1988. (See Exhibit 20.)

Exhibit 20
Florida Compares Similarly or Favorably to the Nation for Kidney Waitlist Trends

	Florida		United States	
Waitlist Measure	1988	2015	1988	2015
Number of Waitlist Registrations Added	463	1,951	11,553	34,648
Percentage of Deceased Donor Transplants Within Three Years of Registering on Waitlist	73%	31%	59%	22%
Percentage of Deaths Within Three Years of Registering on Waitlist[1]	5%	12%	6%	12%

[1] The measure reflects the percentage of registrants who were removed from the waitlist due to death or being too sick to transplant, or who died after exiting the waitlist for other reasons.
Source: OPPAGA analysis of UNOS data.

OPPAGA's analysis of UNOS data on liver waitlist trends yielded similar results as for kidney waitlist trends. Florida has increased the number of waitlist registrations for livers over time, a trend that roughly mirrors the pattern in the rest of the U.S. However, Florida has generally maintained relatively high transplantation rates for livers compared to the nation as a whole. Florida has also maintained a relatively low waitlist death rate for liver transplants compared to the nation as a whole. (See Exhibit 21.) These results provide useful descriptive information but should be viewed with caution, as they do not take into account differences in patient characteristics such as illness or age over time or across states or differences in organ transplant quantity or quality. (See Appendix D for more details on these analyses.)

Exhibit 21
Florida Compares Similarly or Favorably to the Nation for Liver Waitlist Trends

	Florida		United States	
Waitlist Measure	1997	2015	1997	2015
Number of Waitlist Registrations Added	579	702	8,021	11,297
Percentage of Deceased Donor Transplants Within Three Years of Registering on Waitlist	61%	69%	49%	54%
Percentage of Deaths Within Three Years of Registering on Waitlist[1]	17%	11%	20%	20%

[1] The measure reflects the percentage of registrants who were removed from the waitlist due to death or being too sick to transplant, or who died after exiting the waitlist for other reasons.
Source: OPPAGA analysis of UNOS data.

[43] For organs other than kidney and liver, the small number of organs showed a high degree of annual variability and made it difficult to draw conclusions about rates. We do not present a comparison of different organs because transplantation and death rates can be very different for different states. The mix and size of organ programs available in a state can change the apparent pooled relative outcomes for otherwise identical organ-by-organ performance.

What Factors Enhance Transplant Success and What Challenges Are Associated With Organ Donation and Transplantation?

Factors for Transplant Success Rates

We interviewed transplant center surgeons and administrators representing five of Florida's transplant centers and asked them about the factors that lead to higher transplant success rates. The two most consistent responses were multidisciplinary teams and transplant center volume; stakeholders also identified several other factors important to success.

Transplantation is a complex health care issue and multidisciplinary teams bring together a variety of skills to treat patients pre- and post-transplant. These teams include surgeons; infectious disease specialists; nephrologists, if applicable; pharmacists; and social workers that help the patient at varying stages of care. Team collaboration and coordination of care can enhance communication, create a level of comfort among the team members, and provide efficient, comprehensive care for the patient, which is important for a successful transplant.

Several surgeons reported that higher volume is associated with better outcomes, as transplant teams are often able to improve skills and develop routines as they gain more experience. As teams perform a greater number of transplants, they also encounter a greater variety of unique complications and are able to develop protocols to address such anomalies. Performing more transplants also allows teams to develop a routine, which enhances efficiency and allows for better communication among the transplant team members.

Researchers also cite volume as a factor involved in increasing transplant procedure success rates. There is consensus among researchers that patient volume is positively related to successful outcomes for organ transplants.[44] Volume is viewed as a proxy for quality and expertise because large volumes enhance opportunities for surgeons to practice critical, high-risk surgeries, and developing skills and perfecting techniques leads to better outcomes.[45] Studies have suggested that higher volume medical centers have, on average, better short-term and long-term patient survival rates.[46]

While many academic studies have assessed the relationship between volume and patient outcomes for transplant surgeries, these studies do not provide consistent minimum volume recommendations. Many of these studies have estimated the relationship between volume and quality but have used widely different ranges of volumes to define low, medium, and high volume transplant centers.[47]

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[44] *OPPAGA Review of Tertiary Health Services Licensing Standards*, OPPAGA Report No. 19-11, November 2019.

[45] Alhamad, et al., "Transplant center volume and the risk of pancreas allograft failure," *Transplantation 101*(11), 2017: 2757; Sonnenberg, et al., "Association of kidney transplant center volume with 3-year clinical outcomes," *American Journal of Kidney Diseases*, 2019.

[46] Grimm, et al., "The influence of institutional volume on the incidence of complications and their effect on mortality after heart transplantation," *The Journal of Heart and Lung Transplantation 34* (11), 2015: 1390-1397; Barbas, et al., "The volume-outcome relationship in deceased donor kidney transplantation and implications for regionalization," *Annals of Surgery 267*(6), 2018: 1169-1172.

[47] For example, recent studies of adult heart transplantation thresholds for high volume transplant centers range from 9 to 48 or more procedures per year; adult liver transplants studies' thresholds for high volume centers range from 21 to 176 or more procedures per year; and pediatric lung transplant studies' thresholds for high volume range from 4 to 11 or more procedures per year. For more information, see Appendix A in OPPAGA Report No. 19-11, November 2019.

Academic studies identify several other factors related to transplant success and quality. Specifically, these studies highlight factors such as patient demographics and health characteristics or hospital and center-specific characteristics, such as staffing ratios and the surgeon's skill.[48] For example, one study of pancreas transplants shows that although there was a relationship between low-volume centers and inferior outcomes, some low-volume pancreas transplant programs have excellent outcomes. The researchers noted that surgical expertise, recipient selection criteria, pre- and post-operative multidisciplinary care and follow-up care were also part of the complex explanation for a transplant program's success.[49]

Factors That May Lead to Higher Transplant Success Rates

- Multidisciplinary teams
- Volume
- Factors such as patient demographics and health characteristics, hospital and center characteristics
- Post-transplant care
- Regulation of the organ transplantation system

According to several studies, post-transplant care is another important factor related to transplant success. Improvement of and access to medications that prevent organ rejection have helped increase the success of organ transplant procedures.[50] Ensuring that patients adhere to their schedule for taking medication is important to transplant success.[51] Along with this, making medication affordable or providing financial assistance to patients can be crucial in guaranteeing that they are able to have access to the medications they need to live successfully post-transplant.[52] Minimizing the common complications of organ transplant procedures is also important, and this is best done through regular follow-up care with physicians and maintaining a healthy lifestyle.[53]

Federal regulatory oversight over transplant center performance and quality may also affect transplant success. For example, the OPTN Membership and Professional Standard Committee conducts reviews of transplant program performance to identify underperforming programs and requires implementation of quality assessment and performance improvement measures. A key source of performance information the MPSC uses is data from SRTR on transplant program one-year post-transplant graft and patient mortality rates. The Centers for Medicare and Medicaid Services conducts a one-year post transplant graft and patient survival rate review for initial approval of a transplant center but rescinded this review for re-approvals in a final rule published on September 30, 2019. Instead, CMS expects transplant programs to continue to use their quality assessment and performance improvement programs to monitor quality of care. CMS stated that the quality improvement programs and CMS surveys will be sufficient to ensure transplant programs continue to achieve and maintain high standards of care.

Challenges Associated With the Organ Donation and Transplantation System

In our interviews with representatives of transplant centers, four Organ Procurement Organizations, and other stakeholders, we asked about hurdles or barriers in the state's organ donation and transplantation system. Challenges noted by these stakeholders include the following.

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[48] Sonnenberg, et al., 2019; Scully, et al., "Waiting list outcomes in pediatric lung transplantation: Poor results for children listed in adult transplant programs," *The Journal of Heart and Lung Transplantation 36*(11), 2017: 1201-1208; Hayes et al., "Transplant center volume and outcomes in lung transplantation for cystic fibrosis," *Transplant International 30*, 2017: 371–377.

[49] Alhamad, et al., 2017.

[50] Keller, C., "Solid Organ Transplantation Overview and Selection Criteria," *American Journal of Managed Care 21*, 2015.

[51] Mathis, A.S., "Managed Care Implications of Improving Long-Term Outcomes in Organ Transplantation," *American Journal of Managed Care 21*, 2015.

[52] Mathis, A.S., 2015.

[53] Keller, C., 2015; Mathis, A.S., 2015.

- ***Misunderstanding or lack of support for organ donation*.** Stakeholders reported that people do not always realize the importance of organ donation and registering as an organ donor, or they have fears or misunderstanding about what it means to register. For example, a representative of an OPO in south Florida reported that the extremely racially and culturally diverse population they serve presents barriers related to language, mistrust of the medical community, fear of deportation, and anti-donation cultural beliefs.[54] Another reported barrier is that families sometimes believe that a hospital wants to declare a family member brain dead so that they can take their organs. Another stakeholder said that people might not think about the fact than when they die, someone else could benefit from their organs. To help overcome such barriers, stakeholders recommended additional public education about organ donation and its importance.
- ***Needing financial support to cover the costs incurred by living donors*.** Living donation in Florida is below the national level; living organ donors make up 43% of all organ donors in the U.S. since 1988, while only 30% of Florida's organ donors have been living donors during the same timeframe. One barrier noted by stakeholders is the financial burden of living donation. For example, a stakeholder from a transplant center reported that a family member was not able to afford the expense of donating an organ to a patient on Medicaid, and that Medicaid would not cover these expenses. We verified with AHCA that Medicaid does not reimburse for living donor medical expenses, but AHCA reported that Medicare will cover the cost of living kidney donation for end-stage renal disease. Although Medicaid covers the recipient cost of an adult or pediatric kidney transplant, a bone marrow transplant, or a pediatric liver transplant in which the recipient may be able to receive the organ from a living donor, it does not cover the expenses incurred by the living donor for these types of donations.[55] Another stakeholder mentioned that, while many potential living donors are dedicated to the process, numerous financial constraints can be a major barrier.[56] According to UNOS, a transplant recipient's insurance typically covers the donor's medical costs, including the donation surgery and living donor evaluation. However, other expenses are not covered by insurance, which could include annual physicals, travel, lodging, lost wages, and other non-medical expenses. The National Living Donor Assistance Center may help with some of these expenses for eligible recipients.[57]
- ***Issues identified in hospital communication with families.*** Two OPOs reported that the communication from hospital personnel with grieving families could make a difference in whether a family chooses to agree to donation. According to these stakeholders, if the hospital notifies the OPO in time to support the family through the process, the family is more likely to agree to donation. However, if the hospital does not notify the OPO until it is time to end life support, and hospital personnel have been abrupt with the family or otherwise seem lacking in compassion, the family may be angry and see disagreeing to donation as one thing they can control. These two OPOs and one other recommended additional education on organ donation for health care professionals. State law already provides for such education of nurses and physicians. Section 464.013(3), *Florida Statutes*, requires the Board of Nursing to prescribe by rule up to 30 hours of continuing education biennially for nurses.[58] Similarly, s. 456.013, *Florida*

[54] A systematic review of studies that explored community attitudes toward organ donation substantiates their perceptions. It found that the decision to donate was influenced by culture and medical mistrust, among other factors. See Irving et. al "Factors That Influence the Decision to Be an Organ Donor: A Systematic Review of Qualitative Literature," Nephrology Dialysis Transplant 27 (2012): 2526-2533.

[55] Although the costs associated with living donation have not been systematically captured, a review of 10 studies that collected data on costs that donors incurred found that an average of 9 to 45% of living kidney donors incurred at least some costs as a result of donation. See Clarke, et al. "The Direct and Indirect Economic Costs Incurred by Living Kidney Donors—a Systematic Review," *Nephrology Dialysis Transplantation*, 21 (2006): 1764-1765.

[56] The rate of living kidney donation is much higher for people with higher incomes in both African-American and white populations. See Gill et al, "The Effect of Race and Income on Living Kidney Donation in the United States," *Journal of American Nephrology* 24(11): 2013, 1872-1879.

[57] The National Living Donor Assistance Center is funded by a federal grant awarded by the Health Resources and Services Administration (HRSA). Priority is given to those who cannot otherwise afford the travel and subsidence expenses associated with donation.

[58] Section 464.013(3), *F.S.*

Statutes, directs the Board of Medicine and the Board of Osteopathic Medicine to require licensees to periodically demonstrate their professional competency by completing at least 40 hours of continuing education every two years.[59]

- ***Lack of consistent organ donation education in tax collector offices.*** Tax collectors around the state provide driver license and motor vehicle services in partnership with the Department of Highway Safety and Motor Vehicles, with nearly 90% of Florida's donor registrations coming through driver license offices. Typically, staff filling out the computerized driver license application ask people if they consent to become an organ donor. If so, this information is transferred overnight to the state donor registry. The OPOs work to educate driver license staff and place promotional materials in driver license offices to educate the public. One OPO reported that a tax collector in its donation service area does not allow the OPO to engage in these educational activities in the tax collector's offices. The tax collector said that their offices keep organ donor educational materials at a vendor station with information on license plate options, but organ donor registration is not the responsibility of tax collector staff. Their focus is on customer wait times.

What Policies Have Other States and Countries Pursued to Improve Organ Availability?

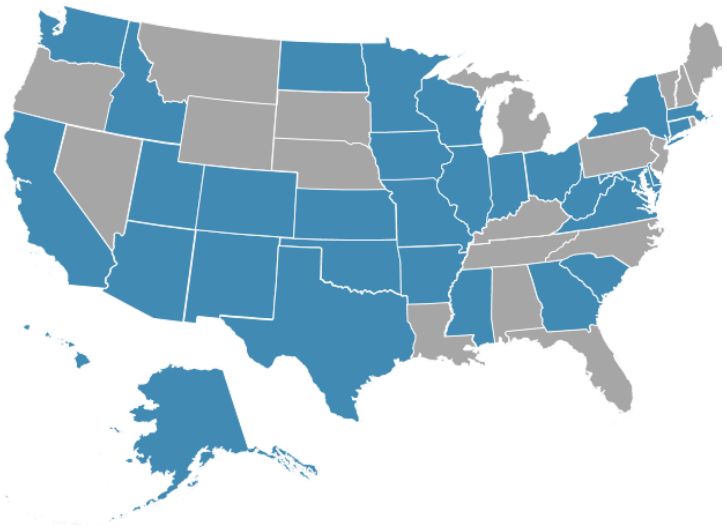
To mitigate the organ shortage in the U.S., many states have considered or adopted legislation to increase organ donor availability, with policies to increase both registered and living donors. To improve organ availability through living organ donation, other states have passed legislation

- requiring certain employers to offer paid leave to living organ donors;
- offering tax credits or tax deductions to living donors or to employers who allow employees a leave of absence for living organ donation; and
- prohibiting insurance providers from denying coverage to living donors based solely on their status as living donors.

[59] Section 456.013, *F.S.*

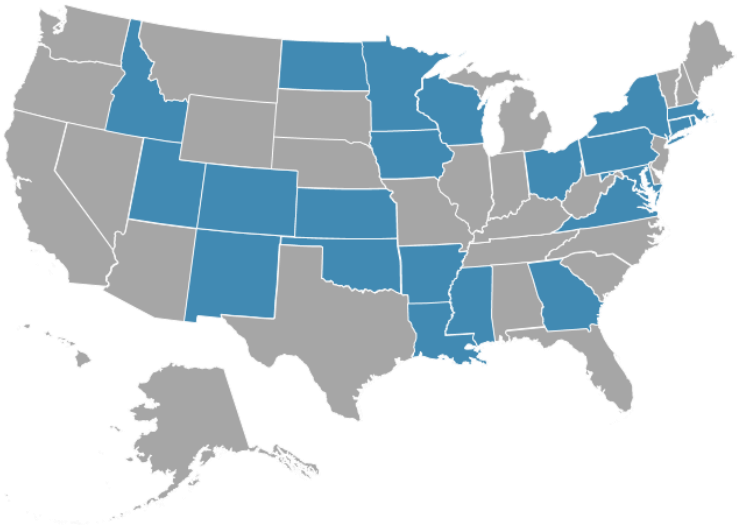
Many states have passed donor leave legislation to make living organ donation a more affordable and viable option. OPPAGA identified 31 states that have laws offering paid leave to living organ donors employed by certain entities. (See Exhibit 22.) These entities include state, county, school, and private sector employers. For example, California, Georgia, and Texas offer state employees a leave of absence of up to 30 days without a reduction in salary to serve as an organ donor. In regards to unpaid leave, according to the U.S. Department of Labor, organ donation qualifies for unpaid, job-protected leave under the Family Medical Leave Act when it involves inpatient care or continuing treatment. These leave laws provide greater opportunities for living donors.

Exhibit 22
States With Donor Leave Laws



Source: OPPAGA analysis of state legislation.

Exhibit 23
States Offering Donor Tax Deductions and Credits



Source: OPPAGA analysis of state legislation.

OPPAGA identified 22 states that currently offer tax deductions or credits for living organ donation.[60] (See Exhibit 23.) Most of these states offer personal income tax deductions and credits, while three offer employer tax credits. For personal income tax, some states, such as Georgia and New York, offer a tax deduction of up to $10,000 for expenses related to organ donation. Other states, such as Colorado, offer employers a tax credit for expenses incurred related to paying an employee or receiving temporary replacement help during the employee's leave of absence for organ donation. These laws may help provide incentives for living organ donation.

Some states, such as Arizona, Colorado, and New York, have also enacted legislation that prohibits insurance providers from denying coverage to living donors based solely on their status as living donors. These laws prohibit discrimination of living donors in receiving coverage such as life, disability, and long-term care insurance. While some states have also enacted legislation to specify that this protection extends to health care coverage as well, the Patient Protection and Affordable Care

[60] Florida does not have a state income tax, so tax deductions and credits may not be applicable.

Act prohibits insurance companies from denying health insurance coverage or charging more for premiums due to a pre-existing condition.

While living donation is the focus of some policies, many states also focus on increasing donor registration. To improve organ availability through increased donor registration, others states have passed or proposed legislation

- focusing on education and public awareness of donor registration;
- expanding the opportunities to register as an organ donor;
- implementing a presumed consent organ donation system; and
- giving registered organ donors priority in organ allocation.

To increase public awareness of organ donor registration, some states, in addition to Florida, have established a fund for education and public awareness campaigns.[61] Texas recently passed legislation designating February 26 as Bone Marrow, Blood, and Organ Donation Registry Day to focus attention on these causes.

Some states have considered or passed policies to expand the opportunities to register as an organ donor. In these policies, residents have the option to register on library card applications or college and university applications, in addition to driver's licenses. Texas and West Virginia passed legislation requiring hunting and fishing licenses to include the election to be an organ donor. In Missouri, a proposed policy would authorize all state agencies and departments to include a link to the donor registry on their website, though this initiative has not passed.

Options Implemented by Other States

To improve organ availability through living organ donation:

- Employee paid leave for living donors
- Employer tax credits or deductions
- Prohibition of denial of insurance coverage for living donors

To improve organ availability through increased donor registration:

- Education and public awareness
- Increased opportunities to register as a donor

Though the legislation was not successful, some states have recently considered proposals to change the donor registry system in their state. One policy proposed in states such as Colorado and New York would create a presumed consent system of organ donation. In this system, residents would be registered as organ donors unless they stated otherwise when applying for their driver license or at some other pre-determined time. New Jersey considered a system where registered organ donors would receive priority in organ allocation if they ever needed an organ, but this is another legislative proposal that has not passed.

Other countries have implemented policies that aim to increase organ donation and availability rates and decrease the time patients spend on waitlists. These policies encompass two main models of organ donation systems that are frequently used throughout the world and mentioned in literature: presumed consent and organ allocation priority. Literature also discusses an additional concept of an organ donor registration system, mandated choice, though we could not identify any countries that use this model.

[61] Arkansas, Illinois, Louisiana, and New York have established a fund for education and public awareness of organ donor registration.

Presumed consent, also known as the opt-out system, is an organ donation system where every citizen is presumed to be an organ donor upon death unless they specifically opt out. Many countries use the presumed consent model, including Austria, England, France, Scotland, Singapore, Spain, and Wales. Proponents of presumed consent organ donation state that the model will increase donation rates, remove next-of-kin interference with the donor's donation decision, and remove the stress that grieving relatives feel when forced to make donation decisions on behalf of their loved ones.[62] Opponents believe that the model will lead to increased levels of mistrust towards medical professionals and the loss of patient autonomy.[63]

Some of the countries that have implemented a presumed consent model have experienced increases in their overall organ donation rates.[64] However, there is a lack of empirical evidence citing presumed consent as the sole reason for the increase.[65] For example, in Spain, the increase in organ donation coincided with a transformation of the organ donation system, specifically growth in the number of hospital coordinators. Hospital coordinators are medical doctors located in hospitals who are in charge of the entire organ donation process and report directly to the hospital director, cutting out middle management. This system is unique to Spain and has been another factor credited with the country's rise in organ donation.[66] In addition, some countries have experienced reduced donation rates after implementing the presumed consent model, and some have reverted back to their prior system of organ donation. In Chile, the detrimental effects of implementing a presumed consent model centered on the concern that the Chilean people were not informed of the implications and scope of the new opt-out system.[67] However, in France and Brazil, decreased donation rates were attributed to increased levels of mistrust towards medical professionals after the presumed consent model was implemented.[68]

Organ allocation priority systems allow countries to offer priority status on the waiting list to individuals who have expressed their consent to donate their organs after death. In this system, a registered potential donor will have a priority advantage over someone on the waitlist who did not consent to being an organ donor. In 1987, Singapore enacted the Human Organ Transplant Act, which established an organ allocation priority system. Those who choose to opt-out of the donor registry receive lower priority if they ever need an organ. In 2008, Israel also enacted legislation to offer an organ allocation priority system. The Israeli Organ Transplantation Law imposes a three-year waiting period after signing up as an organ donor to eliminate an individual's ability to engage in strategic behavior to get priority in organ allocation, and the law still prioritizes medical necessity as the main concern when allocating organs.[69] The Israeli legislation has been credited with increasing the number of individuals registered as organ donors.[70]

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[62] Prabhu, P., "Is Presumed Consent an Ethically Acceptable Way of Obtaining Organs for Transplant?," *Journal of the Intensive Care Society 20*(2), 2019; Zink, S. et al., "Presumed vs Expressed Consent in the US and Internationally," *Ethics Journal of the American Medical Association 7*(9), 2005; Zuniga-Fajuri, A., "Increasing Organ Donation by Presumed Consent and Allocation Priority: Chile," *Bulletin of the World Health Organization 93*, 2015.

[63] Prabhu, P., 2019; Shepherd et al., "An International Comparison of Deceased and Living Organ Donation/Transplant Rates in Opt-In and Opt-Out Systems: A Panel Study," BMC Medicine *12*(131), 2014; Zink, S. et al., 2005.

[64] Austria experienced a quadrupled donation rate within eight years of shifting to a presumed consent model.

[65] Gallagher, S., "The Spanish Model's Capacity to Save Lives by Increasing Organ Donation Rates," *Temple International and Comparative Law Journal 18*, 2004; Shepherd et al., 2014.

[66] Gallagher, S., 2004.

[67] Zuniga-Fajuri, A., 2015.

[68] Shepherd et al., 2014.

[69] Levy, M., "State Incentives to Promote Organ Donation: Honoring the Principles of Reciprocity and Solidarity Inherent in the Gift Relationship," *Journal of Law and the Biosciences*, 2018.

[70] Levy, M., 2018; Zuniga-Fajuri, A., 2015.

Mandated choice is a concept where individuals are required to opt into or out of the transplant registry at a certain point, such as when filing a tax return or renewing a driver license. While completing these tasks, the individual is required to respond to questions regarding organ donation before the task can be considered complete. In such a system, an individual's decision is legally binding upon the individual's death. The model requires individuals to record their choice, but it does not require individuals to register as an organ donor. For example, a person would still receive their driver license or tax return if they chose not to register as an organ donor.[71]

Proponents state that requiring people to make a choice regarding organ donation will reduce the number of individuals that die without ever expressing their decision regarding organ donation.[72] While a choice is required, a person's autonomy is still protected in not requiring them to make a specific choice. In addition, proponents believe that this model eliminates the next-of-kin's ability to reverse the donor's decision regarding their own body and organs.[73] It also removes the burden from families of making a consent decision during an emotional time.[74]

Opponents of the mandated choice model state that it may be a financial burden to some states or countries to maintain a system of every citizen's organ donation choice and educate the public about this system.[75,76] Researchers have noted that some people also feel that mandated choice is a coercive system because individuals are forced to register their decision, and it may not increase donation greatly because many may err on the side of perceived caution and withhold consent.[77]

What Options Could the Legislature Consider to Improve Organ Availability in Florida?

Two ways to improve organ availability in Florida are to increase the rate of living donation and increase organ donor registration. Increasing the rate of living donation would help offset federal changes in organ allocation policies, as these organs would stay within the state. Of all organ donors in Florida since 1988, 30% of donors were living rather than deceased, which is below the national level of 43%. According to research and stakeholders we interviewed, a major barrier to living donation is that people may not be able to afford the cost of the procedure and/or loss of income from being out of work. Another way to increase organ availability is to increase the rate of organ donor registration, even though some of these organs will go out of the state.

To improve organ availability in Florida, the Legislature could consider a number of options implemented in other states, proposed by stakeholders, or identified through OPPAGA fieldwork. These options would increase support for living donation and awareness and education surrounding organ donation in general. Options include

- offering employers a corporate income tax or insurance premium tax credit for expenses incurred related to paying an employee or obtaining temporary assistance during the employee's leave of absence for living organ donation;

[71] Cotter, H., "Increasing Consent for Organ Donation: Mandated Choice, Individual Autonomy, and Informed Consent," *Health Matrix: The Journal of Law-Medicine 21*(2), 2012.
[72] Cotter, H., 2012.
[73] Cotter, H., 2012.
[74] Spellman, D., "Encouragement is Not Enough: The Benefits of Instituting a Mandated Choice Organ Procurement System," *Syracuse Law Review 56*, 2006.
[75] Cotter, H., 2012; Spellman, D., 2006.
[76] Donate Life America currently operates a national donor registry in the U.S.
[77] Cotter, H., 2012; Spellman, D., 2006.

- increasing public education about both living and deceased organ donation;
- adding the topic of organ donation to continuing education requirements for health care professionals;
- expanding Medicaid coverage to include medical expenses incurred by living organ donors;
- prohibiting insurers from denying coverage to living organ donors based solely on their status as living donors; and
- requiring state and local government employers to offer paid leave for living organ donation.

The Legislature could also consider options to improve organ availability in Florida through increased donor registration. Options include

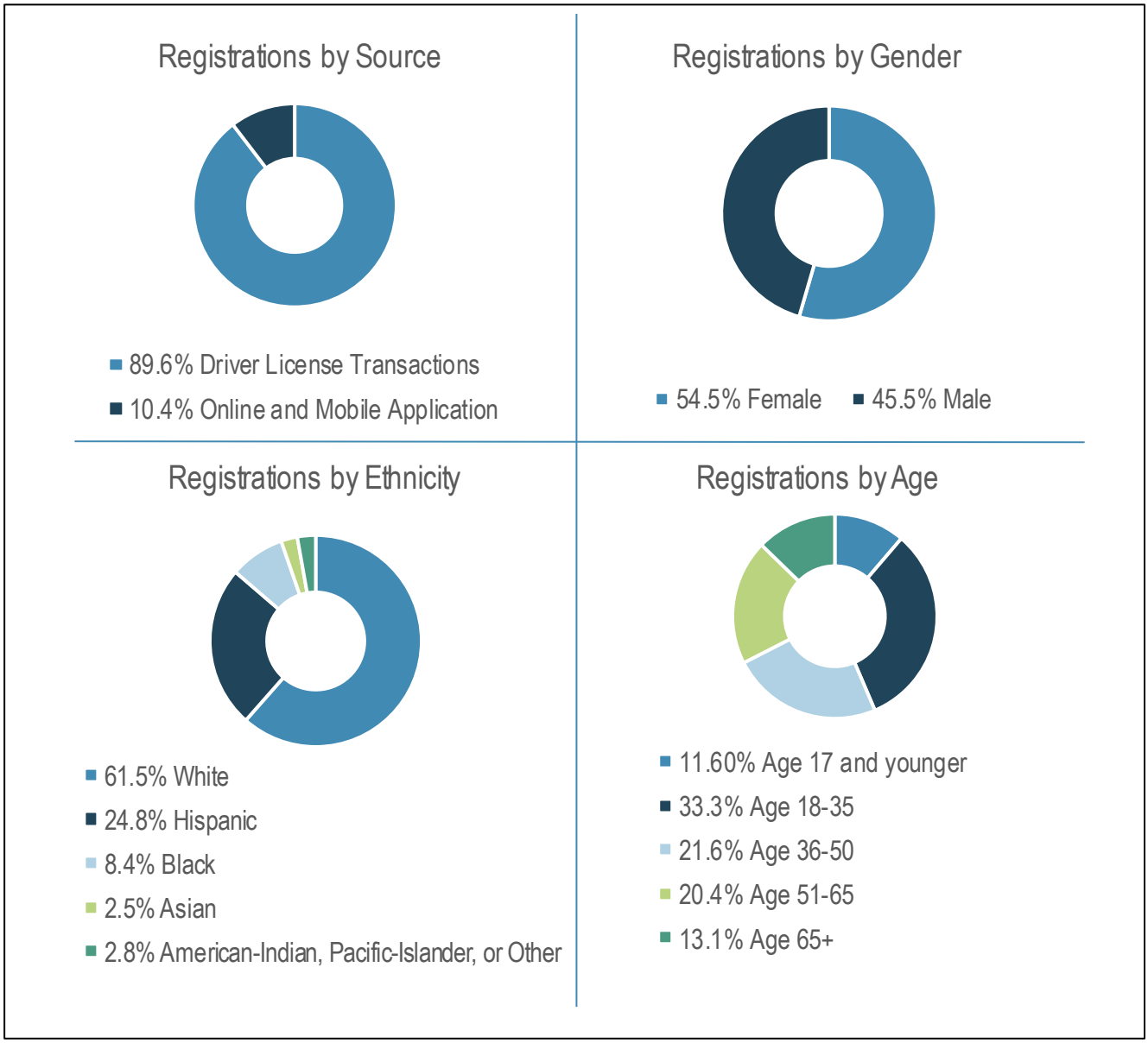
- directing AHCA to use all excess revenues from fees paid by OPOs and tissue and eye banks for public education on donation;
- increasing public education about donor registration;
- adding the topic of organ donation to high school curriculum requirements (e.g., health science classes) to increase familiarity when teenagers first apply for a driver license;
- requiring county tax collectors to allow prominent display of organ donation educational materials in their offices; and
- expanding the opportunities to register as an organ donor to include additional points of access such as hunting and fishing licenses and state agency webpages.

APPENDIX A

Source and Demographic Characteristics of Donor Registrations

In 2018, the majority (89.6%) of organ donor registrations in Florida were from driver license transactions. Slightly more females than males registered to be donors during the period (54.5% compared to 45.5%). The most frequently represented ethnicities among organ donor registrants in Florida were white (61.5%) and Hispanic (24.8%). The age group with the highest frequency of donor registrations was the 18-35 age group. (See Exhibit A-1.)

Exhibit A-1
Most Donor Registrations in Florida Are From Driver License Transactions



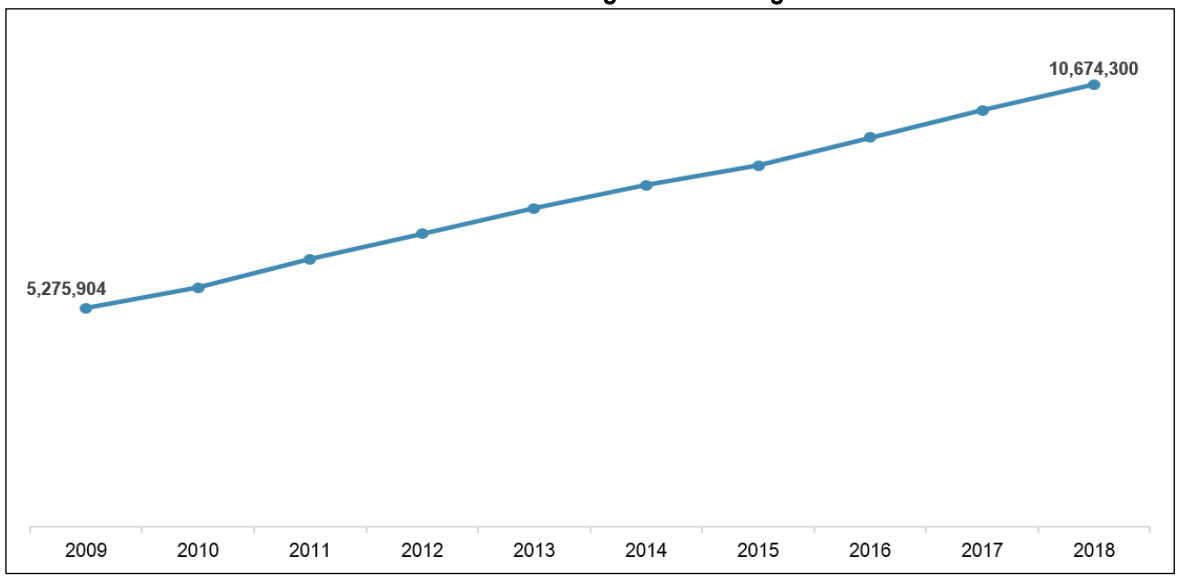
Source: OPPAGA analysis of data from the *Donate Life Florida 2018 Annual Report*.

APPENDIX B

Florida's Donor Registration Rate Over Time

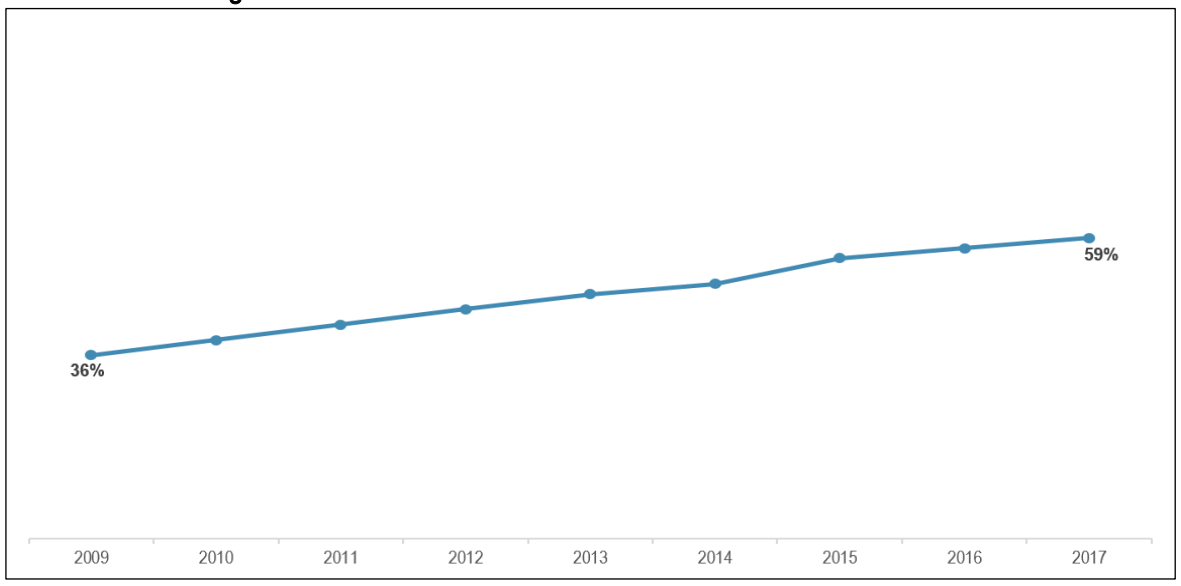
Florida has improved its donor registration rate over time, both in whole numbers and as a percentage of the population. In 2009, Florida had 5,275,904 registered donors, compared to 10,674,300 in 2018. (See Exhibit B-1.) As a percentage, Florida increased its donor registration rate of adults 18 and older from 36% in 2009 to 59% in 2017. (See Exhibit B-2.)

Exhibit B-1
Florida Has More Than Doubled the Number of Organ Donor Registrants From 2009 to 2018



Source: OPPAGA analysis of Donate Life Florida data.

Exhibit B-2
Florida's Donor Registration Rate Has Increased From 36% in 2009 to 59% in 2017



Source: OPPAGA analysis of Donate Life America data.

APPENDIX C

Florida Adult Transplant Program Performance Based on SRTR Program-Specific Five-Tier Assessment Results

Florida's 12 transplant centers each administer one or more organ-specific transplant programs. The Scientific Registry of Transplant Recipients (SRTR) produces outcome assessments for all transplant programs in the U.S. using a five-tier assessment system.[78] The SRTR tiers rank transplant programs on metrics that include adults "getting a deceased donor transplant faster" and adult survival on the waitlist.[79] "Getting a deceased donor transplant faster" is a measure of how quickly those on the wait list get a transplant during the two-year period evaluated relative to how quickly they would be expected to get a transplant based on national data. The metric provides a measure of the rate at which the program finds deceased donor organs for its candidates.[80]

The SRTR tier rankings are as follows.

- Tiers 1 and 2: the program is performing worse than expected.
- Tier 3: the transplant program is performing roughly as expected.
- Tiers 4 and 5: the program is performing better than expected.[81]

Additional details on each transplant program can be found in SRTR's searchable database. Exhibits C-1 through C-3 show the outcomes for Florida transplant centers for adult transplant programs categorized by the number of programs each transplant center administers (six or more programs, two to three programs, and one program).[82] Exhibit C-4 shows the same five-tier assessment results organized by transplant program and organ type.

Transplant Centers With Six or More Transplant Programs

Florida's five transplant centers with six or more transplant programs are AdventHealth Orlando, Jackson Memorial Hospital University of Miami School of Medicine, Mayo Clinic Florida, Tampa General Hospital, and UF Health Shands. Among these programs, AdventHealth Orlando and Tampa General are the only two transplant centers that were rated as expected or better than expected for every organ program for adults getting a transplant faster. None of these centers were rated as expected or better than expected for every organ program for adult survival on the waitlist. Mayo Clinic Florida, Tampa General Hospital, and UF Health Shands were the only transplant centers that had only one program that was rated as worse than expected for adult survival on the waitlist.

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[78] A transplant program is organ-specific within a single transplant center. Transplant centers that conduct transplants for more than one organ would thus have more than one transplant program and multiple rankings.

[79] The strength of the tier-rating system is that it controls for patient characteristics, organs used, and volume of transplants conducted. If Florida's transplant centers had older and sicker transplant patients, the tier ranking they received would not penalize them for these factors; rather, it should reflect their performance. The tier ranking also takes into account the likelihood of getting an especially high or low tier score due to a small volume of transplants.

[80] SRTR excludes individuals who undergo living donor transplants from the analysis.

[81] Ratings are based on a probabilistic estimate; thus, a specific rating represents a range of outcomes that are driven by both performance relative to expected performance as well as the volume of transplants in a program. For details about the computation of the rating tiers, see SRTR's Calculating the Five-Tier Assessments: A Guide for Pre-and Posttransplant Metrics.

[82] This analysis excludes the pediatric transplant program at the Johns Hopkins All Children's Hospital. It includes the transplant program at the Gulf Coast Medical Center, which was operational during the time period of the assessment but ceased operation at the end of 2018.

Of these large transplant centers, there were nine programs that were rated as worse than expected for adults getting a deceased donor transplant faster; of these nine, four were in UF Health Shands, three were in Jackson Memorial, and two were in Mayo Clinic. Of these large transplant centers, there were 11 programs that were rated as worse than expected for adult survival on the waitlist. More than half of them (six) were in Jackson Memorial. (See Exhibit C-1.)

Exhibit C-1
SRTR Five-Tier Assessment Results for the Five Transplant Centers With Six or More Adult Transplant Programs

Transplant Clinic/Organ Program[1]	Adults Getting a Deceased Donor Transplant Faster	Adult Survival on the Waitlist[2]
AdventHealth Orlando		
Heart	Better Than Expected	Worse Than Expected
Kidney	Better Than Expected	Worse Than Expected
Kidney-Pancreas	Better Than Expected	Better Than Expected
Liver	Better Than Expected	Better Than Expected
Lung	Better Than Expected	As Expected
Pancreas	As Expected	As Expected
Jackson Memorial Hospital University of Miami School of Medicine		
Heart	Worse Than Expected	Worse Than Expected
Heart-Lung	Worse Than Expected	Worse Than Expected
Intestine	As Expected	Better Than Expected
Kidney	As Expected	Worse Than Expected
Kidney-Pancreas	Better Than Expected	Worse Than Expected
Liver	Better Than Expected	Worse Than Expected
Lung	Worse Than Expected	Worse Than Expected
Pancreas	As Expected	As Expected
Mayo Clinic Florida		
Heart	Worse Than Expected	Better Than Expected
Heart-Lung	Worse Than Expected	Better Than Expected
Kidney	As Expected	Worse Than Expected
Kidney-Pancreas	As Expected	As Expected
Liver	Better Than Expected	As Expected
Lung	As Expected	Better Than Expected
Pancreas	Better Than Expected	As Expected
Tampa General Hospital		
Heart	Better Than Expected	Worse Than Expected
Heart-Lung	As Expected	As Expected
Kidney	Better Than Expected	Better Than Expected
Kidney-Pancreas	Better Than Expected	As Expected
Liver	Better Than Expected	Better Than Expected
Lung	As Expected	As Expected
Pancreas	As Expected	As Expected
UF Health Shands Hospital		
Heart	Worse Than Expected	As Expected
Kidney	Worse Than Expected	Worse Than Expected
Kidney-Pancreas	As Expected	Better Than Expected
Liver	Worse Than Expected	Better Than Expected
Lung	Better Than Expected	Better Than Expected
Pancreas	Worse Than Expected	As Expected

[1] UF Health Shands has a heart-lung transplant program but did not perform any transplants in this period, so it does not have a tier assignment.

[2] SRTR cautions that it received feedback regarding its waitlist mortality measure for kidney transplant programs because many kidney transplant candidates are not cared for by the program at which they are listed. As a result, SRTR does not display the kidney waitlist mortality measure in its searchable database results for kidney transplant programs, even though SRTR provides this measure in its program-specific reports.

Source: OPPAGA analysis of SRTR outcome assessment data, July 1, 2017 through June 30, 2019, program-specific reports.

Transplant Centers With Two to Three Transplant Programs

The three transplant centers with two to three transplant programs are Cleveland Clinic Florida Weston, Largo Medical Center, and Memorial Regional Hospital. Among these programs, Cleveland Clinic Florida Weston and Memorial Regional Hospital were rated as better than expected or as expected for all of their programs on both metrics. Largo Medical Center was rated as better than expected for both of its transplant programs for adults getting a transplant faster. However, of these mid-sized transplant centers, Largo Medical Center was the only transplant hospital with a worse than expected rating, which it received for adult survival on its kidney program waitlist. (See Exhibit C-2.)

Exhibit C-2
SRTR Five-Tier Assessment Results for the Three Transplant Centers With Two to Three Adult Transplant Programs

Transplant Clinic/Organ Program	Adults Getting a Deceased Donor Transplant Faster	Adult Survival on the Waitlist[1]
Cleveland Clinic Florida Weston		
Heart	Better Than Expected	As Expected
Kidney	Better Than Expected	Better Than Expected
Liver	Better Than Expected	Better Than Expected
Largo Medical Center		
Kidney	Better Than Expected	Worse Than Expected
Liver	Better Than Expected	Better Than Expected
Memorial Regional Hospital		
Heart	As Expected	Better Than Expected
Kidney	Better Than Expected	As Expected

[1] SRTR cautions that it received feedback regarding its waitlist mortality measure for kidney transplant programs because many kidney transplant candidates are not cared for by the program at which they are listed. As a result, SRTR does not display the kidney waitlist mortality measure in its searchable database results for kidney transplant programs, even though SRTR provides this measure in its program-specific reports.

Source: OPPAGA analysis of SRTR outcome assessment data, July 1, 2017 through June 30, 2019, program-specific reports.

Transplant Centers With One Transplant Program

The four transplant centers with one transplant program are Broward Health Medical Center, Gulf Coast Medical Center, Halifax Medical Center, and Sacred Heart Hospital Pensacola. Among these programs, Broward Health Medical Center was rated as expected or better than expected for its liver program for both metrics. Gulf Coast Medical Center was rated as expected for its kidney program for both metrics. Halifax Medical Center and Sacred Heart Hospital had mixed results; both were rated as better than expected for their kidney programs for one measure but have the only two worse than expected ratings among the small programs. (See Exhibit C-3.)

Exhibit C-3
SRTR Five-Tier Assessment Results for the Four Transplant Centers With One Adult Transplant Programs

Transplant Center/Organ Program	Adults Getting a Deceased Donor Transplant Faster	Adult Survival on the Waitlist[1]
Broward Health Medical Center		
Liver	As Expected	Better Than Expected
Gulf Coast Medical Center[2]		
Kidney	As Expected	As Expected
Halifax Medical Center		
Kidney	Better Than Expected	Worse Than Expected
Sacred Heart Hospital Pensacola		
Kidney	Worse Than Expected	Better Than Expected

[1] SRTR cautions that it received feedback regarding its waitlist mortality measure for kidney transplant programs because many kidney transplant candidates are not cared for by the program at which they are listed. As a result, SRTR does not display the kidney waitlist mortality measure in its searchable database results for kidney transplant programs, even though SRTR provides this measure in its program-specific reports.

[2] Gulf Coast Medical Center had a transplant program during the time period of the assessment but the program ceased operation at the end of 2018.
Source: OPPAGA analysis of SRTR outcome assessment data, July 1, 2017 through June 30, 2019, program-specific reports.

Transplant Program-Level Results

Exhibit C-4 shows the five-tier assessment results organized by transplant program/organ type. Overall results by type of program are summarized below.

- Among the seven **heart transplant programs**, only Cleveland Clinic Florida Weston and Memorial Regional Hospital was rated as expected or better than expected across both metrics. Jackson Memorial Hospital University of Miami School of Medicine is the only heart program that was rated as worse than expected for both metrics.
- Among the three **heart-lung transplant programs**, only Tampa General Hospital was rated as expected or better than expected across both metrics. Jackson Memorial Hospital University of Miami School of Medicine was rated as worse than expected for both metrics.
- Jackson Memorial Hospital University of Miami School of Medicine had the only **intestine transplant program** and was rated as expected for adults getting a deceased donor transplant faster and better than expected for adult survival on the waitlist.
- Among the 11 **kidney transplant programs**, Cleveland Clinic Florida Weston and Tampa General Hospital had the only programs that were rated as better than expected for both metrics. Gulf Coast Medical Center and Memorial Regional Hospital were rated as expected or better than expected for both metrics. More than half of kidney programs overall (6 out of 11) were rated as worse than expected for adult survival on the waitlist.
- Among the five **kidney-pancreas programs**, AdventHealth Orlando had the only program that was rated as better than expected across both metrics. Jackson Memorial Hospital University of Miami School of Medicine had the only worse than expected rating, which was for adult survival on the waitlist. The other three programs (Mayo Clinic Florida, Tampa General Hospital, and UF Health Shands) were rated as expected or better than expected for both metrics.
- Florida's eight **liver transplant programs** did well overall. Out of the 16 ratings across the two metrics, 12 were better than expected, 2 were as expected, and only 2 were worse than expected. AdventHealth Orlando, Cleveland Clinic Florida Weston, Largo Medical Center, and Tampa General Hospital had programs that were rated as better than expected for both metrics.
- Among the five **lung transplant programs**, UF Health Shands Hospital is the only program that was rated as better than expected for both metrics. In addition to UF Health Shands

Hospital, AdventHealth Orlando, Mayo Clinic Florida, and Tampa General Hospital were rated as expected or better than expected for both metrics. Jackson Memorial Hospital University of Miami School of Medicine had the only clinic with a worse than expected rating, which it received for both metrics.

- The five **pancreas transplant programs** were rated as expected or better than expected for four out of five ratings for adults getting a deceased transplant faster, and as expected for all of their ratings for adult survival on the waitlist. UF Health Shands is the only center that was rated as worse than expected, which was for adults getting a transplant faster.

Exhibit C-4
SRTR Five-Tier Assessment Results by Organ for Florida Transplant Centers

Organ Program/Transplant Center[1]	Adults Getting a Deceased Donor Transplant Faster	Adult Survival on the Waitlist
Heart		
AdventHealth Orlando	Better Than Expected	Worse Than Expected
Cleveland Clinic Florida Weston	Better Than Expected	As Expected
Jackson Memorial Hospital University of Miami School of Medicine	Worse Than Expected	Worse Than Expected
Mayo Clinic Florida	Worse Than Expected	Better Than Expected
Memorial Regional Hospital	As Expected	Better Than Expected
Tampa General Hospital	Better Than Expected	Worse Than Expected
UF Health Shands Hospital	Worse Than Expected	As Expected
Heart-Lung		
Jackson Memorial Hospital University of Miami School of Medicine	Worse Than Expected	Worse Than Expected
Mayo Clinic Florida	Worse Than Expected	Better Than Expected
Tampa General Hospital	As Expected	As Expected
Intestine		
Jackson Memorial Hospital University of Miami School of Medicine	As Expected	Better Than Expected
Kidney[2]		
AdventHealth Orlando	Better Than Expected	Worse Than Expected
Cleveland Clinic Florida Weston	Better Than Expected	Better Than Expected
Gulf Coast Medical Center	As Expected	As Expected
Halifax Medical Center	Better Than Expected	Worse Than Expected
Jackson Memorial Hospital University of Miami School of Medicine	As Expected	Worse Than Expected
Largo Medical Center	Better Than Expected	Worse Than Expected
Mayo Clinic Florida	As Expected	Worse Than Expected
Memorial Regional Hospital	Better Than Expected	As Expected
Sacred Heart Hospital Pensacola	Worse Than Expected	Better Than Expected
Tampa General Hospital	Better Than Expected	Better Than Expected
UF Health Shands Hospital	Worse Than Expected	Worse Than Expected
Kidney-Pancreas		
AdventHealth Orlando	Better Than Expected	Better Than Expected
Jackson Memorial Hospital University of Miami School of Medicine	Better Than Expected	Worse Than Expected
Mayo Clinic Florida	As Expected	As Expected
Tampa General Hospital	Better Than Expected	As Expected
UF Health Shands Hospital	As Expected	Better Than Expected

Organ Program/Transplant Center[1]	Adults Getting a Deceased Donor Transplant Faster	Adult Survival on the Waitlist
Liver		
AdventHealth Orlando	Better Than Expected	Better Than Expected
Broward Health Medical Center	As Expected	Better Than Expected
Cleveland Clinic Florida Weston	Better Than Expected	Better Than Expected
Jackson Memorial Hospital University of Miami School of Medicine	Better Than Expected	Worse Than Expected
Largo Medical Center	Better Than Expected	Better Than Expected
Mayo Clinic Florida	Better Than Expected	As Expected
Tampa General Hospital	Better Than Expected	Better Than Expected
UF Health Shands Hospital	Worse Than Expected	Better Than Expected
Lung		
AdventHealth Orlando	Better Than Expected	As Expected
Jackson Memorial Hospital University of Miami School of Medicine	Worse Than Expected	Worse Than Expected
Mayo Clinic Florida	As Expected	Better Than Expected
Tampa General Hospital	As Expected	As Expected
UF Health Shands Hospital	Better Than Expected	Better than Expected
Pancreas		
AdventHealth Orlando	As Expected	As Expected
Jackson Memorial Hospital University of Miami School of Medicine	As Expected	As Expected
Mayo Clinic Florida	Better Than Expected	As Expected
Tampa General Hospital	As Expected	As Expected
UF Health Shands Hospital	Worse Than Expected	As Expected

[1] UF Health Shands has a heart-lung transplant program but did not perform any transplants in this period, so they do not have a tier assignment. Gulf Coast Medical Center had a transplant program during the time period of the assessment but the program ceased operation at the end of 2018.

[2] SRTR cautions that it received feedback regarding its waitlist mortality measure for kidney transplant programs because many kidney transplant candidates are not cared for by the program at which they are listed. As a result, SRTR does not display the kidney waitlist mortality measure in its searchable database results for kidney transplant programs, even though SRTR provides this measure in its program-specific reports.

Source: OPPAGA analysis of SRTR outcome assessment data, July 1, 2017 through June 30, 2019, program-specific reports.

APPENDIX D

Comparison of Florida to U.S. Kidney and Liver Transplant Program Waitlist Trends

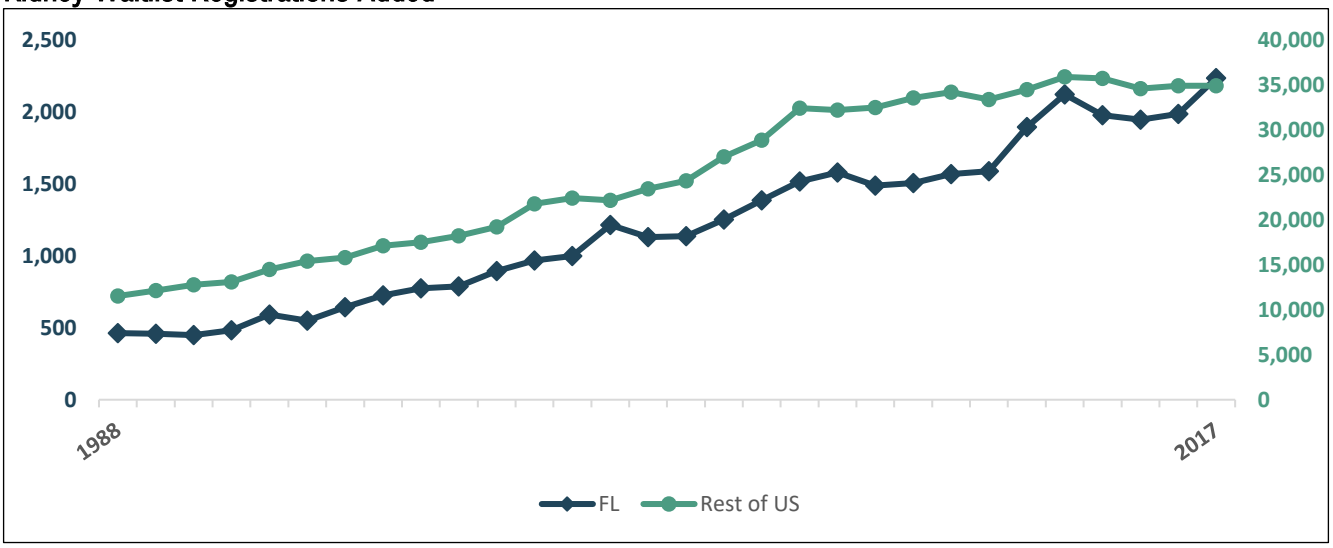
OPPAGA's analysis of data from UNOS shows that Florida compares similarly or favorably to the nation for kidney and liver waitlist trends.[83] UNOS provided data showing the outcomes of patients within three years of being placed on a transplant waitlist in Florida and in other states. While these results provide useful descriptive information, they should be viewed with caution, as they do not take into account differences in patient mixes over time or across states or differences in organ transplant quantity or quality. For example, if Florida transplant centers have older and sicker transplant patients on a waitlist, whether a result of waitlist acceptance and management practices or Florida's population characteristics, Florida's percentage of deaths on a waitlist would be worse than the rest of the nation's centers even if transplant success on comparable populations were identical. These results also do not take into account the mix of organs transplanted in Florida versus other states. For example, if Florida centers transplanted more organs that were less likely to be successful, either because of the type or quality of organ that the centers accept, their percentage of deaths on the waitlist would be higher than the rest of the nation's centers, even if transplants were similarly successful on equivalent organs.

Kidney Waitlist Trends

Florida's trend in new kidney waitlist registrations generally follows the same pattern of increase as the U.S. as a whole, with an increase in registrations over time. (See Exhibit D-1.) As registrations (demand for kidneys) grew rapidly, likely outstripping the growth in supply of kidneys, there was a decline in the percentage of new registrants who were able to receive a kidney. So despite the fact that there has been growth in the number of kidney recipients, there has been a decline in the percentage of registrants who received a kidney. (See Exhibit D-2.) However, Florida's percentage of patients who received a deceased donor transplant within three years of registering on the waitlist has remained better than the nation as a whole over time. In addition, Florida's percentage of patient deaths within three years of registering on the waitlist for a kidney has been similar to or slightly lower than the rest of the nation since 1988. (See Exhibit D-3.)

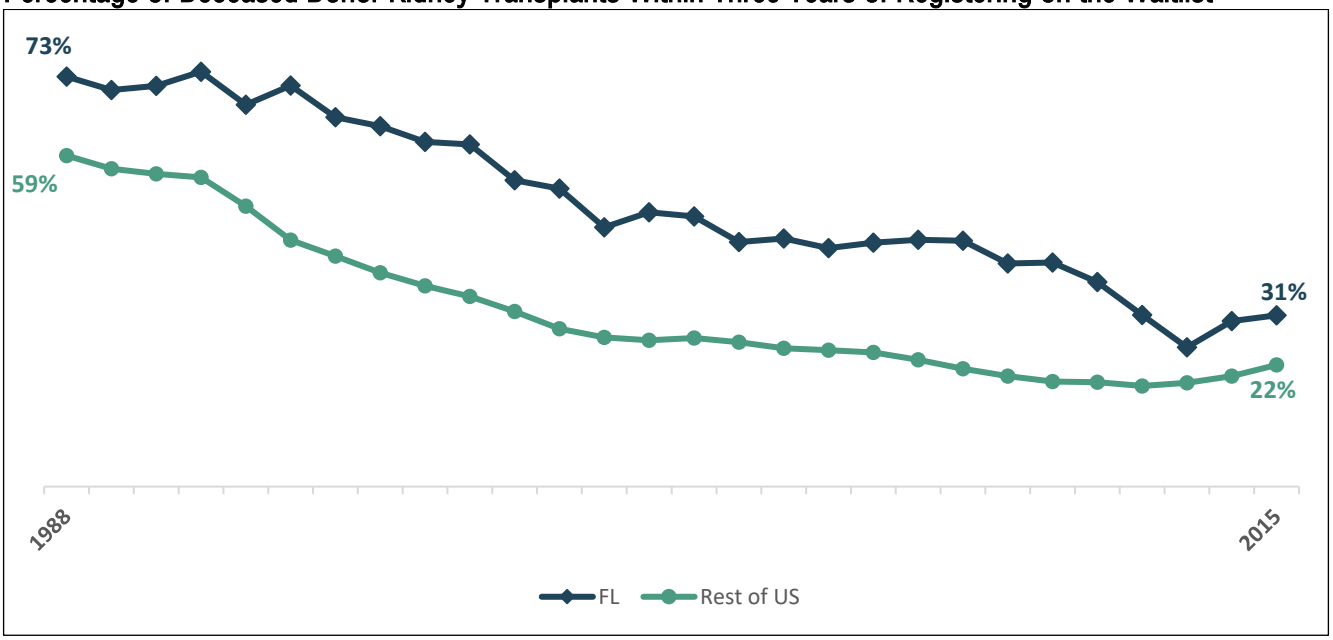
[83] For organs other than kidney and liver, the small number of organs showed a high degree of annual variability and made it difficult to draw conclusions about rates. We do not present a comparison of different organs because transplantation and death rates can be very different for different states. The mix and size of organ programs available in a state can change the apparent pooled relative outcomes for otherwise identical organ-by-organ performance.

Exhibit D-1
Kidney Waitlist Registrations Added



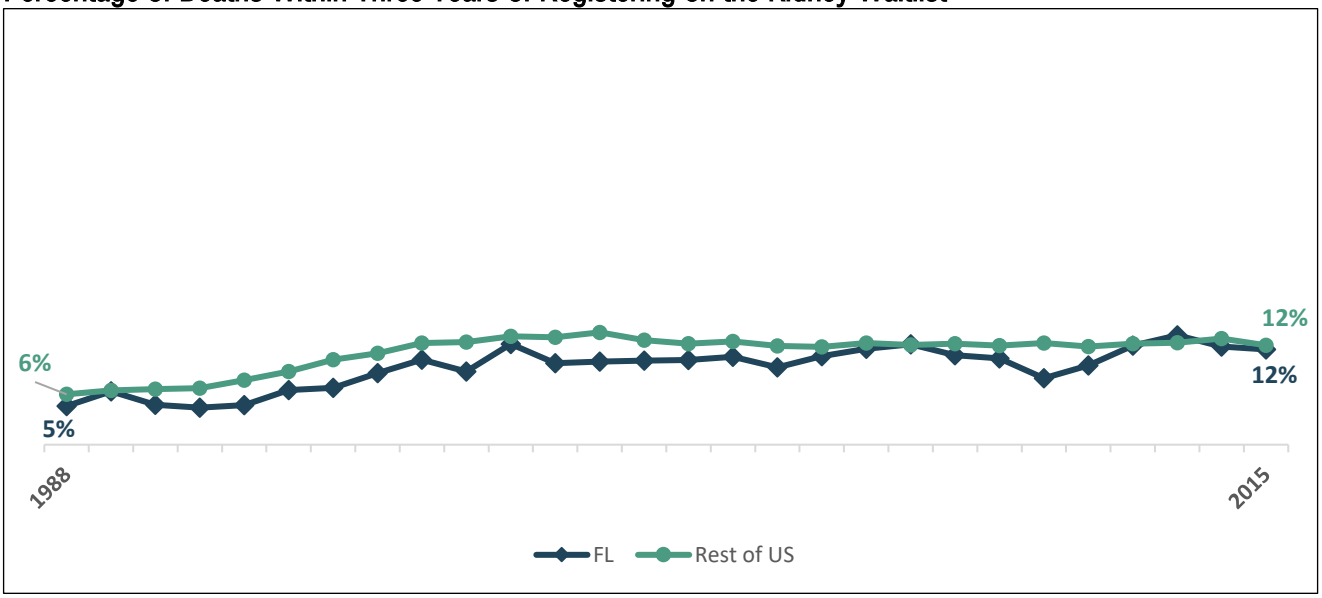
Source: OPPAGA analysis of UNOS data.

Exhibit D-2
Percentage of Deceased Donor Kidney Transplants Within Three Years of Registering on the Waitlist



Source: OPPAGA analysis of UNOS data

Exhibit D-3
Percentage of Deaths Within Three Years of Registering on the Kidney Waitlist[1]



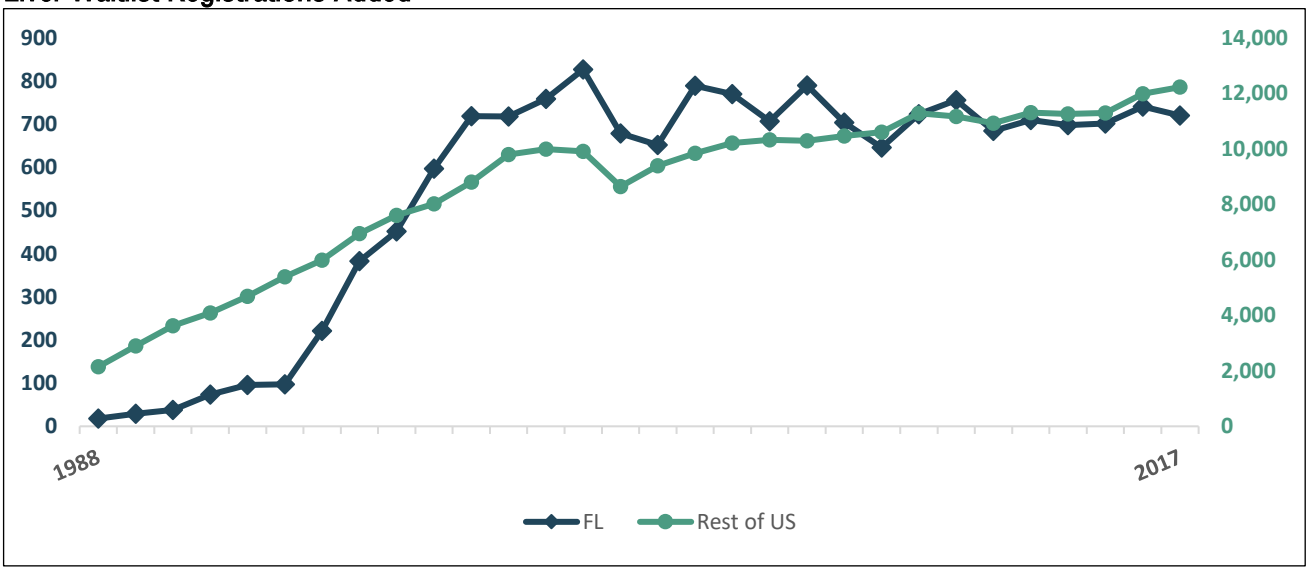
[1] The measure reflects the percentage of registrants who were removed from the waitlist due to death or being too sick to transplant, or who died after exiting the waitlist for other reasons.

Source: OPPAGA analysis of UNOS data.

Liver Waitlist Trends

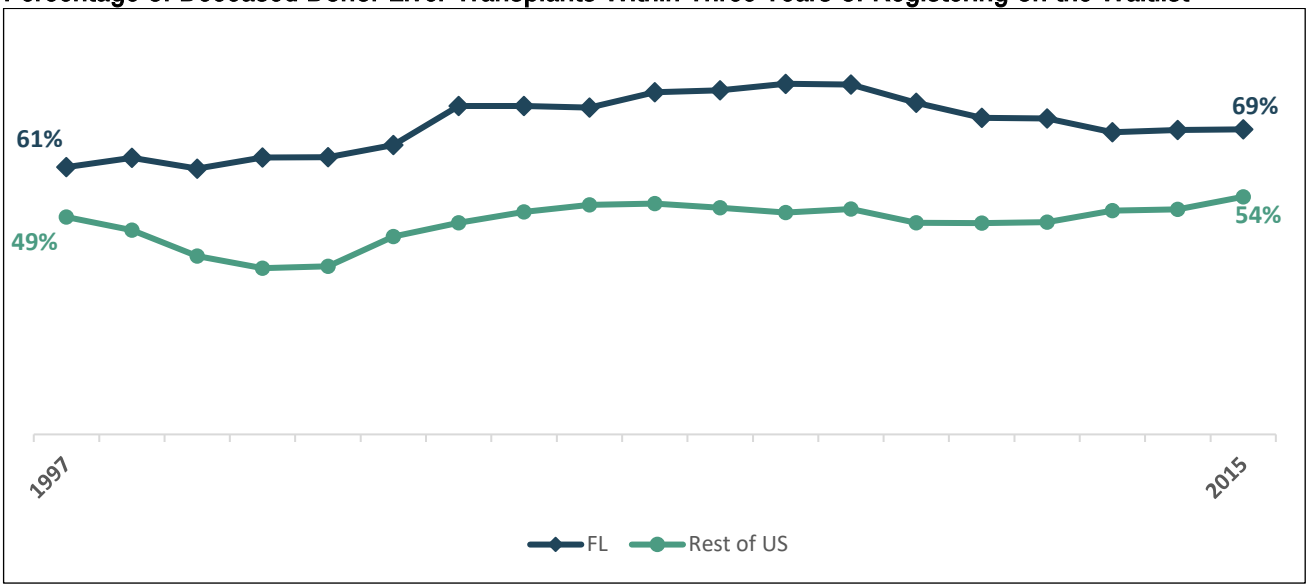
OPPAGA's analysis of UNOS data on liver waitlist trends yielded similar results as for kidney waitlist trends. Florida has increased the number of waitlist registrations for livers over time, a trend that roughly mirrors the pattern in the rest of the U.S. (See Exhibit D-4.) However, Florida has generally maintained relatively high transplantation rates for livers compared to the nation as a whole. These differences have been statistically significant in nearly all years of available data. (See Exhibit D-5.) Florida has also maintained a relatively low waitlist death rate for liver transplants compared to the nation as a whole. The differences have been statistically significant in nearly all years of available data. (See Exhibit D-6.)

Exhibit D-4
Liver Waitlist Registrations Added



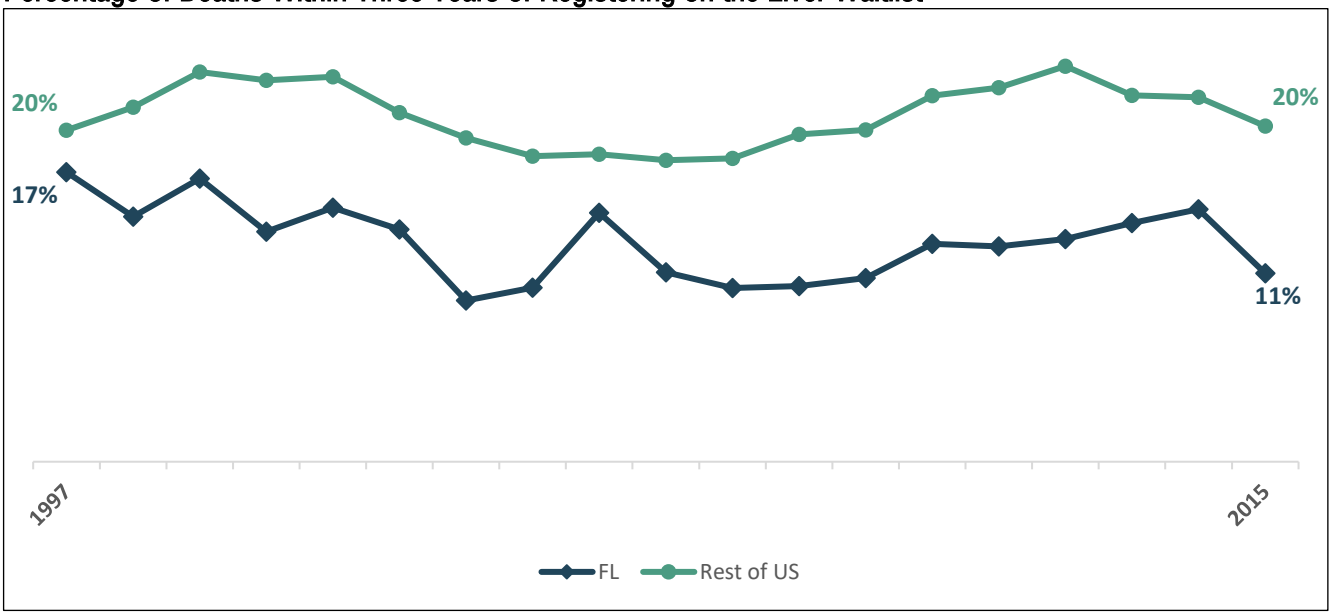
Source: OPPAGA analysis of UNOS data.

Exhibit D-5
Percentage of Deceased Donor Liver Transplants Within Three Years of Registering on the Waitlist



Source: OPPAGA analysis of UNOS data.

Exhibit D-6
Percentage of Deaths Within Three Years of Registering on the Liver Waitlist[1]



[1] The measure reflects the percentage of registrants who were removed from the waitlist due to death or being too sick to transplant, or who died after exiting the waitlist for other reasons.

Source: OPPAGA analysis of UNOS data.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 1726
INTRODUCER:	Senator Bean
SUBJECT:	Agency for Health Care Administration
DATE:	January 31, 2020
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Kibbey	Brown	HP	**Fav/CS**
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1726 addresses statutory duties and responsibilities of the Agency for Health Care Administration (AHCA) relating to the regulation of health care facilities and providers. The bill:

- Removes provisions requiring fixed inspection time frames for nursing home facilities, hospices, assisted living facilities, and adult family care homes.
- Authorizes the AHCA to exempt specified low-risk providers from licensure inspection.
- Authorizes the AHCA to adopt rules to waive a routine inspection, to waive an inspection for relicensure, or to allow an extended period between inspections for any provider type based upon specified factors.
- Establishes that health care clinic licensure is not required for Medicaid providers.
- Creates an exemption to health care clinic licensure for federally-certified providers.
- Repeals multiphasic health testing center licensure.
- Authorizes the AHCA to issue a provisional license to all provider types.
- Increases the frequency of birth center reports to the AHCA.
- Revises background screening regulations for health care provider staff.
- Authorize the collection of legal fees on Medicaid overpayment and licensure cases.
- Clarifies the AHCA's authority to retrospectively review Medicaid inpatient hospital admissions and payments.
- Revises definitions and licensure requirements related to home health agencies.
- Revises language for listing hospital beds on license.
- Repeals an unenforceable annual assessment.

- Revises requirements for the approval of comprehensive emergency management plans for newly-licensed facilities.
- Replaces legislatively-mandated reports with online publications and repeals specified reports.

The bill takes effect on July 1, 2020, except as otherwise expressly provided in the bill and except for the effective date section, which takes effect upon this act becoming a law.

II. Present Situation:

The AHCA is created in s. 20.42, F.S. It is the chief health policy and planning entity for the state and is responsible for, among other things, health facility licensure, inspection, and regulatory enforcement. It licenses or certifies and regulates 40 different types of health care providers, including hospitals, nursing homes, assisted living facilities, and home health agencies. In total, the AHCA licenses, certifies, regulates or provides exemptions for more than 48,000 providers.[1]

Generally applicable provisions of health care provider licensure are addressed in the Health Care Licensing Procedures Act in part II of ch. 408, F.S. Additional chapters or sections in the Florida Statutes provide specific licensure or regulatory requirements pertaining to health care providers in this state.[2]

Due to the many diverse issues within the bill, pertinent background information is provided within the effect of proposed changes for the reader's convenience.

III. Effect of Proposed Changes:

Birth Center Reporting

Section 1 amends s. 383.327, F.S. Birth centers are required under current law to immediately report each maternal death, newborn death, and stillbirth to the medical examiner. Changes to subsection (2) of this section require birth centers to immediately report this information to the AHCA as well. Changes to subsection (4) of this section remove the requirement that birth centers submit a report to the AHCA annually and instead require the reports to be submitted at a frequency adopted by the AHCA in rule. These changes could enable the AHCA to have more current information to review during the inspection of a birth center.

Listing Hospital Beds on a License

Chapter No. 2019-136, L.O.F. (enacted by the Legislature in 2019 as CS/HB 21) removes certificate of need review requirements for hospitals over time, with the final change occurring on July 1, 2021. **Section 2** amends s. 395.003(4), F.S., to remove the requirement that all beds not covered by any specialty-bed-need methodology be specified as general beds on the face of the hospital's license. If this subsection is not updated to reflect recent changes to certificate of

[1] *See* the Agency for Health Care Administration, Division of Health Quality Assurance http://ahca.myflorida.com/MCHQ/index.shtml (last visited Jan. 23, 2020).
[2] *See* s. 408.802, F.S., for the health care provider types and applicable licensure statutes.

need requirements, specialty hospital beds such as neonatal intensive care beds will incorrectly be reported as general acute care beds on the face of the hospital's license.

Repeal of an Unenforceable Assessment

Section 3 repeals s. 395.7015, F.S., which imposes an annual assessment on ambulatory surgical centers and certain diagnostic-imaging centers that are freestanding outpatient facilities. These assessments were ruled to be unconstitutional and are no longer collected. [3] **Section 4** amends s. 395.7016, F.S., to conform a cross-reference to this section.

Licensure Inspections for Nursing Home Facilities, Hospices, Assisted Living Facilities, and Adult Day Care Centers

Uniform licensing requirements in s. 408.811, F.S., require the biennial inspections of health care facilities unless otherwise specified in statute or in rule. Sections of the bill listed below remove the frequency required in statute for nursing home facilities, hospices, assisted living facilities, and adult day care centers.

Federal law currently requires the AHCA to inspect a nursing home facility, at a minimum, every 15 months.[4] Section 400.19, F.S., also requires the AHCA to inspect a nursing home facility every 15 months. The AHCA is required to inspect a nursing home facility every six months for two years if the facility has been cited for a class I deficiency, has been cited for two or more class II deficiencies arising from separate surveys or investigations within a 60-day period, or has had three or more substantiated complaints within a six-month period, each resulting in at least one class I or class II deficiency. Those nursing home facilities are required to pay a $6,000 fine for the two additional inspections.

Section 5 amends s. 400.19, F.S., to remove the 15-month inspection requirement from state law and instead requires the AHCA to conduct periodic unannounced licensure inspections. This provision would require the AHCA to conduct only one additional licensure survey for a facility that has been cited for a class I deficiency or for two or more class II deficiencies within a 60-day period. The $6,000 fine for the two additional inspections is removed and is replaced with a $3,000 fine for each additional licensure survey.

Section 12 amends s. 400.605(3), F.S., to remove the requirement that the AHCA must inspect hospices annually or biennially for hospices having a three-year record of substantial compliance and instead requires the AHCA to conduct inspections and investigations of hospices as necessary to determine compliance.

Sections 41 and 42 amend ss. 429.35 and 429.905(2), F.S., to remove the requirement (and related provisions) that the AHCA inspect assisted living facilities biennially.

Section 43 amends s. 429.929, F.S., to remove a provision authorizing the AHCA to conduct an abbreviated biennial inspection of an adult day care center that has a record of good

[3] *Agency for Health Care Admin. v. Hameroff*, 816 So. 2d 1145, 1149-1150 (Fla. 1st DCA 2002).
[4] 42 C.F.R. s. 488.308(a).

performance. It also removes a provision requiring the AHCA to conduct a full inspection of an adult day care center that has had one or more confirmed complaints.

Home Health Agencies

Section 400.462(12), F.S., defines the term "home health agency" as an organization that provides home health services and staffing services. An organization that provides only home health services does not meet the definition of a home health agency.

Subsection (30) of that section defines the term "staffing services" as services provided to a health care facility, school, or other business entity on a temporary or school-year basis pursuant to a written contract by licensed health care personnel and by certified nursing assistants and home health aides who are employed by, or work under the auspices of, a licensed home health agency or who are registered with a licensed nurse registry.

Subsection (14) of that section defines "home health services" as the following services that are provided by an organization:
- Nursing care.
- Physical, occupational, respiratory, or speech therapy.
- Home health aide services.
- Dietetics and nutrition practice and nutrition counseling.
- Medical supplies, restricted to drugs and biologicals prescribed by a physician.

Section 6 amends s. 400.462, F.S., to revise the definitions of the terms "home health agency," "home health services," "home infusion therapy provider," and "nurse registry" and deletes the definition of the term "organization."
- "Home health agency" is redefined to mean a person or an entity that provides one or more home health services, as opposed to an organization that provides home health services (plural) and staffing services as under current law. The new definition will include individuals who provide one or more types of home health service, and the provision of staffing services will no longer be necessary in order to meet the definition.
- "Home infusion therapy provider" is redefined to pertain to "a person or an entity," as opposed to "an organization" that meets the definition's criteria.
- "Nurse registry" is redefined to include an "entity" that meets the definition of the term, as opposed to only a person who does so.
- "Home health services" is redefined to conform to elimination of the term "organization" in other definitions, and the definition of "organization" itself is eliminated since that term becomes obsolete under the bill for this section of statute.

Currently, an individual could employ health care personnel for the provision of home health services without having to obtain a license. Under the bill, such an individual must obtain a license. Section 400.471(5), F.S., requires an applicant or licensee for home health agency licensure to pay a fee for each submitted application. The fee must be established by the AHCA in rule at an amount sufficient to cover the AHCA's costs in carrying out its responsibilities, not

to exceed $2,000 per biennium. Under this statutory authority in current law, the AHCA is imposing a $1,705 fee for initial licensure, change of ownership, or licensure renewal.[5]

Section 7 amends s. 400.464, F.S., to make conforming changes and to make exemptions from licensure as a home health agency for a person or entity that provides skilled care by health care professionals licensed solely under part I of ch. 464, F.S., (nursing); part I, part III, or part V of ch. 468, F.S., (speech therapy, occupational therapy, or respiratory therapy); or ch. 486, F.S., (physical therapy). Skilled care services are currently defined in s. 400.462(29), F.S. This exemption currently indirectly exists within the definition of "organization" that is being stricken in Section 6 of the bill.

Section 8 amends s. 400.471(2)(g), F.S., to require applicants for change of ownership or license renewal to provide proof of accreditation and a survey demonstrating compliance with the applicable licensure requirements prior to licensure for the addition of skilled services.

Sections 9-11 amend ss. 400.492, 400.506, and 400.509, F.S., to conform provisions to changes made to the definitions section for part III of ch. 400, F.S., in Section 6 of the bill.

AHCA Reporting Requirements

Section 13 amends s. 400.60501, F.S., to delete a requirement that the AHCA develop an annual report that analyzes and evaluates the information collected under the Health Care Clinic Act. It also removes an obsolete date. Hospice outcome and quality information is currently published on FloridaHealthFinder.gov.

Section 19 amends s. 408.0611, F.S., to require the AHCA to report on its website information on the implementation of electronic prescribing rather than issuing an annual report to the Governor and the Legislature. The AHCA already updates this information quarterly on the ePrescribing dashboard of its website.[6]

Section 20 amends s. 408.062, F.S., to require the AHCA to report on its website information relating to the use of hospital emergency department services by patient acuity level and on health care quality measures rather than issuing an annual status report to the Governor and the Legislature. Most information that is required to be in the report is available on FloridaHealthFinder.gov.

Section 21 amends s. 408.063, F.S., to remove the requirement that the AHCA publish an annual comprehensive report of state health expenditures. This report currently identifies the contribution of health care dollars made by all payors and the dollars expended by the type of health care service. The AHCA indicates that this report has little value because of a three-year delay in reporting information.[7]

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[5] 59A-8.003, F.A.C.
[6] Agency for Health Care Administration, *ePrescribing Clearinghouse* https://ahca.myflorida.com/SCHS/ePrescribing/metrics.shtml (last visited Jan. 24, 2020).
[7] Agency for Health Care Administration, *Senate Bill 1726 Agency Analysis* (on file with the Senate Committee on Health Policy).

Section 32 amends s. 408.909, F.S., to delete a provision requiring the AHCA to evaluate and provide an annual assessment to the Governor and the Legislature relating to the Health Flex Plan. The Health Flex Plan program was a pilot program established to benefit low-income families who were not eligible for public assistance programs and not covered by private insurance.[8] There were initially only three plans in limited service areas available for consumers. There is currently only one remaining Health Flex Plan with fewer than 300 members.[9]

Section 33 amends s. 408.9091, F.S., to remove the requirement that the AHCA and the Office of Insurance Regulation of the Financial Services Commission jointly submit an annual report to the Governor and the Legislature relating to the implementation of the Cover Florida Health Care Access Program. There are currently no plans participating in the Cover Florida Health Care Access Program.[10] The last participating health plan terminated its Cover Florida policies in January of 2015.[11]

Section 37 amends s. 409.913, F.S., to move the Medicaid Program Integrity Annual Report due date from January 1, which is a national holiday, to January 15. Other changes made to this section of statute are discussed below.

Section 40 amends s. 429.19(9), F.S., to remove the requirement that the AHCA develop and disseminate a list of all assisted living facilities sanctioned or fined for violations of state standards, the number and class of violations involved, the penalties imposed, and the current status of cases. The AHCA is required by s. 429.55(2), F.S., to create an accessible website containing this information and has done so with FloridaHealthFinder.gov.[12]

Health Care Clinics

Section 14 amends s. 400.9905, F.S., to provide exemptions from health care clinic licensure for Medicaid providers, for certain federally certified-providers, for entities under common ownership by a mutual insurance holding company, and for certain entities that are owned by an entity that is a behavioral health service provider.

There are currently over 14 exemptions listed in the health care clinic licensure laws.[13] Most of these exemptions are made for health care providers that are already licensed and regulated by the AHCA, an establishment or profession regulated by the Department of Health, a provider that is federally certified, a non-profit entity, or an entity with substantial financial commitment.

Comprehensive outpatient rehabilitation facilities (42 C.F.R. part 485, subpart B), outpatient physical therapy and speech-language pathology providers (42 C.F.R. part 485, subpart H), end stage renal diseases (42 C.F.R. part 494), and clinical laboratories are all federally certified providers that are regulated by the AHCA. These providers qualify for an exemption from health care clinic licensure.

[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] *Id.*

Changes made in this section of the bill provide exemptions for other federally certified providers that are regulated by the AHCA, including community mental health center-partial hospitalization programs (42 C.F.R. part 485, subpart J), portable X-ray providers (42 C.F.R. part 486, subpart C) and rural health care clinics (42 C.F.R. part 491, subpart A).

The Implementing Bill accompanying the 2019 General Appropriations Act created two additional exemptions from clinic licensure for entities owned by an insurance holding company with over $1 billion in annual sales and entities owned by a behavioral health provider in at least five states with $90 million in annual revenues from behavioral health.[14] These exemptions are in effect until June 30, 2020.[15] Language in this section of CS/SB 1726 provides that those two exemptions will be permanent.

Providers that meet the definition of health care clinic who do not qualify for an exemption must obtain a license, and providers that participate in Medicaid must meet all requirements in applicable state laws. Medicaid recently initiated rule-making to add licensure as a health care clinic when required by law to be a pre-requisite to enrollment as a Medicaid provider. Over 20,000 providers have been identified as possibly requiring a health care clinic license to remain in Medicaid, though some will likely meet an exemption.[16] An estimated 13,000 may require licensure to meet Medicaid requirements by December 2020.[17] The AHCA asked for 13 positions to support this workload through a legislative budget request.[18]

Section 15 amends s. 400.991(3)(c), F.S., to remove the option for a health care clinic to file a surety bond of at least $500,000 as an alternative to submitting proof of financial ability to operate with its application for initial licensure or a change in ownership. No health care clinics have submitted the surety bond in lieu of proof of financial ability to operate.[19]

Section 16 amends s. 400.9935(1)(i), F.S., to authorize a health care clinic's schedule of charges to group services by price level. This section of the bill revises the requirement that the schedule must be posted in the reception area of the urgent care center of a clinic to only the reception area of a clinic that meets the definition of an "urgent care center" as defined in s. 395.002(29)(b), F.S.

Deleting a Reference to a Specific Data Collection Rule

Section 18 amends s. 408.061, F.S., to remove a reference to a repealed Rule 59E-7.012, F.A.C. Rules 59E-7.011-7.020, F.A.C., were repealed and replaced with Rules 59E-7.021-7.030, F.A.C.

[14] Chapter No. 2019-116, s. 38, Laws of Fla.
[15] *Id.*
[16] Agency for Health Care Administration, *Senate Bill 1726 Agency Analysis* (on file with the Senate Committee on Health Policy).
[17] *Id.*
[18] *Id.*
[19] *Id.*

Low-Risk Providers and Licensure Inspections

Section 23 amends s. 408.803, F.S., to define the term "low-risk provider" as nurse registries, home medical equipment providers, and health care clinics. The AHCA has determined these specific provider types to be low-risk with infrequently cited deficiencies.[20] This section of the bill also conforms a provision to changes made in Section 42 of the bill.

Section 24 amends s. 408.806, F.S., to exempt low-risk providers from an initial licensure inspection as required under s. 408.811, F.S.

Section 27 amends s. 408.811, F.S., to authorize the AHCA to exempt a low-risk provider from licensure inspections if the provider or controlling interest has an excellent regulatory history with regard to deficiencies, sanctions, complains, and other regulatory actions, as defined by the AHCA in rule. Under the bill, the AHCA is required to conduct unannounced licensure inspections for at least 10 percent of exempt low-risk providers.

The bill also authorizes the AHCA to adopt rules to waive routine inspections and inspections for relicensure or to allow for an extended period between relicensure inspections for specific providers based upon:

- A favorable regulatory history with regard to deficiencies, sanctions, complaints, and other regulatory measures.
- Outcome measures that demonstrate quality performance.
- Successful participation in a recognized quality assurance program.
- Accreditation status.
- Other measures reflective of quality and safety.
- The length of time between inspections.

With these changes, a provider will not necessarily have to meet any specific statutory requirement for the AHCA to waive the routine inspection. The AHCA's rules must base the decision to grant a waiver upon one or all of the factors listed above.

As it does with low-risk providers, the bill also requires the AHCA to conduct unannounced licensure inspections for at least 10 percent of providers that qualify for a waiver or extended period between licensure inspections.

Provisional Licenses for Health Care Facilities

Section 408.808(2), F.S., currently authorizes the AHCA to issue a provisional license for health care providers regulated under ch. 408, F.S., to a provider applying for a change of ownership or to a provider that is in litigation with the AHCA regarding the denial or revocation of its license.

Section 429.11(6), F.S., currently authorizes the AHCA to issue a provisional license for an assisted living facility when the provider is making an initial application for licensure.

[20] *Id.*

Section 25 amends s. 408.808(2), F.S., to authorize the AHCA to issue a provisional license to an applicant for initial licensure as a health care provider under ch. 408, F.S., in addition to applicants for a change of ownership.

Section 39 amends s. 429.11(6), F.S., to remove provisions authorizing the AHCA to issue a provisional license to an assisted living facility because the AHCA would be authorized to issue a provisional licensed to an assisted living facility through the bill's changes to s. 408.808, F.S.

Background Screening Requirements for Health Care Providers and Employees

Seven state agencies participate in the Care Providers Background Screening Clearinghouse authorized in ch. 435, F.S. **Section 26** amends s. 408.809(2), F.S., to remove an obsolete provision relating to agencies that were once in the process of joining the Clearinghouse. All seven agencies are now fully implemented in the Clearinghouse.

Section 26 also amends s. 408.809(5), F.S., to remove an expired provision that allowed for an employee who becomes disqualified from employment because of legislation that created a new disqualifying offense, to continue to work pending the employee's request for an exemption from disqualification. That authority expired in 2014.

Section 36 amends s. 409.907, F.S., to revise background screening requirements for Medicaid providers. This section of the bill requires a new level 2 background screening to be conducted through the AHCA for certain persons who render services to Medicaid recipients, who have direct access to Medicaid recipients, recipient living areas, or the financial, medical or service records of a Medicaid recipient, or who supervises the delivery of goods or services to a Medicaid recipient. This change aligns the background screening requirements of this chapter with those for licensees in ch. 408, F.S.

Comprehensive Emergency Management Plans

Different provider types are subject to different comprehensive emergency management plan requirements in their authorizing statutes. Assisted living facilities are required to get plan approval by local emergency management officials before they may be licensed. The AHCA indicates that some local jurisdictions refuse to review a plan until the provider is licensed.[21] This makes it impossible for providers within those jurisdictions to become lawfully licensed.

Section 29 amends s. 408.821, F.S., to require providers that are required by authorizing statutes and AHCA rule to have a comprehensive emergency management plan to:

- Submit the plan to the local emergency management agency, county health department, or Department of Health within 30 days after initial licensure and change of ownership, and notify the AHCA within 30 days after submission of the plan.
- Submit the plan to the local emergency management agency, county health department, or Department of Health annually and within 30 days after any significant modification, as defined by AHCA rule, to a previously approved plan.

[21] *Id.*

- Respond to the local emergency management agency, county health department, or Department of Health with necessary plan revisions within 30 days after notification that plan revisions are required.
- Notify the AHCA within 30 days after approval of its plan by the local emergency management agency, county health department, or Department of Health.

These changes establish consistent timeframes for the submission and review of comprehensive emergency management plans among provider types. This change allows for the licensure of a facility before its comprehensive emergency management plan is approved.

The Medicaid Program's Retrospective Review of Hospital Inpatient Admissions

The AHCA performs routine pre- and post-payment claim reviews to determine the appropriateness of Medicaid provider reimbursement.[22]

Section 34 amends s. 409.905(5), F.S., to clarify that a specific provision in paragraph (a) of that subsection may not be construed to prevent the AHCA from conducting retrospective reviews in its efforts to combat Medicaid fraud and abuse and to recoup overpayments in the Medicaid Program.

The provision of current law that the bill seeks to clarify was enacted under ch. 2001-104, L.O.F. Before the enactment of that law, the AHCA had statutory authority to prior authorize inpatient hospital admissions for Medicaid patients with psychiatric and substance abuse diagnoses. However, there was no specific authority for the AHCA to prior authorize inpatient hospital admissions for any other diagnoses.[23]

In lieu of prior authorization of inpatient hospital admissions for general acute care Medicaid services, the Medicaid Program was under contract in 2001 with a peer review organization for retrospective review of such admissions. If those retrospective reviews encountered inpatient admissions that should have been denied or inpatient services that were provided outside of medical necessity, the AHCA would require the hospital to repay the Medicaid program for the associated costs.[24]

Under ch. 2001-104, L.O.F., the Legislature amended s. 409.905(5)(a), F.S., to give the Medicaid Program authority to prior authorize nonemergency hospital inpatient admissions for individuals 21 years of age or older. The statute was also amended to allow Medicaid to require authorization of emergency and urgent-care admissions within 24 hours after Medicaid patients were admitted under such conditions.

Along with this new authority, the statute was further amended in 2001, in the same paragraph, to require the AHCA, upon implementing the prior authorization program for hospital inpatient services, to discontinue the Medicaid Program's hospital retrospective review efforts.

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[22] *Id.*
[23] *See* Chapter 2001-104, L.O.F., *available at* http://laws.flrules.org/files/Ch_2001-104.pdf (last visited Jan. 30, 2020).
[24] Senate Committee on Health Care, *Senate Staff Analysis and Economic Impact Statement for CS/SB 792* (April 5, 2001), *available at* http://www.flsenate.gov/Session/Bill/2001/792/Analyses/20010792SHC_2001s0792.hc.pdf (last visited Jan. 30, 2020).

CS/SB 1726 specifically addresses this latter provision of the 2001 law to clarify that the required discontinuation of the Medicaid Program's preexisting retrospective review program, which was being conducted in 2001 in lieu of prior authorization, may not be construed to prevent the AHCA's Office of Medicaid Program Integrity (MPI)[25] from conducting retrospective reviews under s. 409.913, F.S.

The Office of Medicaid Program Integrity

Section 409.913, F.S., is entitled, "Oversight of the integrity of the Medicaid program." This section of statute requires the AHCA to:

- Operate a program to oversee the activities of Florida Medicaid recipients, and providers and their representatives, to ensure that fraudulent and abusive behavior and neglect of recipients occur to the minimum extent possible, and to recover overpayments and impose sanctions as appropriate;
- Conduct, or cause to be conducted by contract or otherwise, reviews, investigations, analyses, audits, or any combination thereof, to determine possible fraud, abuse, overpayment, or recipient neglect in the Medicaid program and shall report the findings of any overpayments in audit reports as appropriate; and
- Conduct reviews of provider exceptions to peer group norms and shall, using statistical methodologies, provider profiling, and analysis of billing patterns, detect and investigate abnormal or unusual increases in billing or payment of claims for Medicaid services and medically unnecessary provision of services.

Section 409.913, F.S., further provides that a Medicaid provider is subject to having goods and services that are paid for by the Medicaid program reviewed by an appropriate peer-review organization designated by the AHCA. The written findings of the applicable peer-review organization are admissible in any court or administrative proceeding as evidence of medical necessity or the lack of medical necessity.

MPI and the Medicaid Fraud Control Unit of the Department of Legal Affairs must submit a joint report to the Legislature each January, documenting the results of their work to control Medicaid fraud and abuse and to recover Medicaid overpayments during the previous fiscal year. The report for State Fiscal Year 2018-2019 indicates that overpayments of approximately $32.7 million were identified in that fiscal year, with approximately $13.4 million in accounts-receivable collections and reversals. MPI also prevented approximately $385.2 million in overpayments from occurring during the fiscal year, according to the 2018-2019 report.[26]

The bill clarifies that the Legislature's direction to the AHCA in 2001 to discontinue the Medicaid Program's hospital retrospective review efforts upon implementing its newly-granted authority to prior authorize Medicaid hospital inpatient admissions, may not be construed to

[25] See the Office of Medicaid Program Integrity's web page at https://ahca.myflorida.com/MCHQ/MPI/ (last visited Jan. 30, 2020).
[26] The Agency for Health Care Administration and the Department of Legal Affairs, *Florida's Efforts to Control Medicaid Fraud & Abuse: Fiscal Year 2018-2019* (December 30, 2019) *available at* https://ahca.myflorida.com/MCHQ/MPI/docs/FraudReports/FraudReport2018-19.pdf (last visited Jan. 30, 2020).

prevent MPI from conducting retrospective reviews under s. 409.913, F.S. This provision of the bill takes effect upon becoming law.[27]

Section 35 provides that it is the intent of the Legislature that the amendment to s. 409.905(5)(a), F.S., in Section 34 of the bill, is intended to confirm and clarify existing law.

Legal Fees in Medicaid Program Integrity Cases

Section 37 amends s. 409.913, F.S., to authorize the AHCA to recover legal fees in Medicaid Program Integrity and licensure cases. The AHCA has indicated that it spends significant funds defending Medicaid overpayment cases. The Division of Administrative Hearings (DOAH) ruled that s. 409.913(23)(a), F.S., does not authorize the AHCA to recover full legal fees on Medicaid Program Integrity legal cases.[28] The specific ruling came in DOAH case number 18-5986F involving Covenant Hospice.[29] The case had an overpayment of $637,973.10 and sanction of $127,594.62, and the AHCA was seeking fees and costs in the amount of $330,186.14 as of February 7, 2019.[30] The AHCA has the ability to collect the "costs" amount of the $330,186.14 but not the "fees" amount.[31]

Multiphasic Health Testing Centers

Multiphasic health testing centers, regulated under part I of ch. 483, F.S., are facilities where, in addition to taking specimens from the human body for delivery to registered clinical laboratories for analysis, certain measurements such as height and weight determinations, blood pressure determinations, limited audio and visual tests, and electrocardiograms are also made. These additional services are not required to be provided by licensed personnel but can be provided by a medical assistant that is certified or registered through a national organization. These clinics would also fall under the definition of a health care clinic in part X of ch. 400, F.S., but are exempt since they are already regulated by the AHCA.

Section 44 repeals part I of ch. 483, F.S., relating to multiphasic health testing centers, which thereby repeals the requirements for and the licensing of multiphasic health testing centers as a provider type. Current multiphasic health testing centers would need to become licensed as health care clinics, in accordance with part X of ch. 400, F.S., unless they otherwise qualify for an exemption from health care clinic licensure.

As of January 21, 2020, there were 187 multiphasic health testing centers licensed in Florida. Of these, 69 were owned and operated by Laboratory Corporation of America and 111 were owned

[27] In February 2019, Florida's First District Court of Appeal construed the discontinuation provision in s. 409.905(5)(a), F.S., to mean that the AHCA is "barred from conducting a retrospective review of prior authorization claims" under s. 409.913, F.S., or any other existing statutory authority. See *Lee Memorial Health System Gulf Coast Medical Center v. State of Florida, Agency for Health Care Administration,* 272 So.3d 431 (Fla. 1st DCA 2019). The AHCA reports that, under this ruling: (1) The AHCA is at risk of being required to repay overpayments that have already been recouped by MPI from hospitals, and (2) MPI is prohibited from conducting any hospital retrospective audits, except those relating to suspected fraud or abuse.
[28] *Agency for Health Care Administration v. Covenant Hospice, Inc.,* Case No.18-5986F (Fla. DOAH 2018).
[29] *Id.*
[30] *Id.*
[31] *Id.*

and operated by Quest Diagnostics, including one out-of-state center.[32] Both Laboratory Corporation of America and Quest Diagnostics also own and operate several clinical laboratories throughout the state that are regulated under the federal Clinical Laboratory Improvement Amendments (CLIA).[33] The remaining seven multiphasic health testing centers are owned by Professional Health Examiners, Inc.[34] Services are provided by licensed personnel under the direction of a medical director, and the company does not bill insurance and thus would also be exempt from health care clinic licensure as would those centers owned and operated by clinical laboratories regulated under the federal CLIA.[35]

Under current law, the AHCA assesses multiphasic health testing centers with a biennial licensure fee of $652.64 and a biennial health care assessment fee of $300 on multiphasic health testing centers. The AHCA collects an estimated $89,071.84 annually ($178,143.68 biennially) from 187 multiphasic health testing centers, roughly half of which renew each year.[36]

Since 2011, there have been six fine cases imposed against multiphasic health testing centers.[37] In this timeframe, only 10 complaints were received with none substantiated while 195 deficiencies have been cited since 2011.[38]

Sections 17, 22, 28, 30, and 31 amend ss. 408.033, 408.802, s. 408.820, 408.831, and 408.832, F.S., to delete references to multiphasic health testing centers or chapter 483, to conform to changes made by Section 42 of the bill, which repeals part I of ch. 483, F.S., relating to multiphasic health testing centers.

Managed Care Plan Contracts

Section 38 amends s. 409.967, F.S. to require the AHCA to establish a 6-year, rather than a 5-year, contract with each managed care plan selected through the procurement process. It also requires the AHCA to extend the term of contracts awarded to managed care plans pursuant to the invitation to negotiate published in July 2017, through December 31, 2024, effectively extending the duration of those contracts by one year.

Cross-references

Sections 45-50 amend ss. 20.43, 381.0034, 456.001, 456.057, 456.076, and 456.47, F.S., to conform cross-references to changes made by the bill.

Effective Date

Section 51 provides that except as otherwise expressly provided in the bill and except for this section, which will take effect upon the bill becoming a law, the bill will take effect July 1, 2020.

[32] Agency for Health Care Administration, *Senate Bill 1726 Agency Analysis* (on file with the Senate Committee on Health Policy).
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] *Id.*

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:

Article VII, section 19, of the State Constitution requires that a new state tax or fee, as well as an increased state tax or fee, be approved by two-thirds of the membership of each house of the Legislature and be contained in a separate bill that contains no other subject. Article VII, section 19(d)(1), of the State Constitution defines "fee" to mean "any charge or payment required by law, including any fee for service, fee or cost for licenses, and charge for service."

Currently, an individual could employ health care personnel for the provision of home health services without having to obtain a license. Section 6 of the bill amends s. 400.462, F.S., to require such an individual to obtain a home health agency license by paying the licensure fee required in s. 400.471(5), F.S. This fee is an existing statutory fee that is not being increased; however, the bill expands the scope of licensure of a home health agency which expands the application of the licensure fee.

It is unclear if Article VII, section 19, applies to this bill. As such, the State Constitution may require that the fees be passed in a separate bill by a two-thirds vote of the membership of each house of the Legislature.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

By excluding additional providers from health care clinic licensure, those providers will not be required to pay the $2,000 biennial clinic licensure fee.

Multiphasic health testing centers would no longer have to pay licensure fees to be licensed as a multiphasic health testing center, although some of these centers will need to pay licensure fees to become licensed as a heath care clinic.

Nursing home facilities that are cited for certain deficiencies and require additional inspections would only be required to pay a $3,000 fine for an additional inspection rather than the $6,000 fine for two additional inspections as under current law.

C. Government Sector Impact:

Under CS/SB 1726:

- Exempting Medicaid providers from health care clinic law will result in a cost avoidance. The exemptions created in the bill would eliminate the need for the 13 employees requested by the AHCA in its legislative budget request to process health care clinic licensure applications.[39]
- The AHCA will be able to recover legal fees in Medicaid Program Integrity and licensure cases. The AHCA would likely experience a positive fiscal impact from this, although the amount of legal fees arising from future litigation is indeterminate.
- A loss of $89,071.84 per year will occur in licensure fees from the repeal of multiphasic health testing center licensure.[40]

The AHCA will experience a reduction in workload from removing requirements that the AHCA submit various reports to the Governor and the Legislature.

VI. Technical Deficiencies:

Section 27 of the bill amends s. 408.811, F.S., to authorize the AHCA to adopt rules to waive routine inspections and inspections for relicensure or to allow for an extended period between relicensure inspections for specific providers based upon a list of factors. It is unclear as to whether one or all of the listed factors are intended to be included in the decision to grant a waiver under the bill.

The bill's amendment to s. 409.905(5)(a), F.S., in Section 34 of the bill, takes effect upon becoming a law. Section 35 of the bill provides legislative intent for the changes made in Section 34; however, Section 35 will not take effect until July 1, 2020. Sections 34 and 35 should take effect at the same time.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 20.43, 381.0034, 383.327, 395.003, 395.7016, 400.19, 400.462, 400.464, 400.471, 400.492, 400.506, 400.509,

[39] *Id.*
[40] *Id.*

400.605, 400.60501, 400.9905, 400.991, 400.9935, 408.033, 408.061, 408.0611, 408.062, 408.063, 408.802, 408.803, 408.806, 408.808, 408.809, 408.811, 408.820, 408.821, 408.831, 408.832, 408.909, 408.9091, 409.905, 409.907, 409.913, 429.11, 429.19, 429.35, 429.905, 429.929, 456.001, 456.057, 456.076, and 456.47.

This bill repeals section 395.7015 and part I of chapter 483 of the Florida Statutes

IX. Additional Information:

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

CS by Health Policy on January 28, 2020:
The CS:

- Changes a reference from chapter 624 to chapter 627 to revise and make permanent an exemption from health care clinic licensure for entities owned by an insurance holding company with over $1 billion in annual sales.
- Clarifies that the Legislature's 2001 direction to the AHCA under s. 409.905(5)(a), F.S., to discontinue the Medicaid Program's hospital retrospective review program upon implementing its new authority (also granted in 2001) to prior authorize Medicaid hospital inpatient admissions, may not be construed to prevent MPI from conducting retrospective reviews under s. 409.913, F.S. This provision of the bill takes effect upon becoming law.
- Provides that it is the intent of the Legislature that the bill's amendment to s. 409.905(5)(a), F.S., is intended to confirm and clarify existing law
- Requires the AHCA to establish a six-year, rather than a five-year, contract with each managed care plan selected through the procurement process. Requires the AHCA to extend the term of contracts awarded to managed care plans pursuant to the invitation to negotiate published in July 2017, through December 31, 2024.
- Changes the effective date of the bill to allow for certain sections to take effect upon becoming a law as expressly provided. Unless expressly provided, the bill takes effect on July 1, 2020.

B. Amendments:

None.

By Senator Bean

4-00874E-20 20201726__

A bill to be entitled

An act relating to the Agency for Health Care Administration; amending s. 383.327, F.S.; requiring birth centers to report certain deaths and stillbirths to the agency; removing a requirement that a certain report be submitted annually to the agency; authorizing the agency to prescribe by rule the frequency at which such report is submitted; amending s. 395.003, F.S.; removing a requirement that specified information be listed on licenses for certain facilities; repealing s. 395.7015, F.S., relating to an annual assessment on health care entities; amending s. 395.7016, F.S.; conforming a provision to changes made by the act; amending s. 400.19, F.S.; revising provisions requiring the agency to conduct licensure inspections of nursing homes; requiring the agency to conduct additional licensure surveys under certain circumstances; requiring the agency to assess a specified fine for such surveys; amending s. 400.462, F.S.; revising definitions; amending s. 400.464, F.S.; revising licensure requirements for home health agencies; amending s. 400.471, F.S.; revising provisions related to certain application requirements for home health agencies; amending s. 400.492, F.S.; revising provisions related to services provided by home health agencies during an emergency; amending s. 400.506, F.S.; revising provisions related to licensure requirements for nurse registries; amending s. 400.509, F.S.; revising

provisions related to the registration of certain service providers; amending s. 400.605, F.S.; removing a requirement that the agency conduct specified inspections of certain licensees; amending s. 400.60501, F.S.; deleting an obsolete date; removing a requirement that the agency develop a specified annual report; amending s. 400.9905, F.S.; revising the definition of the term "clinic"; amending s. 400.991, F.S.; removing the option for health care clinics to file a surety bond under certain circumstances; amending s. 400.9935, F.S.; removing a requirement that certain directors conduct specified reviews; requiring certain clinics to publish and post a schedule of charges; amending s. 408.033, F.S.; conforming a provision to changes made by the act; amending s. 408.061, F.S.; revising provisions requiring health care facilities to submit specified data to the agency; amending s. 408.0611, F.S.; removing the requirement that the agency annually report to the Governor and the Legislature by a specified date on the progress of implementation of electronic prescribing; amending s. 408.062, F.S.; removing requirements that the agency annually report specified information to the Governor and Legislature by a specified date and, instead, requiring the agency to annually publish such information on its website; amending s. 408.063, F.S.; removing a requirement that the agency publish certain annual reports; amending s. 408.803, F.S.; conforming a definition to changes made

by the act; defining the term "low-risk provider"; amending ss. 408.802, 408.820, 408.831, and 408.832, F.S.; conforming provisions to changes made by the act; amending s. 408.806, F.S.; exempting certain providers from a specified inspection; amending s. 408.808, F.S.; authorizing the issuance of a provisional license to certain applicants; amending ss. 408.809 and 409.907, F.S.; revising background screening requirements for certain licensees and providers; amending s. 408.811, F.S.; authorizing the agency to grant certain providers an exemption from a specified inspection under certain circumstances; authorizing the agency to adopt rules to grant waivers of certain inspections and extended inspection periods under certain circumstances; amending s. 408.821, F.S.; revising provisions requiring licensees to have a specified plan; providing requirements for the submission of such plan; amending s. 408.909, F.S.; removing a requirement that the agency and Office of Insurance Regulation evaluate a specified program; amending s. 408.9091, F.S.; requiring the agency and office to each, instead of jointly, submit a specified annual report to the Governor and Legislature; amending s. 409.905, F.S.; deleting the requirement that the agency discontinue its hospital retrospective review program under certain circumstances; amending s. 409.913, F.S.; revising the due date for a certain annual report; deleting the requirement that certain agencies submit their annual reports jointly; amending

s. 429.11, F.S.; removing an authorization for the issuance of a provisional license to certain facilities; amending s. 429.19, F.S.; removing requirements that the agency develop and disseminate a specified list and the Department of Children and Families disseminate such list to certain providers; amending ss. 429.35, 429.905, and 429.929, F.S.; revising provisions requiring a biennial inspection cycle for specified facilities and centers, respectively; repealing part I of ch. 483, F.S., relating to the Florida Multiphasic Health Testing Center Law; redesignating parts II and III of ch. 483, F.S., as parts I and II, respectively; amending ss. 20.43, 381.0034, 456.001, 456.057, 456.076, and 456.47, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Subsections (2) and (4) of section 383.327, Florida Statutes, are amended to read:

383.327 Birth and death records; reports.—

(2) Each maternal death, newborn death, and stillbirth shall be reported immediately to the medical examiner and the agency.

(4) A report shall be submitted ~~annually~~ to the agency. The contents of the report and the frequency with which it is submitted shall be prescribed by rule of the agency.

Section 2. Subsection (4) of section 395.003, Florida

Statutes, is amended to read:

395.003 Licensure; denial, suspension, and revocation.—

(4) The agency shall issue a license that ~~which~~ specifies the service categories and the number of hospital beds in each bed category for which a license is received. Such information shall be listed on the face of the license. ~~All beds which are not covered by any specialty-bed-need methodology shall be specified as general beds.~~ A licensed facility shall not operate a number of hospital beds greater than the number indicated by the agency on the face of the license without approval from the agency under conditions established by rule.

Section 3. Section 395.7015, Florida Statutes, is repealed.

Section 4. Section 395.7016, Florida Statutes, is amended to read:

395.7016 Annual appropriation.—The Legislature shall appropriate each fiscal year from either the General Revenue Fund or the Agency for Health Care Administration Tobacco Settlement Trust Fund an amount sufficient to replace the funds lost due to ~~reduction by chapter 2000-256, Laws of Florida, of the assessment on other health care entities under s. 395.7015,~~ ~~and~~ the reduction by chapter 2000-256, Laws of Florida, in the assessment on hospitals under s. 395.701~~,~~ and to maintain federal approval of the reduced amount of funds deposited into the Public Medical Assistance Trust Fund under s. 395.701~~,~~ as state match for the state's Medicaid program.

Section 5. Subsection (3) of section 400.19, Florida Statutes, is amended to read:

400.19 Right of entry and inspection.—

(3) The agency shall conduct periodic, ~~every 15 months~~

~~conduct at least one~~ unannounced licensure inspections ~~inspection~~ to determine compliance by the licensee with statutes, and with rules adopted ~~promulgated~~ under ~~the provisions of~~ those statutes, governing minimum standards of construction, quality and adequacy of care, and rights of residents. ~~The survey shall be conducted every 6 months for the next 2-year period~~ If the facility has been cited for a class I deficiency or~~,~~ has been cited for two or more class II deficiencies ~~arising from separate surveys or investigations~~ within a 60-day period, the agency shall conduct an additional licensure survey ~~or has had three or more substantiated complaints within a 6-month period, each resulting in at least one class I or class II deficiency~~. In addition to any other fees or fines in this part, the agency shall assess a fine for each facility that is subject to the additional licensure survey ~~6-month survey cycle~~. The fine for the additional licensure survey is $3,000 ~~2-year period shall be $6,000, one-half to be paid at the completion of each survey~~. The agency may adjust such ~~this~~ fine by the change in the Consumer Price Index, based on the 12 months immediately preceding the increase, to cover the cost of the additional surveys. The agency shall verify through subsequent inspection that any deficiency identified during inspection is corrected. However, the agency may verify the correction of a class III or class IV deficiency unrelated to resident rights or resident care without reinspecting the facility if adequate written documentation has been received from the facility, which provides assurance that the deficiency has been corrected. The giving or causing to be given of advance notice of such unannounced inspections by an employee of the

agency to any unauthorized person shall constitute cause for suspension of not fewer than 5 working days according to ~~the provisions of~~ chapter 110.

Section 6. Subsections (12), (14), (17), (21), and (22) of section 400.462, Florida Statutes, are amended to read:

400.462 Definitions.—As used in this part, the term:

(12) "Home health agency" means a person or an entity ~~an organization~~ that provides one or more home health services ~~and staffing services~~.

(14) "Home health services" means health and medical services and medical supplies furnished ~~by an organization~~ to an individual in the individual's home or place of residence. The term includes ~~organizations that provide one or more of~~ the following:

(a) Nursing care.

(b) Physical, occupational, respiratory, or speech therapy.

(c) Home health aide services.

(d) Dietetics and nutrition practice and nutrition counseling.

(e) Medical supplies, restricted to drugs and biologicals prescribed by a physician.

(17) "Home infusion therapy provider" means a person or an entity ~~an organization~~ that employs, contracts with, or refers a licensed professional who has received advanced training and experience in intravenous infusion therapy and who administers infusion therapy to a patient in the patient's home or place of residence.

(21) "Nurse registry" means any person or entity that procures, offers, promises, or attempts to secure health-care-

related contracts for registered nurses, licensed practical nurses, certified nursing assistants, home health aides, companions, or homemakers, who are compensated by fees as independent contractors, including, but not limited to, contracts for the provision of services to patients and contracts to provide private duty or staffing services to health care facilities licensed under chapter 395, this chapter, or chapter 429 or other business entities.

~~(22) "Organization" means a corporation, government or governmental subdivision or agency, partnership or association, or any other legal or commercial entity, any of which involve more than one health care professional discipline; a health care professional and a home health aide or certified nursing assistant; more than one home health aide; more than one certified nursing assistant; or a home health aide and a certified nursing assistant. The term does not include an entity that provides services using only volunteers or only individuals related by blood or marriage to the patient or client.~~

Section 7. Subsections (1), (4), and (5) of section 400.464, Florida Statutes, are amended to read:

400.464 Home health agencies to be licensed; expiration of license; exemptions; unlawful acts; penalties.—

(1) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to this part and part II of chapter 408 and entities licensed or registered by or applying for such licensure or registration from the Agency for Health Care Administration pursuant to this part. A license issued by the agency is required in order to operate a home health agency in this state. A license issued on

or after July 1, 2018, must specify the home health services the licensee ~~organization~~ is authorized to perform and indicate whether such specified services are considered skilled care. The provision or advertising of services that require licensure pursuant to this part without such services being specified on the face of the license issued on or after July 1, 2018, constitutes unlicensed activity as prohibited under s. 408.812.

(4)(a) A licensee ~~An organization~~ that offers or advertises to the public any service for which licensure or registration is required under this part must include in the advertisement the license number or registration number issued to the licensee ~~organization~~ by the agency. The agency shall assess a fine of not less than $100 to any licensee or registrant who fails to include the license or registration number when submitting the advertisement for publication, broadcast, or printing. The fine for a second or subsequent offense is $500. The holder of a license issued under this part may not advertise or indicate to the public that it holds a home health agency or nurse registry license other than the one it has been issued.

(b) The operation or maintenance of an unlicensed home health agency or the performance of any home health services in violation of this part is declared a nuisance, inimical to the public health, welfare, and safety. The agency or any state attorney may, in addition to other remedies provided in this part, bring an action for an injunction to restrain such violation, or to enjoin the future operation or maintenance of the home health agency or the provision of home health services in violation of this part or part II of chapter 408, until compliance with this part or the rules adopted under this part

has been demonstrated to the satisfaction of the agency.

(c) A person or entity that ~~who~~ violates paragraph (a) is subject to an injunctive proceeding under s. 408.816. A violation of paragraph (a) or s. 408.812 is a deceptive and unfair trade practice and constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act under part II of chapter 501.

(d) A person or entity that ~~who~~ violates ~~the provisions of~~ paragraph (a) commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Any person or entity that ~~who~~ commits a second or subsequent violation commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continuing violation constitutes a separate offense.

(e) Any person or entity that ~~who~~ owns, operates, or maintains an unlicensed home health agency and who, after receiving notification from the agency, fails to cease operation and apply for a license under this part commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continued operation is a separate offense.

(f) Any home health agency that fails to cease operation after agency notification may be fined in accordance with s. 408.812.

(5) The following are exempt from ~~the~~ licensure as a home health agency under ~~requirements of~~ this part:

(a) A home health agency operated by the Federal Government.

(b) Home health services provided by a state agency, either directly or through a contractor with:

1. The Department of Elderly Affairs.

2. The Department of Health, a community health center, or a rural health network that furnishes home visits for the purpose of providing environmental assessments, case management, health education, personal care services, family planning, or followup treatment, or for the purpose of monitoring and tracking disease.

3. Services provided to persons with developmental disabilities, as defined in s. 393.063.

4. Companion and sitter organizations that were registered under s. 400.509(1) on January 1, 1999, and were authorized to provide personal services under a developmental services provider certificate on January 1, 1999, may continue to provide such services to past, present, and future clients of the organization who need such services, notwithstanding the provisions of this act.

5. The Department of Children and Families.

(c) A health care professional, whether or not incorporated, who is licensed under chapter 457; chapter 458; chapter 459; part I of chapter 464; chapter 467; part I, part III, part V, or part X of chapter 468; chapter 480; chapter 486; chapter 490; or chapter 491; and who is acting alone within the scope of his or her professional license to provide care to patients in their homes.

(d) A home health aide or certified nursing assistant who is acting in his or her individual capacity, within the definitions and standards of his or her occupation, and who provides hands-on care to patients in their homes.

(e) An individual who acts alone, in his or her individual

capacity, and who is not employed by or affiliated with a licensed home health agency or registered with a licensed nurse registry. This exemption does not entitle an individual to perform home health services without the required professional license.

(f) The delivery of instructional services in home dialysis and home dialysis supplies and equipment.

(g) The delivery of nursing home services for which the nursing home is licensed under part II of this chapter, to serve its residents in its facility.

(h) The delivery of assisted living facility services for which the assisted living facility is licensed under part I of chapter 429, to serve its residents in its facility.

(i) The delivery of hospice services for which the hospice is licensed under part IV of this chapter, to serve hospice patients admitted to its service.

(j) A hospital that provides services for which it is licensed under chapter 395.

(k) The delivery of community residential services for which the community residential home is licensed under chapter 419, to serve the residents in its facility.

(l) A not-for-profit, community-based agency that provides early intervention services to infants and toddlers.

(m) Certified rehabilitation agencies and comprehensive outpatient rehabilitation facilities that are certified under Title 18 of the Social Security Act.

(n) The delivery of adult family-care home services for which the adult family-care home is licensed under part II of chapter 429, to serve the residents in its facility.

(o) A person or entity that provides skilled care by health care professionals licensed solely under part I of chapter 464; part I, part III, or part V of chapter 468; or chapter 486.

(p) A person or entity that provides services using only volunteers or only individuals related by blood or marriage to the patient or client.

Section 8. Paragraph (g) of subsection (2) of section 400.471, Florida Statutes, is amended to read:

400.471 Application for license; fee.—

(2) In addition to the requirements of part II of chapter 408, the initial applicant, the applicant for a change of ownership, and the applicant for the addition of skilled care services must file with the application satisfactory proof that the home health agency is in compliance with this part and applicable rules, including:

(g) In the case of an application for initial licensure, an application for a change of ownership, or an application for the addition of skilled care services, documentation of accreditation, or an application for accreditation, from an accrediting organization that is recognized by the agency as having standards comparable to those required by this part and part II of chapter 408. A home health agency that does not provide skilled care is exempt from this paragraph. Notwithstanding s. 408.806, the ~~an initial~~ applicant must provide proof of accreditation that is not conditional or provisional and a survey demonstrating compliance with the requirements of this part, part II of chapter 408, and applicable rules from an accrediting organization that is recognized by the agency as having standards comparable to those

required by this part and part II of chapter 408 within 120 days after the date of the agency's receipt of the application for licensure. Such accreditation must be continuously maintained by the home health agency to maintain licensure. The agency shall accept, in lieu of its own periodic licensure survey, the submission of the survey of an accrediting organization that is recognized by the agency if the accreditation of the licensed home health agency is not provisional and if the licensed home health agency authorizes release of, and the agency receives the report of, the accrediting organization.

Section 9. Section 400.492, Florida Statutes, is amended to read:

400.492 Provision of services during an emergency.—Each home health agency shall prepare and maintain a comprehensive emergency management plan that is consistent with the standards adopted by national or state accreditation organizations and consistent with the local special needs plan. The plan shall be updated annually and shall provide for continuing home health services during an emergency that interrupts patient care or services in the patient's home. The plan shall include the means by which the home health agency will continue to provide staff to perform the same type and quantity of services to their patients who evacuate to special needs shelters that were being provided to those patients prior to evacuation. The plan shall describe how the home health agency establishes and maintains an effective response to emergencies and disasters, including: notifying staff when emergency response measures are initiated; providing for communication between staff members, county health departments, and local emergency management agencies, including

a backup system; identifying resources necessary to continue essential care or services or referrals to other health care providers ~~organizations~~ subject to written agreement; and prioritizing and contacting patients who need continued care or services.

(1) Each patient record for patients who are listed in the registry established pursuant to s. 252.355 shall include a description of how care or services will be continued in the event of an emergency or disaster. The home health agency shall discuss the emergency provisions with the patient and the patient's caregivers, including where and how the patient is to evacuate, procedures for notifying the home health agency in the event that the patient evacuates to a location other than the shelter identified in the patient record, and a list of medications and equipment which must either accompany the patient or will be needed by the patient in the event of an evacuation.

(2) Each home health agency shall maintain a current prioritized list of patients who need continued services during an emergency. The list shall indicate how services shall be continued in the event of an emergency or disaster for each patient and if the patient is to be transported to a special needs shelter, and shall indicate if the patient is receiving skilled nursing services and the patient's medication and equipment needs. The list shall be furnished to county health departments and to local emergency management agencies, upon request.

(3) Home health agencies shall not be required to continue to provide care to patients in emergency situations that are

beyond their control and that make it impossible to provide services, such as when roads are impassable or when patients do not go to the location specified in their patient records. Home health agencies may establish links to local emergency operations centers to determine a mechanism by which to approach specific areas within a disaster area in order for the agency to reach its clients. Home health agencies shall demonstrate a good faith effort to comply with the requirements of this subsection by documenting attempts of staff to follow procedures outlined in the home health agency's comprehensive emergency management plan, and by the patient's record, which support a finding that the provision of continuing care has been attempted for those patients who have been identified as needing care by the home health agency and registered under s. 252.355, in the event of an emergency or disaster under subsection (1).

(4) Notwithstanding the provisions of s. 400.464(2) or any other provision of law to the contrary, a home health agency may provide services in a special needs shelter located in any county.

Section 10. Subsection (4) and paragraph (a) of subsection (5) of section 400.506, Florida Statutes, are amended to read:

400.506 Licensure of nurse registries; requirements; penalties.—

(4) A licensee who ~~person that~~ provides, offers, or advertises to the public any service for which licensure is required under this section must include in such advertisement the license number issued to the licensee ~~it~~ by the Agency for Health Care Administration. The agency shall assess a fine of not less than $100 against any licensee who fails to include the

license number when submitting the advertisement for publication, broadcast, or printing. The fine for a second or subsequent offense is $500.

(5)(a) In addition to the requirements of s. 408.812, any person or entity that ~~who~~ owns, operates, or maintains an unlicensed nurse registry and who, after receiving notification from the agency, fails to cease operation and apply for a license under this part commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continued operation is a separate offense.

Section 11. Subsections (1), (2), (4), and (5) of section 400.509, Florida Statutes, are amended to read:

400.509 Registration of particular service providers exempt from licensure; certificate of registration; regulation of registrants.—

(1) Any person or entity ~~organization~~ that provides companion services or homemaker services and does not provide a home health service to a person is exempt from licensure under this part. However, any person or entity ~~organization~~ that provides companion services or homemaker services must register with the agency. A person or an entity ~~An organization~~ under contract with the Agency for Persons with Disabilities which provides companion services only for persons with a developmental disability, as defined in s. 393.063, is exempt from registration.

(2) The requirements of part II of chapter 408 apply to the provision of services that require registration or licensure pursuant to this section and part II of chapter 408 and entities registered by or applying for such registration from the Agency

for Health Care Administration pursuant to this section. Each applicant for registration and each registrant must comply with all provisions of part II of chapter 408. Registration or a license issued by the agency is required for a person or an entity to provide ~~the operation of an organization that provides~~ companion services or homemaker services.

(4) Each registrant must obtain the employment or contract history of persons who are employed by or under contract with the person or entity ~~organization~~ and who will have contact at any time with patients or clients in their homes by:

(a) Requiring such persons to submit an employment or contractual history to the registrant; and

(b) Verifying the employment or contractual history, unless through diligent efforts such verification is not possible. The agency shall prescribe by rule the minimum requirements for establishing that diligent efforts have been made.

There is no monetary liability on the part of, and no cause of action for damages arises against, a former employer of a prospective employee of or prospective independent contractor with a registrant who reasonably and in good faith communicates his or her honest opinions about the former employee's or contractor's job performance. This subsection does not affect the official immunity of an officer or employee of a public corporation.

(5) A person or an entity that offers or advertises to the public a service for which registration is required must include in its advertisement the registration number issued by the Agency for Health Care Administration.

Section 12. Subsection (3) of section 400.605, Florida Statutes, is amended to read:

400.605 Administration; forms; fees; rules; inspections; fines.—

(3) In accordance with s. 408.811, the agency shall conduct ~~annual inspections of all licensees, except that licensure inspections may be conducted biennially for hospices having a 3-year record of substantial compliance. The agency shall conduct~~ such inspections and investigations as are necessary in order to determine the state of compliance with ~~the provisions of~~ this part, part II of chapter 408, and applicable rules.

Section 13. Section 400.60501, Florida Statutes, is amended to read:

400.60501 Outcome measures; adoption of federal quality measures; public reporting~~; annual report~~.—

(1) ~~No later than December 31, 2019,~~ The agency shall adopt the national hospice outcome measures and survey data in 42 C.F.R. part 418 to determine the quality and effectiveness of hospice care for hospices licensed in the state.

(2) The agency shall~~:~~

~~(a)~~ make available to the public the national hospice outcome measures and survey data in a format that is comprehensible by a layperson and that allows a consumer to compare such measures of one or more hospices.

~~(b) Develop an annual report that analyzes and evaluates the information collected under this act and any other data collection or reporting provisions of law.~~

Section 14. Subsection (4) of section 400.9905, Florida Statutes, is amended to read:

400.9905 Definitions.—

(4) "Clinic" means an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider. As used in this part, the term does not include and the licensure requirements of this part do not apply to:

(a) Entities licensed or registered by the state under chapter 395; entities licensed or registered by the state and providing only health care services within the scope of services authorized under their respective licenses under ss. 383.30-383.332, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified and providing only health care services within the scope of services authorized under their respective certifications under 42 C.F.R. part 485, subpart B, ~~or~~ subpart H, or subpart J; providers certified and providing only health care services within the scope of services authorized under their respective certifications under 42 C.F.R. part 486, subpart C; providers certified and providing only health care services within the scope of services authorized under their respective certifications under 42 C.F.R. part 491, subpart A; providers certified by the Centers for Medicare and Medicaid services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder; or any entity that provides neonatal or pediatric hospital-based health care services or other health care services by licensed

practitioners solely within a hospital licensed under chapter 395.

(b) Entities that own, directly or indirectly, entities licensed or registered by the state pursuant to chapter 395; entities that own, directly or indirectly, entities licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified and providing only health care services within the scope of services authorized under their respective certifications under 42 C.F.R. part 485, subpart B, ~~or~~ subpart H, or subpart J; providers certified and providing only health care services within the scope of services authorized under their respective certifications under 42 C.F.R. part 486, subpart C; providers certified and providing only health care services within the scope of services authorized under their respective certifications under 42 C.F.R. part 491, subpart A; providers certified by the Centers for Medicare and Medicaid services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.

(c) Entities that are owned, directly or indirectly, by an entity licensed or registered by the state pursuant to chapter

395; entities that are owned, directly or indirectly, by an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified and providing only health care services within the scope of services authorized under their respective certifications under 42 C.F.R. part 485, subpart B, ~~or~~ subpart H, or subpart J; providers certified and providing only health care services within the scope of services authorized under their respective certifications under 42 C.F.R. part 486, subpart C; providers certified and providing only health care services within the scope of services authorized under their respective certifications under 42 C.F.R. part 491, subpart A; providers certified by the Centers for Medicare and Medicaid services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital under chapter 395.

(d) Entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state pursuant to chapter 395; entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their

respective licenses under ss. 383.30-383.332, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified and providing only health care services within the scope of services authorized under their respective certifications under 42 C.F.R. part 485, subpart B, ~~or~~ subpart H, or subpart J; providers certified and providing only health care services within the scope of services authorized under their respective certifications under 42 C.F.R. part 486, subpart C; providers certified and providing only health care services within the scope of services authorized under their respective certifications under 42 C.F.R. part 491, subpart A; providers certified by the Centers for Medicare and Medicaid services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.

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

(f) A sole proprietorship, group practice, partnership, or corporation that provides health care services by physicians covered by s. 627.419, that is directly supervised by one or more of such physicians, and that is wholly owned by one or more of those physicians or by a physician and the spouse, parent, child, or sibling of that physician.

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

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

(i) Entities that provide only oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 or entities that provide oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 which are owned by a corporation whose shares are publicly traded on a recognized stock exchange.

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

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

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

(m) Entities that are owned by a corporation that has $250 million or more in total annual sales of health care services provided by licensed health care practitioners where one or more of the persons responsible for the operations of the entity is a

health care practitioner who is licensed in this state and who is responsible for supervising the business activities of the entity and is responsible for the entity's compliance with state law for purposes of this part.

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

(o) Entities that are, directly or indirectly, under the

common ownership of or that are subject to common control by a mutual insurance holding company, as defined in s. 628.703, with an entity licensed or certified under chapter 624 or chapter 641 which has $1 billion or more in total annual sales in this state.

(p) Entities that are owned by an entity that is a behavioral health service provider in at least 5 states other than Florida and that, together with its affiliates, has $90 million or more in total annual revenues associated with the provision of behavioral health services and where one or more of the persons responsible for the operations of the entity is a health care practitioner who is licensed in this state and who is responsible for supervising the business activities of the entity and who is responsible for the entity's compliance with state law for purposes of this part.

(q) Medicaid providers.

Notwithstanding this subsection, an entity shall be deemed a clinic and must be licensed under this part in order to receive reimbursement under the Florida Motor Vehicle No-Fault Law, ss. 627.730-627.7405, unless exempted under s. 627.736(5)(h).

Section 15. Paragraph (c) of subsection (3) of section 400.991, Florida Statutes, is amended to read:

400.991 License requirements; background screenings; prohibitions.—

(3) In addition to the requirements of part II of chapter 408, the applicant must file with the application satisfactory proof that the clinic is in compliance with this part and applicable rules, including:

(c) Proof of financial ability to operate as required under ss. 408.8065(1) and 408.810(8) ~~s. 408.810(8). As an alternative to submitting proof of financial ability to operate as required under s. 408.810(8), the applicant may file a surety bond of at least $500,000 which guarantees that the clinic will act in full conformity with all legal requirements for operating a clinic, payable to the agency. The agency may adopt rules to specify related requirements for such surety bond~~.

Section 16. Paragraph (i) of subsection (1) of section 400.9935, Florida Statutes, is amended to read:

400.9935 Clinic responsibilities.—

(1) Each clinic shall appoint a medical director or clinic director who shall agree in writing to accept legal responsibility for the following activities on behalf of the clinic. The medical director or the clinic director shall:

(i) Ensure that the clinic publishes a schedule of charges for the medical services offered to patients. The schedule must include the prices charged to an uninsured person paying for such services by cash, check, credit card, or debit card. The schedule may group services by price levels, listing services in each price level. The schedule must be posted in a conspicuous place in the reception area of any clinic that is an ~~the~~ urgent care center as defined in s. 395.002(29)(b) and must include, but is not limited to, the 50 services most frequently provided by the clinic. ~~The schedule may group services by three price levels, listing services in each price level.~~ The posting may be a sign that must be at least 15 square feet in size or through an electronic messaging board that is at least 3 square feet in size. The failure of a clinic, including a clinic that is an

urgent care center, to publish and post a schedule of charges as required by this section shall result in a fine of not more than $1,000, per day, until the schedule is published and posted.

Section 17. Paragraph (a) of subsection (2) of section 408.033, Florida Statutes, is amended to read:

408.033 Local and state health planning.—

(2) FUNDING.—

(a) The Legislature intends that the cost of local health councils be borne by assessments on selected health care facilities subject to facility licensure by the Agency for Health Care Administration, including abortion clinics, assisted living facilities, ambulatory surgical centers, birth centers, home health agencies, hospices, hospitals, intermediate care facilities for the developmentally disabled, nursing homes, and health care clinics, ~~and multiphasic testing centers~~ and by assessments on organizations subject to certification by the agency pursuant to chapter 641, part III, including health maintenance organizations and prepaid health clinics. Fees assessed may be collected prospectively at the time of licensure renewal and prorated for the licensure period.

Section 18. Paragraph (a) of subsection (1) of section 408.061, Florida Statutes, is amended to read:

408.061 Data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.—

(1) The agency shall require the submission by health care facilities, health care providers, and health insurers of data necessary to carry out the agency's duties and to facilitate transparency in health care pricing data and quality measures.

Specifications for data to be collected under this section shall be developed by the agency and applicable contract vendors, with the assistance of technical advisory panels including representatives of affected entities, consumers, purchasers, and such other interested parties as may be determined by the agency.

(a) Data submitted by health care facilities, including the facilities as defined in chapter 395, shall include, but are not limited to, ~~:~~ case-mix data, patient admission and discharge data, hospital emergency department data which shall include the number of patients treated in the emergency department of a licensed hospital reported by patient acuity level, data on hospital-acquired infections as specified by rule, data on complications as specified by rule, data on readmissions as specified by rule, including patient- ~~with patient~~ and provider-specific identifiers ~~included~~, actual charge data by diagnostic groups or other bundled groupings as specified by rule, financial data, accounting data, operating expenses, expenses incurred for rendering services to patients who cannot or do not pay, interest charges, depreciation expenses based on the expected useful life of the property and equipment involved, and demographic data. The agency shall adopt nationally recognized risk adjustment methodologies or software consistent with the standards of the Agency for Healthcare Research and Quality and as selected by the agency for all data submitted as required by this section. Data may be obtained from documents including ~~such as~~, but not limited to, ~~:~~ leases, contracts, debt instruments, itemized patient statements or bills, medical record abstracts, and related diagnostic information. ~~Reported~~ Data elements shall

be reported electronically in accordance with the inpatient data reporting instructions as prescribed by agency rule ~~59E-7.012, Florida Administrative Code~~. Data submitted shall be certified by the chief executive officer or an appropriate and duly authorized representative or employee of the licensed facility that the information submitted is true and accurate.

Section 19. Subsection (4) of section 408.0611, Florida Statutes, is amended to read:

408.0611 Electronic prescribing clearinghouse.—

(4) Pursuant to s. 408.061, the agency shall monitor the implementation of electronic prescribing by health care practitioners, health care facilities, and pharmacies. ~~By January 31 of each year,~~ The agency shall report annually on its website on the progress of implementation of electronic prescribing ~~to the Governor and the Legislature~~. Information reported pursuant to this subsection must ~~shall~~ include federal and private sector electronic prescribing initiatives and, to the extent that data is readily available from organizations that operate electronic prescribing networks, the number of health care practitioners using electronic prescribing and the number of prescriptions electronically transmitted.

Section 20. Paragraphs (i) and (j) of subsection (1) of section 408.062, Florida Statutes, are amended to read:

408.062 Research, analyses, studies, and reports.—

(1) The agency shall conduct research, analyses, and studies relating to health care costs and access to and quality of health care services as access and quality are affected by changes in health care costs. Such research, analyses, and studies shall include, but not be limited to:

(i) The use of emergency department services by patient acuity level ~~and the implication of increasing hospital cost by providing nonurgent care in emergency departments~~. The agency shall publish annually on its website information ~~submit an annual report~~ based on this monitoring and assessment ~~to the Governor, the Speaker of the House of Representatives, the President of the Senate, and the substantive legislative committees, due January 1~~.

(j) The making available on its Internet website, and in a hard-copy format upon request, of patient charge, volumes, length of stay, and performance indicators collected from health care facilities pursuant to s. 408.061(1)(a) for specific medical conditions, surgeries, and procedures provided in inpatient and outpatient facilities as determined by the agency. In making the determination of specific medical conditions, surgeries, and procedures to include, the agency shall consider such factors as volume, severity of the illness, urgency of admission, individual and societal costs, and whether the condition is acute or chronic. Performance outcome indicators shall be risk adjusted or severity adjusted, as applicable, using nationally recognized risk adjustment methodologies or software consistent with the standards of the Agency for Healthcare Research and Quality and as selected by the agency. The website shall also provide an interactive search that allows consumers to view and compare the information for specific facilities, a map that allows consumers to select a county or region, definitions of all of the data, descriptions of each procedure, and an explanation about why the data may differ from facility to facility. Such public data shall be updated

quarterly. The agency shall publish annually on its website information ~~submit an annual status report~~ on the collection of data and publication of health care quality measures ~~to the Governor, the Speaker of the House of Representatives, the President of the Senate, and the substantive legislative committees, due January 1~~.

Section 21. Subsection (5) of section 408.063, Florida Statutes, is amended to read:

408.063 Dissemination of health care information.—

~~(5) The agency shall publish annually a comprehensive report of state health expenditures. The report shall identify:~~

~~(a) The contribution of health care dollars made by all payors.~~

~~(b) The dollars expended by type of health care service in Florida.~~

Section 22. Section 408.802, Florida Statutes, is amended to read:

408.802 Applicability. ~~The provisions of~~ This part applies ~~apply~~ to the provision of services that require licensure as defined in this part and to the following entities licensed, registered, or certified by the agency, as described in chapters 112, 383, 390, 394, 395, 400, 429, 440, ~~483,~~ and 765:

(1) Laboratories authorized to perform testing under the Drug-Free Workplace Act, as provided under ss. 112.0455 and 440.102.

(2) Birth centers, as provided under chapter 383.

(3) Abortion clinics, as provided under chapter 390.

(4) Crisis stabilization units, as provided under parts I and IV of chapter 394.

(5) Short-term residential treatment facilities, as provided under parts I and IV of chapter 394.

(6) Residential treatment facilities, as provided under part IV of chapter 394.

(7) Residential treatment centers for children and adolescents, as provided under part IV of chapter 394.

(8) Hospitals, as provided under part I of chapter 395.

(9) Ambulatory surgical centers, as provided under part I of chapter 395.

(10) Nursing homes, as provided under part II of chapter 400.

(11) Assisted living facilities, as provided under part I of chapter 429.

(12) Home health agencies, as provided under part III of chapter 400.

(13) Nurse registries, as provided under part III of chapter 400.

(14) Companion services or homemaker services providers, as provided under part III of chapter 400.

(15) Adult day care centers, as provided under part III of chapter 429.

(16) Hospices, as provided under part IV of chapter 400.

(17) Adult family-care homes, as provided under part II of chapter 429.

(18) Homes for special services, as provided under part V of chapter 400.

(19) Transitional living facilities, as provided under part XI of chapter 400.

(20) Prescribed pediatric extended care centers, as

provided under part VI of chapter 400.

(21) Home medical equipment providers, as provided under part VII of chapter 400.

(22) Intermediate care facilities for persons with developmental disabilities, as provided under part VIII of chapter 400.

(23) Health care services pools, as provided under part IX of chapter 400.

(24) Health care clinics, as provided under part X of chapter 400.

~~(25) Multiphasic health testing centers, as provided under part I of chapter 483.~~

(25)~~(26)~~ Organ, tissue, and eye procurement organizations, as provided under part V of chapter 765.

Section 23. Present subsections (10) through (14) of section 408.803, Florida Statutes, are redesignated as subsections (11) through (15), respectively, a new subsection (10) is added to that section, and subsection (3) of that section is amended, to read:

408.803 Definitions.—As used in this part, the term:

(3) "Authorizing statute" means the statute authorizing the licensed operation of a provider listed in s. 408.802 and includes chapters 112, 383, 390, 394, 395, 400, 429, 440, ~~483,~~ and 765.

(10) "Low-risk provider" means nurse registries, home medical equipment providers, and health care clinics.

Section 24. Paragraph (b) of subsection (7) of section 408.806, Florida Statutes, is amended to read:

408.806 License application process.—

(7)

(b) An initial inspection is not required for companion services or homemaker services providers~~,~~ as provided under part III of chapter 400, ~~or~~ for health care services pools~~,~~ as provided under part IX of chapter 400, or for low-risk providers as provided under s. 408.811.

Section 25. Subsection (2) of section 408.808, Florida Statutes, is amended to read:

408.808 License categories.—

(2) PROVISIONAL LICENSE.—An applicant against whom a proceeding denying or revoking a license is pending at the time of license renewal may be issued a provisional license effective until final action not subject to further appeal. A provisional license may also be issued to an applicant for initial licensure or applying for a change of ownership. A provisional license must be limited in duration to a specific period of time, up to 12 months, as determined by the agency.

Section 26. Subsections (2) and (5) of section 408.809, Florida Statutes, are amended to read:

408.809 Background screening; prohibited offenses.—

(2) Every 5 years following his or her licensure, employment, or entry into a contract in a capacity that under subsection (1) would require level 2 background screening under chapter 435, each such person must submit to level 2 background rescreening as a condition of retaining such license or continuing in such employment or contractual status. For any such rescreening, the agency shall request the Department of Law Enforcement to forward the person's fingerprints to the Federal Bureau of Investigation for a national criminal history record

check unless the person's fingerprints are enrolled in the Federal Bureau of Investigation's national retained print arrest notification program. If the fingerprints of such a person are not retained by the Department of Law Enforcement under s. 943.05(2)(g) and (h), the person must submit fingerprints electronically to the Department of Law Enforcement for state processing, and the Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check. The fingerprints shall be retained by the Department of Law Enforcement under s. 943.05(2)(g) and (h) and enrolled in the national retained print arrest notification program when the Department of Law Enforcement begins participation in the program. The cost of the state and national criminal history records checks required by level 2 screening may be borne by the licensee or the person fingerprinted. ~~Until a specified agency is fully implemented in the clearinghouse created under s. 435.12,~~ The agency may accept as satisfying the requirements of this section proof of compliance with level 2 screening standards submitted within the previous 5 years to meet any provider or professional licensure requirements of ~~the agency, the Department of Health, the Department of Elderly Affairs, the Agency for Persons with Disabilities, the Department of Children and Families, or~~ the Department of Financial Services for an applicant for a certificate of authority or provisional certificate of authority to operate a continuing care retirement community under chapter 651, provided that:

(a) The screening standards and disqualifying offenses for the prior screening are equivalent to those specified in s.

435.04 and this section;

(b) The person subject to screening has not had a break in service from a position that requires level 2 screening for more than 90 days; and

(c) Such proof is accompanied, under penalty of perjury, by an attestation of compliance with chapter 435 and this section using forms provided by the agency.

~~(5) A person who serves as a controlling interest of, is employed by, or contracts with a licensee on July 31, 2010, who has been screened and qualified according to standards specified in s. 435.03 or s. 435.04 must be rescreened by July 31, 2015, in compliance with the following schedule. If, upon rescreening, such person has a disqualifying offense that was not a disqualifying offense at the time of the last screening, but is a current disqualifying offense and was committed before the last screening, he or she may apply for an exemption from the appropriate licensing agency and, if agreed to by the employer, may continue to perform his or her duties until the licensing agency renders a decision on the application for exemption if the person is eligible to apply for an exemption and the exemption request is received by the agency within 30 days after receipt of the rescreening results by the person. The rescreening schedule shall be:~~

~~(a) Individuals for whom the last screening was conducted on or before December 31, 2004, must be rescreened by July 31, 2013.~~

~~(b) Individuals for whom the last screening conducted was between January 1, 2005, and December 31, 2008, must be rescreened by July 31, 2014.~~

~~(c) Individuals for whom the last screening conducted was between January 1, 2009, through July 31, 2011, must be rescreened by July 31, 2015.~~

Section 27. Subsection (1) of section 408.811, Florida Statutes, is amended to read:

408.811 Right of inspection; copies; inspection reports; plan for correction of deficiencies.—

(1) An authorized officer or employee of the agency may make or cause to be made any inspection or investigation deemed necessary by the agency to determine the state of compliance with this part, authorizing statutes, and applicable rules. The right of inspection extends to any business that the agency has reason to believe is being operated as a provider without a license, but inspection of any business suspected of being operated without the appropriate license may not be made without the permission of the owner or person in charge unless a warrant is first obtained from a circuit court. Any application for a license issued under this part, authorizing statutes, or applicable rules constitutes permission for an appropriate inspection to verify the information submitted on or in connection with the application.

(a) All inspections shall be unannounced, except as specified in s. 408.806.

(b) Inspections for relicensure shall be conducted biennially unless otherwise specified by this section, authorizing statutes, or applicable rules.

(c) The agency may exempt a low-risk provider from licensure inspection if the provider or controlling interest has an excellent regulatory history with regard to deficiencies,

sanctions, complaints, and other regulatory actions, as defined by rule. The agency shall continue to conduct unannounced licensure inspections for at least 10 percent of exempt low-risk providers to verify compliance.

(d) The agency may adopt rules to waive a routine inspection, including inspection for relicensure, or allow for an extended period between relicensure inspections for specific providers based upon:

1. A favorable regulatory history with regard to deficiencies, sanctions, complaints, and other regulatory measures.

2. Outcome measures that demonstrate quality performance.

3. Successful participation in a recognized quality assurance program.

4. Accreditation status.

5. Other measures reflective of quality and safety.

6. The length of time between inspections.

The agency shall continue to conduct unannounced licensure inspections for at least 10 percent of providers that qualify for a waiver or extended period between relicensure inspections.

(e) The agency maintains the authority to conduct an inspection of any provider at any time to determine regulatory compliance.

Section 28. Subsection (24) of section 408.820, Florida Statutes, is amended to read:

408.820 Exemptions.—Except as prescribed in authorizing statutes, the following exemptions shall apply to specified requirements of this part:

~~(24) Multiphasic health testing centers, as provided under part I of chapter 483, are exempt from s. 408.810(5)-(10).~~

Section 29. Subsections (1) and (2) of section 408.821, Florida Statutes, are amended to read:

408.821 Emergency management planning; emergency operations; inactive license.—

(1) A licensee required by authorizing statutes and agency rule to have a comprehensive ~~an~~ emergency management ~~operations~~ plan must designate a safety liaison to serve as the primary contact for emergency operations. Such licensee shall submit its comprehensive emergency management plan to the local emergency management agency, county health department, or Department of Health as follows:

(a) Submit the plan within 30 days after initial licensure and change of ownership, and notify the agency within 30 days after submission of the plan.

(b) Submit the plan annually and within 30 days after any significant modification, as defined by agency rule, to a previously approved plan.

(c) Respond with necessary plan revisions within 30 days after notification that plan revisions are required.

(d) Notify the agency within 30 days after approval of its plan by the local emergency management agency, county health department, or Department of Health.

(2) An entity subject to this part may temporarily exceed its licensed capacity to act as a receiving provider in accordance with an approved comprehensive emergency management ~~operations~~ plan for up to 15 days. While in an overcapacity status, each provider must furnish or arrange for appropriate

care and services to all clients. In addition, the agency may approve requests for overcapacity in excess of 15 days, which approvals may be based upon satisfactory justification and need as provided by the receiving and sending providers.

Section 30. Subsection (3) of section 408.831, Florida Statutes, is amended to read:

408.831 Denial, suspension, or revocation of a license, registration, certificate, or application.—

(3) This section provides standards of enforcement applicable to all entities licensed or regulated by the Agency for Health Care Administration. This section controls over any conflicting provisions of chapters 39, 383, 390, 391, 394, 395, 400, 408, 429, 468, ~~483,~~ and 765 or rules adopted pursuant to those chapters.

Section 31. Section 408.832, Florida Statutes, is amended to read:

408.832 Conflicts.—In case of conflict between the provisions of this part and the authorizing statutes governing the licensure of health care providers by the Agency for Health Care Administration found in s. 112.0455 and chapters 383, 390, 394, 395, 400, 429, 440, ~~483,~~ and 765, the provisions of this part shall prevail.

Section 32. Subsection (9) of section 408.909, Florida Statutes, is amended to read:

408.909 Health flex plans.—

~~(9) PROGRAM EVALUATION.—The agency and the office shall evaluate the pilot program and its effect on the entities that seek approval as health flex plans, on the number of enrollees, and on the scope of the health care coverage offered under a~~

~~health flex plan; shall provide an assessment of the health flex plans and their potential applicability in other settings; shall use health flex plans to gather more information to evaluate low-income consumer driven benefit packages; and shall, by January 15, 2016, and annually thereafter, jointly submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives.~~

Section 33. Paragraph (d) of subsection (10) of section 408.9091, Florida Statutes, is amended to read:

408.9091 Cover Florida Health Care Access Program.—

(10) PROGRAM EVALUATION.—The agency and the office shall:

~~(d) Jointly submit by March 1, annually, a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives which provides the information specified in paragraphs (a)-(c) and recommendations relating to the successful implementation and administration of the program.~~

Section 34. Paragraph (a) of subsection (5) of section 409.905, Florida Statutes, is amended to read:

409.905 Mandatory Medicaid services.—The agency may make payments for the following services, which are required of the state by Title XIX of the Social Security Act, furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any service under this section shall be provided only when medically necessary and in accordance with state and federal law. Mandatory services rendered by providers in mobile units to Medicaid recipients may be restricted by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay,

number of visits, number of services, or any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216.

(5) HOSPITAL INPATIENT SERVICES.—The agency shall pay for all covered services provided for the medical care and treatment of a recipient who is admitted as an inpatient by a licensed physician or dentist to a hospital licensed under part I of chapter 395. However, the agency shall limit the payment for inpatient hospital services for a Medicaid recipient 21 years of age or older to 45 days or the number of days necessary to comply with the General Appropriations Act.

(a) The agency may implement reimbursement and utilization management reforms in order to comply with any limitations or directions in the General Appropriations Act, which may include, but are not limited to: prior authorization for inpatient psychiatric days; prior authorization for nonemergency hospital inpatient admissions for individuals 21 years of age and older; authorization of emergency and urgent-care admissions within 24 hours after admission; enhanced utilization and concurrent review programs for highly utilized services; reduction or elimination of covered days of service; adjusting reimbursement ceilings for variable costs; adjusting reimbursement ceilings for fixed and property costs; and implementing target rates of increase. The agency may limit prior authorization for hospital inpatient services to selected diagnosis-related groups, based on an analysis of the cost and potential for unnecessary hospitalizations represented by certain diagnoses. Admissions for normal delivery and newborns are exempt from requirements

for prior authorization. In implementing the provisions of this section related to prior authorization, the agency shall ensure that the process for authorization is accessible 24 hours per day, 7 days per week and authorization is automatically granted when not denied within 4 hours after the request. Authorization procedures must include steps for review of denials. ~~Upon implementing the prior authorization program for hospital inpatient services, the agency shall discontinue its hospital retrospective review program.~~

Section 35. Subsection (8) of section 409.907, Florida Statutes, is amended to read:

409.907 Medicaid provider agreements.—The agency may make payments for medical assistance and related services rendered to Medicaid recipients only to an individual or entity who has a provider agreement in effect with the agency, who is performing services or supplying goods in accordance with federal, state, and local law, and who agrees that no person shall, on the grounds of handicap, race, color, or national origin, or for any other reason, be subjected to discrimination under any program or activity for which the provider receives payment from the agency.

(8)(a) A level 2 background screening pursuant to chapter 435 must be conducted through the agency on each of the following:

1. The ~~Each~~ provider, or each principal of the provider if the provider is a corporation, partnership, association, or other entity~~, seeking to participate in the Medicaid program must submit a complete set of his or her fingerprints to the agency for the purpose of conducting a criminal history record~~

~~check~~.

2. Principals of the provider, who include any officer, director, billing agent, managing employee, or affiliated person, or any partner or shareholder who has an ownership interest equal to 5 percent or more in the provider. However, for a hospital licensed under chapter 395 or a nursing home licensed under chapter 400, principals of the provider are those who meet the definition of a controlling interest under s. 408.803. A director of a not-for-profit corporation or organization is not a principal for purposes of a background investigation required by this section if the director: serves solely in a voluntary capacity for the corporation or organization, does not regularly take part in the day-to-day operational decisions of the corporation or organization, receives no remuneration from the not-for-profit corporation or organization for his or her service on the board of directors, has no financial interest in the not-for-profit corporation or organization, and has no family members with a financial interest in the not-for-profit corporation or organization; and if the director submits an affidavit, under penalty of perjury, to this effect to the agency and the not-for-profit corporation or organization submits an affidavit, under penalty of perjury, to this effect to the agency as part of the corporation's or organization's Medicaid provider agreement application.

3. Any person who participates or seeks to participate in the Florida Medicaid program by way of rendering services to Medicaid recipients or having direct access to Medicaid recipients, recipient living areas, or the financial, medical, or service records of a Medicaid recipient or who supervises the

delivery of goods or services to a Medicaid recipient. This subparagraph does not impose additional screening requirements on any providers licensed under part II of chapter 408.

(b) Notwithstanding paragraph (a) ~~the above~~, the agency may require a background check for any person reasonably suspected by the agency to have been convicted of a crime.

(c) ~~(a)~~ Paragraph (a) ~~This subsection~~ does not apply to:

1. A unit of local government, except that requirements of this subsection apply to nongovernmental providers and entities contracting with the local government to provide Medicaid services. The actual cost of the state and national criminal history record checks must be borne by the nongovernmental provider or entity; or

2. Any business that derives more than 50 percent of its revenue from the sale of goods to the final consumer, and the business or its controlling parent is required to file a form 10-K or other similar statement with the Securities and Exchange Commission or has a net worth of $50 million or more.

(d) ~~(b)~~ Background screening shall be conducted in accordance with chapter 435 and s. 408.809. The cost of the state and national criminal record check shall be borne by the provider.

Section 36. Section 409.913, Florida Statutes, is amended to read:

409.913 Oversight of the integrity of the Medicaid program.—The agency shall operate a program to oversee the activities of Florida Medicaid recipients, and providers and their representatives, to ensure that fraudulent and abusive behavior and neglect of recipients occur to the minimum extent

possible, and to recover overpayments and impose sanctions as appropriate. Each January 15 ~~January 1~~, the agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs shall submit reports ~~a joint report~~ to the Legislature documenting the effectiveness of the state's efforts to control Medicaid fraud and abuse and to recover Medicaid overpayments during the previous fiscal year. The report must describe the number of cases opened and investigated each year; the sources of the cases opened; the disposition of the cases closed each year; the amount of overpayments alleged in preliminary and final audit letters; the number and amount of fines or penalties imposed; any reductions in overpayment amounts negotiated in settlement agreements or by other means; the amount of final agency determinations of overpayments; the amount deducted from federal claiming as a result of overpayments; the amount of overpayments recovered each year; the amount of cost of investigation recovered each year; the average length of time to collect from the time the case was opened until the overpayment is paid in full; the amount determined as uncollectible and the portion of the uncollectible amount subsequently reclaimed from the Federal Government; the number of providers, by type, that are terminated from participation in the Medicaid program as a result of fraud and abuse; and all costs associated with discovering and prosecuting cases of Medicaid overpayments and making recoveries in such cases. The report must also document actions taken to prevent overpayments and the number of providers prevented from enrolling in or reenrolling in the Medicaid program as a result of documented Medicaid fraud and abuse and must include policy recommendations necessary to

prevent or recover overpayments and changes necessary to prevent and detect Medicaid fraud. All policy recommendations in the report must include a detailed fiscal analysis, including, but not limited to, implementation costs, estimated savings to the Medicaid program, and the return on investment. The agency must submit the policy recommendations and fiscal analyses in the report to the appropriate estimating conference, pursuant to s. 216.137, by February 15 of each year. The agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs each must include detailed unit-specific performance standards, benchmarks, and metrics in the report, including projected cost savings to the state Medicaid program during the following fiscal year.

(1) For the purposes of this section, the term:

(a) "Abuse" means:

1. Provider practices that are inconsistent with generally accepted business or medical practices and that result in an unnecessary cost to the Medicaid program or in reimbursement for goods or services that are not medically necessary or that fail to meet professionally recognized standards for health care.

2. Recipient practices that result in unnecessary cost to the Medicaid program.

(b) "Complaint" means an allegation that fraud, abuse, or an overpayment has occurred.

(c) "Fraud" means an intentional deception or misrepresentation made by a person with the knowledge that the deception results in unauthorized benefit to herself or himself or another person. The term includes any act that constitutes fraud under applicable federal or state law.

(d) "Medical necessity" or "medically necessary" means any goods or services necessary to palliate the effects of a terminal condition, or to prevent, diagnose, correct, cure, alleviate, or preclude deterioration of a condition that threatens life, causes pain or suffering, or results in illness or infirmity, which goods or services are provided in accordance with generally accepted standards of medical practice. For purposes of determining Medicaid reimbursement, the agency is the final arbiter of medical necessity. Determinations of medical necessity must be made by a licensed physician employed by or under contract with the agency and must be based upon information available at the time the goods or services are provided.

(e) "Overpayment" includes any amount that is not authorized to be paid by the Medicaid program whether paid as a result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse, or mistake.

(f) "Person" means any natural person, corporation, partnership, association, clinic, group, or other entity, whether or not such person is enrolled in the Medicaid program or is a provider of health care.

(2) The agency shall conduct, or cause to be conducted by contract or otherwise, reviews, investigations, analyses, audits, or any combination thereof, to determine possible fraud, abuse, overpayment, or recipient neglect in the Medicaid program and shall report the findings of any overpayments in audit reports as appropriate. At least 5 percent of all audits shall be conducted on a random basis. As part of its ongoing fraud detection activities, the agency shall identify and monitor, by

contract or otherwise, patterns of overutilization of Medicaid services based on state averages. The agency shall track Medicaid provider prescription and billing patterns and evaluate them against Medicaid medical necessity criteria and coverage and limitation guidelines adopted by rule. Medical necessity determination requires that service be consistent with symptoms or confirmed diagnosis of illness or injury under treatment and not in excess of the patient's needs. The agency shall conduct reviews of provider exceptions to peer group norms and shall, using statistical methodologies, provider profiling, and analysis of billing patterns, detect and investigate abnormal or unusual increases in billing or payment of claims for Medicaid services and medically unnecessary provision of services.

(3) The agency may conduct, or may contract for, prepayment review of provider claims to ensure cost-effective purchasing; to ensure that billing by a provider to the agency is in accordance with applicable provisions of all Medicaid rules, regulations, handbooks, and policies and in accordance with federal, state, and local law; and to ensure that appropriate care is rendered to Medicaid recipients. Such prepayment reviews may be conducted as determined appropriate by the agency, without any suspicion or allegation of fraud, abuse, or neglect, and may last for up to 1 year. Unless the agency has reliable evidence of fraud, misrepresentation, abuse, or neglect, claims shall be adjudicated for denial or payment within 90 days after receipt of complete documentation by the agency for review. If there is reliable evidence of fraud, misrepresentation, abuse, or neglect, claims shall be adjudicated for denial of payment within 180 days after receipt of complete documentation by the

agency for review.

(4) Any suspected criminal violation identified by the agency must be referred to the Medicaid Fraud Control Unit of the Office of the Attorney General for investigation. The agency and the Attorney General shall enter into a memorandum of understanding, which must include, but need not be limited to, a protocol for regularly sharing information and coordinating casework. The protocol must establish a procedure for the referral by the agency of cases involving suspected Medicaid fraud to the Medicaid Fraud Control Unit for investigation, and the return to the agency of those cases where investigation determines that administrative action by the agency is appropriate. Offices of the Medicaid program integrity program and the Medicaid Fraud Control Unit of the Department of Legal Affairs, shall, to the extent possible, be collocated. The agency and the Department of Legal Affairs shall periodically conduct joint training and other joint activities designed to increase communication and coordination in recovering overpayments.

(5) A Medicaid provider is subject to having goods and services that are paid for by the Medicaid program reviewed by an appropriate peer-review organization designated by the agency. The written findings of the applicable peer-review organization are admissible in any court or administrative proceeding as evidence of medical necessity or the lack thereof.

(6) Any notice required to be given to a provider under this section is presumed to be sufficient notice if sent to the address last shown on the provider enrollment file. It is the responsibility of the provider to furnish and keep the agency

informed of the provider's current address. United States Postal Service proof of mailing or certified or registered mailing of such notice to the provider at the address shown on the provider enrollment file constitutes sufficient proof of notice. Any notice required to be given to the agency by this section must be sent to the agency at an address designated by rule.

(7) When presenting a claim for payment under the Medicaid program, a provider has an affirmative duty to supervise the provision of, and be responsible for, goods and services claimed to have been provided, to supervise and be responsible for preparation and submission of the claim, and to present a claim that is true and accurate and that is for goods and services that:

(a) Have actually been furnished to the recipient by the provider prior to submitting the claim.

(b) Are Medicaid-covered goods or services that are medically necessary.

(c) Are of a quality comparable to those furnished to the general public by the provider's peers.

(d) Have not been billed in whole or in part to a recipient or a recipient's responsible party, except for such copayments, coinsurance, or deductibles as are authorized by the agency.

(e) Are provided in accord with applicable provisions of all Medicaid rules, regulations, handbooks, and policies and in accordance with federal, state, and local law.

(f) Are documented by records made at the time the goods or services were provided, demonstrating the medical necessity for the goods or services rendered. Medicaid goods or services are excessive or not medically necessary unless both the medical

basis and the specific need for them are fully and properly documented in the recipient's medical record.

The agency shall deny payment or require repayment for goods or services that are not presented as required in this subsection.

(8) The agency shall not reimburse any person or entity for any prescription for medications, medical supplies, or medical services if the prescription was written by a physician or other prescribing practitioner who is not enrolled in the Medicaid program. This section does not apply:

(a) In instances involving bona fide emergency medical conditions as determined by the agency;

(b) To a provider of medical services to a patient in a hospital emergency department, hospital inpatient or outpatient setting, or nursing home;

(c) To bona fide pro bono services by preapproved non-Medicaid providers as determined by the agency;

(d) To prescribing physicians who are board-certified specialists treating Medicaid recipients referred for treatment by a treating physician who is enrolled in the Medicaid program;

(e) To prescriptions written for dually eligible Medicare beneficiaries by an authorized Medicare provider who is not enrolled in the Medicaid program;

(f) To other physicians who are not enrolled in the Medicaid program but who provide a medically necessary service or prescription not otherwise reasonably available from a Medicaid-enrolled physician; or

(9) A Medicaid provider shall retain medical, professional, financial, and business records pertaining to services and goods

furnished to a Medicaid recipient and billed to Medicaid for a period of 5 years after the date of furnishing such services or goods. The agency may investigate, review, or analyze such records, which must be made available during normal business hours. However, 24-hour notice must be provided if patient treatment would be disrupted. The provider must keep the agency informed of the location of the provider's Medicaid-related records. The authority of the agency to obtain Medicaid-related records from a provider is neither curtailed nor limited during a period of litigation between the agency and the provider.

(10) Payments for the services of billing agents or persons participating in the preparation of a Medicaid claim shall not be based on amounts for which they bill nor based on the amount a provider receives from the Medicaid program.

(11) The agency shall deny payment or require repayment for inappropriate, medically unnecessary, or excessive goods or services from the person furnishing them, the person under whose supervision they were furnished, or the person causing them to be furnished.

(12) The complaint and all information obtained pursuant to an investigation of a Medicaid provider, or the authorized representative or agent of a provider, relating to an allegation of fraud, abuse, or neglect are confidential and exempt from the provisions of s. 119.07(1):

(a) Until the agency takes final agency action with respect to the provider and requires repayment of any overpayment, or imposes an administrative sanction;

(b) Until the Attorney General refers the case for criminal prosecution;

(c) Until 10 days after the complaint is determined without merit; or

(d) At all times if the complaint or information is otherwise protected by law.

(13) The agency shall terminate participation of a Medicaid provider in the Medicaid program and may seek civil remedies or impose other administrative sanctions against a Medicaid provider, if the provider or any principal, officer, director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership interest in the provider equal to 5 percent or greater, has been convicted of a criminal offense under federal law or the law of any state relating to the practice of the provider's profession, or a criminal offense listed under s. 408.809(4), s. 409.907(10), or s. 435.04(2). If the agency determines that the provider did not participate or acquiesce in the offense, termination will not be imposed. If the agency effects a termination under this subsection, the agency shall take final agency action.

(14) If the provider has been suspended or terminated from participation in the Medicaid program or the Medicare program by the Federal Government or any state, the agency must immediately suspend or terminate, as appropriate, the provider's participation in this state's Medicaid program for a period no less than that imposed by the Federal Government or any other state, and may not enroll such provider in this state's Medicaid program while such foreign suspension or termination remains in effect. The agency shall also immediately suspend or terminate, as appropriate, a provider's participation in this state's Medicaid program if the provider participated or acquiesced in

any action for which any principal, officer, director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership interest in the provider equal to 5 percent or greater, was suspended or terminated from participating in the Medicaid program or the Medicare program by the Federal Government or any state. This sanction is in addition to all other remedies provided by law.

(15) The agency shall seek a remedy provided by law, including, but not limited to, any remedy provided in subsections (13) and (16) and s. 812.035, if:

(a) The provider's license has not been renewed, or has been revoked, suspended, or terminated, for cause, by the licensing agency of any state;

(b) The provider has failed to make available or has refused access to Medicaid-related records to an auditor, investigator, or other authorized employee or agent of the agency, the Attorney General, a state attorney, or the Federal Government;

(c) The provider has not furnished or has failed to make available such Medicaid-related records as the agency has found necessary to determine whether Medicaid payments are or were due and the amounts thereof;

(d) The provider has failed to maintain medical records made at the time of service, or prior to service if prior authorization is required, demonstrating the necessity and appropriateness of the goods or services rendered;

(e) The provider is not in compliance with provisions of Medicaid provider publications that have been adopted by reference as rules in the Florida Administrative Code; with

provisions of state or federal laws, rules, or regulations; with provisions of the provider agreement between the agency and the provider; or with certifications found on claim forms or on transmittal forms for electronically submitted claims that are submitted by the provider or authorized representative, as such provisions apply to the Medicaid program;

(f) The provider or person who ordered, authorized, or prescribed the care, services, or supplies has furnished, or ordered or authorized the furnishing of, goods or services to a recipient which are inappropriate, unnecessary, excessive, or harmful to the recipient or are of inferior quality;

(g) The provider has demonstrated a pattern of failure to provide goods or services that are medically necessary;

(h) The provider or an authorized representative of the provider, or a person who ordered, authorized, or prescribed the goods or services, has submitted or caused to be submitted false or a pattern of erroneous Medicaid claims;

(i) The provider or an authorized representative of the provider, or a person who has ordered, authorized, or prescribed the goods or services, has submitted or caused to be submitted a Medicaid provider enrollment application, a request for prior authorization for Medicaid services, a drug exception request, or a Medicaid cost report that contains materially false or incorrect information;

(j) The provider or an authorized representative of the provider has collected from or billed a recipient or a recipient’s responsible party improperly for amounts that should not have been so collected or billed by reason of the provider’s billing the Medicaid program for the same service;

(k) The provider or an authorized representative of the provider has included in a cost report costs that are not allowable under a Florida Title XIX reimbursement plan after the provider or authorized representative had been advised in an audit exit conference or audit report that the costs were not allowable;

(l) The provider is charged by information or indictment with fraudulent billing practices or an offense referenced in subsection (13). The sanction applied for this reason is limited to suspension of the provider's participation in the Medicaid program for the duration of the indictment unless the provider is found guilty pursuant to the information or indictment;

(m) The provider or a person who ordered, authorized, or prescribed the goods or services is found liable for negligent practice resulting in death or injury to the provider's patient;

(n) The provider fails to demonstrate that it had available during a specific audit or review period sufficient quantities of goods, or sufficient time in the case of services, to support the provider's billings to the Medicaid program;

(o) The provider has failed to comply with the notice and reporting requirements of s. 409.907;

(p) The agency has received reliable information of patient abuse or neglect or of any act prohibited by s. 409.920; or

(q) The provider has failed to comply with an agreed-upon repayment schedule.

A provider is subject to sanctions for violations of this subsection as the result of actions or inactions of the provider, or actions or inactions of any principal, officer,

director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership interest in the provider equal to 5 percent or greater, in which the provider participated or acquiesced.

(16) The agency shall impose any of the following sanctions or disincentives on a provider or a person for any of the acts described in subsection (15):

(a) Suspension for a specific period of time of not more than 1 year. Suspension precludes participation in the Medicaid program, which includes any action that results in a claim for payment to the Medicaid program for furnishing, supervising a person who is furnishing, or causing a person to furnish goods or services.

(b) Termination for a specific period of time ranging from more than 1 year to 20 years. Termination precludes participation in the Medicaid program, which includes any action that results in a claim for payment to the Medicaid program for furnishing, supervising a person who is furnishing, or causing a person to furnish goods or services.

(c) Imposition of a fine of up to $5,000 for each violation. Each day that an ongoing violation continues, such as refusing to furnish Medicaid-related records or refusing access to records, is considered a separate violation. Each instance of improper billing of a Medicaid recipient; each instance of including an unallowable cost on a hospital or nursing home Medicaid cost report after the provider or authorized representative has been advised in an audit exit conference or previous audit report of the cost unallowability; each instance of furnishing a Medicaid recipient goods or professional

services that are inappropriate or of inferior quality as determined by competent peer judgment; each instance of knowingly submitting a materially false or erroneous Medicaid provider enrollment application, request for prior authorization for Medicaid services, drug exception request, or cost report; each instance of inappropriate prescribing of drugs for a Medicaid recipient as determined by competent peer judgment; and each false or erroneous Medicaid claim leading to an overpayment to a provider is considered a separate violation.

(d) Immediate suspension, if the agency has received information of patient abuse or neglect or of any act prohibited by s. 409.920. Upon suspension, the agency must issue an immediate final order under s. 120.569(2)(n).

(e) A fine, not to exceed $10,000, for a violation of paragraph (15)(i).

(f) Imposition of liens against provider assets, including, but not limited to, financial assets and real property, not to exceed the amount of fines or recoveries sought, upon entry of an order determining that such moneys are due or recoverable.

(g) Prepayment reviews of claims for a specified period of time.

(h) Comprehensive followup reviews of providers every 6 months to ensure that they are billing Medicaid correctly.

(i) Corrective-action plans that remain in effect for up to 3 years and that are monitored by the agency every 6 months while in effect.

(j) Other remedies as permitted by law to effect the recovery of a fine or overpayment.

If a provider voluntarily relinquishes its Medicaid provider number or an associated license, or allows the associated licensure to expire after receiving written notice that the agency is conducting, or has conducted, an audit, survey, inspection, or investigation and that a sanction of suspension or termination will or would be imposed for noncompliance discovered as a result of the audit, survey, inspection, or investigation, the agency shall impose the sanction of termination for cause against the provider. The agency's termination with cause is subject to hearing rights as may be provided under chapter 120. The Secretary of Health Care Administration may make a determination that imposition of a sanction or disincentive is not in the best interest of the Medicaid program, in which case a sanction or disincentive may not be imposed.

(17) In determining the appropriate administrative sanction to be applied, or the duration of any suspension or termination, the agency shall consider:

(a) The seriousness and extent of the violation or violations.

(b) Any prior history of violations by the provider relating to the delivery of health care programs which resulted in either a criminal conviction or in administrative sanction or penalty.

(c) Evidence of continued violation within the provider's management control of Medicaid statutes, rules, regulations, or policies after written notification to the provider of improper practice or instance of violation.

(d) The effect, if any, on the quality of medical care

provided to Medicaid recipients as a result of the acts of the provider.

(e) Any action by a licensing agency respecting the provider in any state in which the provider operates or has operated.

(f) The apparent impact on access by recipients to Medicaid services if the provider is suspended or terminated, in the best judgment of the agency.

The agency shall document the basis for all sanctioning actions and recommendations.

(18) The agency may take action to sanction, suspend, or terminate a particular provider working for a group provider, and may suspend or terminate Medicaid participation at a specific location, rather than or in addition to taking action against an entire group.

(19) The agency shall establish a process for conducting followup reviews of a sampling of providers who have a history of overpayment under the Medicaid program. This process must consider the magnitude of previous fraud or abuse and the potential effect of continued fraud or abuse on Medicaid costs.

(20) In making a determination of overpayment to a provider, the agency must use accepted and valid auditing, accounting, analytical, statistical, or peer-review methods, or combinations thereof. Appropriate statistical methods may include, but are not limited to, sampling and extension to the population, parametric and nonparametric statistics, tests of hypotheses, and other generally accepted statistical methods. Appropriate analytical methods may include, but are not limited

to, reviews to determine variances between the quantities of products that a provider had on hand and available to be purveyed to Medicaid recipients during the review period and the quantities of the same products paid for by the Medicaid program for the same period, taking into appropriate consideration sales of the same products to non-Medicaid customers during the same period. In meeting its burden of proof in any administrative or court proceeding, the agency may introduce the results of such statistical methods as evidence of overpayment.

(21) When making a determination that an overpayment has occurred, the agency shall prepare and issue an audit report to the provider showing the calculation of overpayments. The agency's determination must be based solely upon information available to it before issuance of the audit report and, in the case of documentation obtained to substantiate claims for Medicaid reimbursement, based solely upon contemporaneous records. The agency may consider addenda or modifications to a note that was made contemporaneously with the patient care episode if the addenda or modifications are germane to the note.

(22) The audit report, supported by agency work papers, showing an overpayment to a provider constitutes evidence of the overpayment. A provider may not present or elicit testimony on direct examination or cross-examination in any court or administrative proceeding, regarding the purchase or acquisition by any means of drugs, goods, or supplies; sales or divestment by any means of drugs, goods, or supplies; or inventory of drugs, goods, or supplies, unless such acquisition, sales, divestment, or inventory is documented by written invoices, written inventory records, or other competent written

documentary evidence maintained in the normal course of the provider's business. A provider may not present records to contest an overpayment or sanction unless such records are contemporaneous and, if requested during the audit process, were furnished to the agency or its agent upon request. This limitation does not apply to Medicaid cost report audits. This limitation does not preclude consideration by the agency of addenda or modifications to a note if the addenda or modifications are made before notification of the audit, the addenda or modifications are germane to the note, and the note was made contemporaneously with a patient care episode. Notwithstanding the applicable rules of discovery, all documentation to be offered as evidence at an administrative hearing on a Medicaid overpayment or an administrative sanction must be exchanged by all parties at least 14 days before the administrative hearing or be excluded from consideration.

(23)(a) In an audit, ~~or~~ investigation, or enforcement action taken for ~~of~~ a violation committed by a provider which is conducted pursuant to this section, the agency is entitled to recover all investigative and~~,~~ legal costs incurred as a result of such audit, investigation, or enforcement action. The costs associated with an investigation, audit, or enforcement action may include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by an attorney and other personnel working on the case, and any other expenses incurred by the agency or contractor which are associated with the case, including any~~, and~~ expert witness costs and attorney fees incurred on behalf of the agency or contractor if the agency's findings were not contested by the provider or, if

contested, the agency ultimately prevailed.

(b) The agency has the burden of documenting the costs, which include salaries and employee benefits and out-of-pocket expenses. The amount of costs that may be recovered must be reasonable in relation to the seriousness of the violation and must be set taking into consideration the financial resources, earning ability, and needs of the provider, who has the burden of demonstrating such factors.

(c) The provider may pay the costs over a period to be determined by the agency if the agency determines that an extreme hardship would result to the provider from immediate full payment. Any default in payment of costs may be collected by any means authorized by law.

(24) If the agency imposes an administrative sanction pursuant to subsection (13), subsection (14), or subsection (15), except paragraphs (15)(e) and (o), upon any provider or any principal, officer, director, agent, managing employee, or affiliated person of the provider who is regulated by another state entity, the agency shall notify that other entity of the imposition of the sanction within 5 business days. Such notification must include the provider’s or person’s name and license number and the specific reasons for sanction.

(25)(a) The agency shall withhold Medicaid payments, in whole or in part, to a provider upon receipt of reliable evidence that the circumstances giving rise to the need for a withholding of payments involve fraud, willful misrepresentation, or abuse under the Medicaid program, or a crime committed while rendering goods or services to Medicaid recipients. If it is determined that fraud, willful

misrepresentation, abuse, or a crime did not occur, the payments withheld must be paid to the provider within 14 days after such determination. Amounts not paid within 14 days accrue interest at the rate of 10 percent per year, beginning after the 14th day.

(b) The agency shall deny payment, or require repayment, if the goods or services were furnished, supervised, or caused to be furnished by a person who has been suspended or terminated from the Medicaid program or Medicare program by the Federal Government or any state.

(c) Overpayments owed to the agency bear interest at the rate of 10 percent per year from the date of final determination of the overpayment by the agency, and payment arrangements must be made within 30 days after the date of the final order, which is not subject to further appeal.

(d) The agency, upon entry of a final agency order, a judgment or order of a court of competent jurisdiction, or a stipulation or settlement, may collect the moneys owed by all means allowable by law, including, but not limited to, notifying any fiscal intermediary of Medicare benefits that the state has a superior right of payment. Upon receipt of such written notification, the Medicare fiscal intermediary shall remit to the state the sum claimed.

(e) The agency may institute amnesty programs to allow Medicaid providers the opportunity to voluntarily repay overpayments. The agency may adopt rules to administer such programs.

(26) The agency may impose administrative sanctions against a Medicaid recipient, or the agency may seek any other remedy

provided by law, including, but not limited to, the remedies provided in s. 812.035, if the agency finds that a recipient has engaged in solicitation in violation of s. 409.920 or that the recipient has otherwise abused the Medicaid program.

(27) When the Agency for Health Care Administration has made a probable cause determination and alleged that an overpayment to a Medicaid provider has occurred, the agency, after notice to the provider, shall:

(a) Withhold, and continue to withhold during the pendency of an administrative hearing pursuant to chapter 120, any medical assistance reimbursement payments until such time as the overpayment is recovered, unless within 30 days after receiving notice thereof the provider:

1. Makes repayment in full; or

2. Establishes a repayment plan that is satisfactory to the Agency for Health Care Administration.

(b) Withhold, and continue to withhold during the pendency of an administrative hearing pursuant to chapter 120, medical assistance reimbursement payments if the terms of a repayment plan are not adhered to by the provider.

(28) Venue for all Medicaid program integrity cases lies in Leon County, at the discretion of the agency.

(29) Notwithstanding other provisions of law, the agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs may review a provider’s Medicaid-related and non-Medicaid-related records in order to determine the total output of a provider’s practice to reconcile quantities of goods or services billed to Medicaid with quantities of goods or services used in the provider’s total practice.

(30) The agency shall terminate a provider's participation in the Medicaid program if the provider fails to reimburse an overpayment or pay an agency-imposed fine that has been determined by final order, not subject to further appeal, within 30 days after the date of the final order, unless the provider and the agency have entered into a repayment agreement.

(31) If a provider requests an administrative hearing pursuant to chapter 120, such hearing must be conducted within 90 days following assignment of an administrative law judge, absent exceptionally good cause shown as determined by the administrative law judge or hearing officer. Upon issuance of a final order, the outstanding balance of the amount determined to constitute the overpayment and fines is due. If a provider fails to make payments in full, fails to enter into a satisfactory repayment plan, or fails to comply with the terms of a repayment plan or settlement agreement, the agency shall withhold reimbursement payments for Medicaid services until the amount due is paid in full.

(32) Duly authorized agents and employees of the agency shall have the power to inspect, during normal business hours, the records of any pharmacy, wholesale establishment, or manufacturer, or any other place in which drugs and medical supplies are manufactured, packed, packaged, made, stored, sold, or kept for sale, for the purpose of verifying the amount of drugs and medical supplies ordered, delivered, or purchased by a provider. The agency shall provide at least 2 business days' prior notice of any such inspection. The notice must identify the provider whose records will be inspected, and the inspection shall include only records specifically related to that

provider.

(33) In accordance with federal law, Medicaid recipients convicted of a crime pursuant to 42 U.S.C. s. 1320a-7b may be limited, restricted, or suspended from Medicaid eligibility for a period not to exceed 1 year, as determined by the agency head or designee.

(34) To deter fraud and abuse in the Medicaid program, the agency may limit the number of Schedule II and Schedule III refill prescription claims submitted from a pharmacy provider. The agency shall limit the allowable amount of reimbursement of prescription refill claims for Schedule II and Schedule III pharmaceuticals if the agency or the Medicaid Fraud Control Unit determines that the specific prescription refill was not requested by the Medicaid recipient or authorized representative for whom the refill claim is submitted or was not prescribed by the recipient's medical provider or physician. Any such refill request must be consistent with the original prescription.

(35) The Office of Program Policy Analysis and Government Accountability shall provide a report to the President of the Senate and the Speaker of the House of Representatives on a biennial basis, beginning January 31, 2006, on the agency's efforts to prevent, detect, and deter, as well as recover funds lost to, fraud and abuse in the Medicaid program.

(36) The agency may provide to a sample of Medicaid recipients or their representatives through the distribution of explanations of benefits information about services reimbursed by the Medicaid program for goods and services to such recipients, including information on how to report inappropriate or incorrect billing to the agency or other law enforcement

entities for review or investigation, information on how to report criminal Medicaid fraud to the Medicaid Fraud Control Unit's toll-free hotline number, and information about the rewards available under s. 409.9203. The explanation of benefits may not be mailed for Medicaid independent laboratory services as described in s. 409.905(7) or for Medicaid certified match services as described in ss. 409.9071 and 1011.70.

(37) The agency shall post on its website a current list of each Medicaid provider, including any principal, officer, director, agent, managing employee, or affiliated person of the provider, or any partner or shareholder having an ownership interest in the provider equal to 5 percent or greater, who has been terminated for cause from the Medicaid program or sanctioned under this section. The list must be searchable by a variety of search parameters and provide for the creation of formatted lists that may be printed or imported into other applications, including spreadsheets. The agency shall update the list at least monthly.

(38) In order to improve the detection of health care fraud, use technology to prevent and detect fraud, and maximize the electronic exchange of health care fraud information, the agency shall:

(a) Compile, maintain, and publish on its website a detailed list of all state and federal databases that contain health care fraud information and update the list at least biannually;

(b) Develop a strategic plan to connect all databases that contain health care fraud information to facilitate the electronic exchange of health information between the agency,

the Department of Health, the Department of Law Enforcement, and the Attorney General's Office. The plan must include recommended standard data formats, fraud identification strategies, and specifications for the technical interface between state and federal health care fraud databases;

(c) Monitor innovations in health information technology, specifically as it pertains to Medicaid fraud prevention and detection; and

(d) Periodically publish policy briefs that highlight available new technology to prevent or detect health care fraud and projects implemented by other states, the private sector, or the Federal Government which use technology to prevent or detect health care fraud.

Section 37. Subsection (6) of section 429.11, Florida Statutes, is amended to read:

429.11 Initial application for license; provisional license.—

~~(6) In addition to the license categories available in s. 408.808, a provisional license may be issued to an applicant making initial application for licensure or making application for a change of ownership. A provisional license shall be limited in duration to a specific period of time not to exceed 6 months, as determined by the agency.~~

Section 38. Subsection (9) of section 429.19, Florida Statutes, is amended to read:

429.19 Violations; imposition of administrative fines; grounds.—

~~(9) The agency shall develop and disseminate an annual list of all facilities sanctioned or fined for violations of state~~

~~standards, the number and class of violations involved, the penalties imposed, and the current status of cases. The list shall be disseminated, at no charge, to the Department of Elderly Affairs, the Department of Health, the Department of Children and Families, the Agency for Persons with Disabilities, the area agencies on aging, the Florida Statewide Advocacy Council, the State Long-Term Care Ombudsman Program, and state and local ombudsman councils. The Department of Children and Families shall disseminate the list to service providers under contract to the department who are responsible for referring persons to a facility for residency. The agency may charge a fee commensurate with the cost of printing and postage to other interested parties requesting a copy of this list. This information may be provided electronically or through the agency's Internet site.~~

Section 39. Subsection (2) of section 429.35, Florida Statutes, is amended to read:

429.35 Maintenance of records; reports.—

(2) Within 60 days after the date of an ~~the biennial~~ inspection conducted ~~visit required~~ under s. 408.811 or within 30 days after the date of an ~~any~~ interim visit, the agency shall forward the results of the inspection to the local ombudsman council in the district where the facility is located; to at least one public library or, in the absence of a public library, the county seat in the county in which the inspected assisted living facility is located; and, when appropriate, to the district Adult Services and Mental Health Program Offices.

Section 40. Subsection (2) of section 429.905, Florida Statutes, is amended to read:

429.905 Exemptions; monitoring of adult day care center programs colocated with assisted living facilities or licensed nursing home facilities.—

(2) A licensed assisted living facility, a licensed hospital, or a licensed nursing home facility may provide services during the day which include, but are not limited to, social, health, therapeutic, recreational, nutritional, and respite services, to adults who are not residents. Such a facility need not be licensed as an adult day care center; however, the agency must monitor the facility during the regular inspection ~~and at least biennially~~ to ensure adequate space and sufficient staff. If an assisted living facility, a hospital, or a nursing home holds itself out to the public as an adult day care center, it must be licensed as such and meet all standards prescribed by statute and rule. For the purpose of this subsection, the term "day" means any portion of a 24-hour day.

Section 41. Section 429.929, Florida Statutes, is amended to read:

429.929 Rules establishing standards.—

~~(1)~~ The agency shall adopt rules to implement this part. The rules must include reasonable and fair standards. Any conflict between these standards and those that may be set forth in local, county, or municipal ordinances shall be resolved in favor of those having statewide effect. Such standards must relate to:

(1)~~(a)~~ The maintenance of adult day care centers with respect to plumbing, heating, lighting, ventilation, and other building conditions, including adequate meeting space, to ensure the health, safety, and comfort of participants and protection

from fire hazard. Such standards may not conflict with chapter 553 and must be based upon the size of the structure and the number of participants.

(2) ~~(b)~~ The number and qualifications of all personnel employed by adult day care centers who have responsibilities for the care of participants.

(3) ~~(c)~~ All sanitary conditions within adult day care centers and their surroundings, including water supply, sewage disposal, food handling, and general hygiene, and maintenance of sanitary conditions, to ensure the health and comfort of participants.

(4) ~~(d)~~ Basic services provided by adult day care centers.

(5) ~~(e)~~ Supportive and optional services provided by adult day care centers.

(6) ~~(f)~~ Data and information relative to participants and programs of adult day care centers, including, but not limited to, the physical and mental capabilities and needs of the participants, the availability, frequency, and intensity of basic services and of supportive and optional services provided, the frequency of participation, the distances traveled by participants, the hours of operation, the number of referrals to other centers or elsewhere, and the incidence of illness.

(7) ~~(g)~~ Components of a comprehensive emergency management plan, developed in consultation with the Department of Health and the Division of Emergency Management.

~~(2) Pursuant to this part, s. 408.811, and applicable rules, the agency may conduct an abbreviated biennial inspection of key quality-of-care standards, in lieu of a full inspection, of a center that has a record of good performance. However, the~~

~~agency must conduct a full inspection of a center that has had one or more confirmed complaints within the licensure period immediately preceding the inspection or which has a serious problem identified during the abbreviated inspection. The agency shall develop the key quality-of-care standards, taking into consideration the comments and recommendations of provider groups. These standards shall be included in rules adopted by the agency.~~

Section 42. Part I of chapter 483, Florida Statutes, is repealed, and part II and part III of that chapter are redesignated as part I and part II, respectively.

Section 43. Paragraph (g) of subsection (3) of section 20.43, Florida Statutes, is amended to read:

20.43 Department of Health.—There is created a Department of Health.

(3) The following divisions of the Department of Health are established:

(g) Division of Medical Quality Assurance, which is responsible for the following boards and professions established within the division:

1. The Board of Acupuncture, created under chapter 457.

2. The Board of Medicine, created under chapter 458.

3. The Board of Osteopathic Medicine, created under chapter 459.

4. The Board of Chiropractic Medicine, created under chapter 460.

5. The Board of Podiatric Medicine, created under chapter 461.

6. Naturopathy, as provided under chapter 462.

7. The Board of Optometry, created under chapter 463.

8. The Board of Nursing, created under part I of chapter 464.

9. Nursing assistants, as provided under part II of chapter 464.

10. The Board of Pharmacy, created under chapter 465.

11. The Board of Dentistry, created under chapter 466.

12. Midwifery, as provided under chapter 467.

13. The Board of Speech-Language Pathology and Audiology, created under part I of chapter 468.

14. The Board of Nursing Home Administrators, created under part II of chapter 468.

15. The Board of Occupational Therapy, created under part III of chapter 468.

16. Respiratory therapy, as provided under part V of chapter 468.

17. Dietetics and nutrition practice, as provided under part X of chapter 468.

18. The Board of Athletic Training, created under part XIII of chapter 468.

19. The Board of Orthotists and Prosthetists, created under part XIV of chapter 468.

20. Electrolysis, as provided under chapter 478.

21. The Board of Massage Therapy, created under chapter 480.

22. The Board of Clinical Laboratory Personnel, created under part I ~~part II~~ of chapter 483.

23. Medical physicists, as provided under part II ~~part III~~ of chapter 483.

24. The Board of Opticianry, created under part I of chapter 484.

25. The Board of Hearing Aid Specialists, created under part II of chapter 484.

26. The Board of Physical Therapy Practice, created under chapter 486.

27. The Board of Psychology, created under chapter 490.

28. School psychologists, as provided under chapter 490.

29. The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, created under chapter 491.

30. Emergency medical technicians and paramedics, as provided under part III of chapter 401.

Section 44. Subsection (3) of section 381.0034, Florida Statutes, is amended to read:

381.0034 Requirement for instruction on HIV and AIDS.—

(3) The department shall require, as a condition of granting a license under chapter 467 or part I ~~part II~~ of chapter 483, that an applicant making initial application for licensure complete an educational course acceptable to the department on human immunodeficiency virus and acquired immune deficiency syndrome. Upon submission of an affidavit showing good cause, an applicant who has not taken a course at the time of licensure shall be allowed 6 months to complete this requirement.

Section 45. Subsection (4) of section 456.001, Florida Statutes, is amended to read:

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

(4) "Health care practitioner" means any person licensed

under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part I or part II ~~part II or part III~~ of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

Section 46. Paragraphs (h) and (i) of subsection (2) of section 456.057, Florida Statutes, are amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

(2) As used in this section, the terms "records owner," "health care practitioner," and "health care practitioner's employer" do not include any of the following persons or entities; furthermore, the following persons or entities are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of this section to maintain those documents required by the part or chapter under which they are licensed or regulated:

(h) Clinical laboratory personnel licensed under part I ~~part II~~ of chapter 483.

(i) Medical physicists licensed under part II ~~part III~~ of chapter 483.

Section 47. Paragraph (j) of subsection (1) of section 456.076, Florida Statutes, is amended to read:

456.076 Impaired practitioner programs.—

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

(j) "Practitioner" means a person licensed, registered, certified, or regulated by the department under part III of chapter 401; chapter 457; chapter 458; chapter 459; chapter 460;

chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part I or part II ~~part II or part III~~ of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491; or an applicant for a license, registration, or certification under the same laws.

Section 48. Paragraph (b) of subsection (1) of section 456.47, Florida Statutes, is amended to read:

456.47 Use of telehealth to provide services.—

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

(b) "Telehealth provider" means any individual who provides health care and related services using telehealth and who is licensed or certified under s. 393.17; part III of chapter 401; chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part III, part IV, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part I or part II ~~part II or part III~~ of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491; who is licensed under a multistate health care licensure compact of which Florida is a member state; or who is registered under and complies with subsection (4).

Section 49. This act shall take effect July 1, 2020.

The Florida Senate

Committee Agenda Request

To: Senator Gayle Harrell, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 19, 2020

I respectfully request that **Senate Bill # 1726**, relating to Agency for Health Care Administration, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Aaron Bean

Senator Aaron Bean
Florida Senate, District 4

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/28/20
Meeting Date

1726
Bill Number (if applicable)

~~942012~~ 367544
Amendment Barcode (if applicable)

Topic Medicaid

Name Robert Beck

Job Title

Address 150 S. Monroe St. Suite 303
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Speaking: ☐ For ☐ Against ☐ Information

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

Representing FLORIDA Community Care

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)

1/28/20
Meeting Date

1726
Bill Number (if applicable)

Topic AHCA

Amendment Barcode (if applicable)

Name DOUG RUSSELL

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing QUEST DIAGNOSTIC LABS

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)

2020 AGENCY LEGISLATIVE BILL ANALYSIS

Agency for Health Care Administration

BILL INFORMATION	
BILL NUMBER:	SB 1726
BILL TITLE:	Agency for Health Care Administration
BILL SPONSOR:	Senator Bean
EFFECTIVE DATE:	July 1, 2020

COMMITTEES OF REFERENCE
1) Health Policy
2) Appropriations Subcommittee on Health and Human Services
3) Appropriations
4)
5)

CURRENT COMMITTEE

SIMILAR BILLS	
BILL NUMBER:	HB 731
SPONSOR:	Rep. Perez

PREVIOUS LEGISLATION	
BILL NUMBER:	
SPONSOR:	
YEAR:	
LAST ACTION:	

IDENTICAL BILLS	
BILL NUMBER:	
SPONSOR:	

Is this bill part of an agency package?
Y _X__ N ___

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	January 24, 2020
LEAD AGENCY ANALYST:	
ADDITIONAL ANALYST(S):	
LEGAL ANALYST:	
FISCAL ANALYST:	

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

The proposed bill is the Agency for Health Care Administration's regulatory reform proposal. The bill makes substantive, technical, and clarifying changes to current law.

Major changes include:

- Risk-based licensure inspections for health care facilities and providers - Provide flexibility to inspect high-performing health care facilities less frequently than poor performers. Maximizes staffing resources to focus on higher risk and lower performing facilities and providers.

- Specify that health care clinic licensure is not required for Medicaid enrollment.

- Create an exemption to health care clinic licensure for federally certified providers - Creating a health care clinic exemption for community mental health center-partial hospitalization programs, portable x-ray providers and rural health care clinics aligns these programs with other federally certified providers and would provide an exemption for approximately 200 providers. Certification requirements are more stringent than health care clinic licensure standards.

Minor changes include:

- Repeal of duplicative multiphasic health testing center licensure - Multiphasic health testing centers collect specimens and perform tests for review by licensed health care practitioners, such as height, weight, blood pressure and EKGs. Most centers are also certified as clinical laboratories under the federal Clinical Laboratory Improvement Amendments (CLIA). Repeal of this provider type eliminates duplication. Current licenses: 187.

- Expand the Agency's ability to issue a provisional license to all provider types - Current law authorizes a provisional license for all provider types during a change of ownership or litigation case, but a provisional license for initial applicants is only available for assisted living facilities. The bill will expand the authority for provisional licenses for all licensed providers and other types of applications.

- Modify frequency of birth centers reports to the Agency – Replace the annual requirement for birth center reporting to allow more frequent submission as defined by rule of data regarding number of hospital transfers, and infant and maternal deaths.

- Update background screening regulations for staff in health care providers - Provide clarity that Medicaid providers must screen those employees who provide personal care or services directly to Medicaid beneficiaries or have access to beneficiary funds, personal property, or living areas. Align terms in licensure to eliminate confusion regarding contract staff.

Technical changes:

- Medicaid authority for retrospective review of hospital payments - Eliminate a perceived contradiction that 409.905, F.S., supersedes 409.913, F.S., which currently limits the Agency's Medicaid program integrity efforts to audit and recover overpayments and inappropriate payments.

- Strengthen authority to collect legal fees in licensure and Medicaid overpayment cases - Adopt language modeled after Department of Health practitioner cases language to clarify the authority to recover attorney's fees on Medicaid Program Integrity and licensure legal cases. Based on a recent DOAH case, this clarification is necessary; the Agency spends significant funds defending overpayment cases.

- Clarifying the definitions and licensure requirements related to home health agencies - Removes staffing services as a requirement of home health agency licensure and replaces the term "organization" with "person or entity" to align to the language with uniform licensing requirements. Clarifies home health agency exemptions. Addresses a gap to require applicants for change or ownership and the addition of skilled services to provide proof of accreditation.

- Listing hospital beds on the license - Oversight issue with the repeal of hospital Certificate of Need law. Current law states that only those beds for which there is a "need" methodology are to be listed on the hospital licenses.

- Repeal an unenforceable annual assessment - 395.7015, F.S. required ambulatory surgical centers and diagnostic imaging centers to pay a Public Medical Assistance Trust Fund (PMATF) assessment on health care entity revenue. Upon implementation of the law in 2000, the statute was immediately challenged in court and found to be unconstitutional. The Agency has never collected assessments under the statute. All rules referencing the statute were repealed. The statute is unenforceable.

- Repeal reference to an administrative rule in statute - The proposal would remove reference to a rule number that has been repealed and replaced with another rule related to health care data collection.

- Update requirements for approval of comprehensive emergency management plans for newly licensed facilities – create consistency across provider types.

- Replace legislatively mandated reports with online publications and repeal obsolete reports - E-prescribing, Emergency Department Utilization Report, Expenditures Report, Florida Center Annual Report, Assisted Living Facility Sanction Report, Health Flex Program Annual Report, Cover Florida Annual Report, Hospice Annual Report.

- Delete health care clinic surety bond language in health care clinic law - No providers have selected the option of posting this bond in lieu of demonstrating proof of financial ability to operate.

- Addition of definition of "urgent care center" for health care clinics - Health care clinic law states all clinics must publish a schedule of charges for the services offered to patients. Current text goes on to state an "urgent care center," which is defined in hospital statute but not health care clinic statute, must post these charges in its reception area. The posting must be of a specific type and size. Providers are often confused as to whether all health care clinics or only "urgent care centers" must post charges. Clarification is needed in health care clinic statute.

2. <u>SUBSTANTIVE BILL ANALYSIS</u>

1. PRESENT SITUATION:

<u>Birth center reports to the Agency</u> – Section 383.327, F.S.
Licensed birth centers are required per s. 383.327, F.S., to submit an annual report to the Agency summarizing the services provided by the birth center. The current reporting period is July 1 through June 30 and is due no later than July 30. The report must be submitted on AHCA Form 3130-3004, which is only available through the Agency's online portal. Once complete, the birth center certifies the entries and the data is electronically transmitted to the Agency. The data does not attribute services to individual practitioners.

Midwives licensed pursuant to s. 467, F.S., are required to submit the Annual Report of Midwifery Practice on form DH-MQA 5011 to the Department of Health (DOH). The reporting period is July 1 through June 30 and is due no later than July 31. The report collects the services provided by a licensed midwife. It does not attribute services to specific licensed facilities such as birth centers or hospitals.

Data collected by the Agency and DOH are similar, serving separate purposes. Both reports collect the number of:

- Maternal clients accepted for care
- Births/deliveries
- Episiotomy/laceration repairs
- Maternal transfers, including when, why, and health status
- Newborn transfers, including when, why and health status
- Newborn deaths, including specific details
- Fetal/stillborn deaths, including specific details

Additional information collected by the Agency includes births by birth weight, shortest, longest and average length of stay in the birth center, and number of circumcisions performed.

Additional information collected by DOH includes number of initial maternal visits, number of assigned licensed midwife students, number delivered at home or birth center or hospital, number of unplanned breach or multiple births, number of primary and subsequent vaginal birth after cesarean deliveries, number of water births and number of maternal deaths. Submission of an annual report does not allow this information to be reviewed in a timely manner and used during the inspection process.

Listing hospital beds on the license – Section 395.003(4), F.S.

Section 395.003(4), F.S., states that only beds for which there is a "need" methodology are to be listed on a hospital license. HB 21, Hospital Licensure (2019 Legislative Session) removes certificate of need requirements for hospitals in a tiered approach with the final change occurring July 1, 2021. Without a change to law in s. 395.003(4), F.S., current language would result in specialty hospital beds, such as neonatal intensive care beds, incorrectly being reported as general acute care beds on the face of the license.

Unenforceable annual assessment – Sections 395.7015 and 395.7016, F.S.
Section 395.7015, F.S., required ambulatory surgical centers and diagnostic imaging centers to pay a Public Medical Assistance Trust Fund (PMATF) assessment on health care entity revenue. Upon implementation of the law several years ago, the statute was immediately challenged in court and found to be unconstitutional, so repeal is being sought. The case was Hameroff v. PMATF, 911 So. 2nd 827 (Fla. 1st DCA 2005).

The Agency does not collect revenue data for ambulatory surgical centers and diagnostic imaging centers as it does for hospitals. Applying a methodology based on national data estimates the Agency may expect to collect $22 million annually and $16 million annually from ambulatory surgical centers and diagnostic imaging centers, respectively, if the statute was constitutional. However these estimates are not based on Florida specific data due to the inability to collect revenue data aforementioned. The hospital assessments totaled $690 million for the most recent year, 2018.

Health care provider risk-based licensure inspections – Sections 400.19, 400.605, 429.35, 429.905, 429.929
Health care facilities and providers licensed by the Agency are generally required by statute to have a biennial licensure inspection. Sections 400.19, 400.605, 429.35, 429.905 and 429.929 references the nursing home, hospice, assisted living facility and adult day care center inspection cycles. As the number of Florida providers continues to grow, resources are strained by this requirement to treat all providers equally. Currently uniform licensing requirements in s. 408.811, require biennial inspections unless otherwise specified in statutes or rules. However, other regulatory programs like Medicare, allow for extended inspection periods (greater than biennial) for some health care provider types such as home health, hospice and dialysis centers. The number of health care facilities and providers in Florida continues to grow as our state population grows. Current law does not authorize any flexibility to spend less time inspecting providers with good regulatory performance to allow the agency to devote more resources to those providers with problematic performance.

Specific provider changes:

Nursing Homes: s. 400.19, F.S., requires nursing homes be inspected every 15 months. Federal regulations (42 CFR 488.308(a)) for nursing homes allow up to 15 months between inspections, however, recent comments by the Federal Centers for Medicare and Medicaid Services have expressed an interest in allowing more flexibility for high performing providers. This section also requires a nursing home be placed on a 6-month inspection cycle for two years based on certain deficiencies. In some cases, a nursing home may have an isolated incident and not warrant the enhanced oversight for the full two-year period. The fine for the 6-month inspection period is $6,000 for the two extra inspections.
Hospice: s. 400.605, F.S., addresses program specific language related to the frequency of hospice inspections. This section references annual inspections with a biennial option for a record of compliance.
Assisted living facilities: s. 429.35(2), F.S., requires ALFs receive biennial licensure inspections. Chapter 408., Part II also requires biennial licensure inspections.
Adult day care centers: s. 429.905(2), F.S. and s. 429.929, F.S., require biennial licensure inspections. Chapter 408, Part II also requires biennial licensure inspections.

Home health agency licensure – Sections 400.462, 400.464, 400.471, 400.492, 400.497, 400.506 and 400.509 F.S.
Currently, the definition of a home health agency in section 400.462(12), F.S., requires an organization to provide both home health and staffing services. If an organization provides only home health services, it does not meet the definition of a home health agency, which is not the intent of the law to ensure proper licensure. Staffing services are defined in ss. 400.462(30), F.S., to include services provided to health care facilities, schools, and other business entities by health care personnel employed by or working under the auspices of a licensed home health agency or nurse registry.
Home health services are defined in section 400.462(14), F.S. as the following services that are provided by an organization.

- Nursing care.
- Physical, occupational, respiratory, or speech therapy.
- Home health aide services.
- Dietetics and nutrition practice and nutrition counseling.
- Medical supplies, restricted to drugs and biologicals prescribed by a physician.

As stated in the definition, the term “home health services” includes organizations that provide one or more of these services, which conflicts with the definition of “organization” in s. 400.462(22).

The definition of "organization” in section 400.462(22), F.S. is problematic because the term “health care discipline” contained within the definition of an organization is not itself defined in statute. It is not clear as to which health care professional licenses, fields or professions are covered under a single discipline (i.e. occupational and physical therapy). Providers question the need for a license if employing or contracting both occupational and physical therapists to provide health care services in the home. Additionally, as defined, an organization does not include an individual, creating a loophole for an individual to employ health care personnel for the provision of home health services without having to obtain a license. The term organization is used in multiple definitions in section 400.462 and in sections 400.464, 400.492, and 400.509, F.S., and creates a conflict with Chapter 408, Part II, the Agency’s uniform licensing statute, because an organization does not include persons but entities only.

Home health agencies providing skilled care services are required to maintain accreditation as a condition of licensure. As provided in section 400.471(2)(g), applicants for initial licensure, change of ownership or the addition of skilled care services must submit proof of accreditation or application for accreditation with an application for licensure, however only “initial” licensure applicants are required to provide evidence of accreditation and a survey demonstrating compliance with applicable licensure requirements prior to receiving a license from the Agency.

Legislatively mandated reports

The Agency is required by law to publish several reports:
Hospice annual report – s. 400.60501, F.S. - this report has historically been published by the Department of Elder Affairs. The requirement was amended in 2017 to include national hospice outcome measures to be

published by December 31, 2019. Florida Health Finder also displays information related to hospices for consumers.

E-prescribing - s. 408.061, F.S. - The Agency hosts a website where E-prescribing information is updated quarterly at http://fhin.net/eprescribing/dashboard/index.shtml.

Emergency Department Utilization Report – s. 408.062 (1)(i). An annual report is produced and data is available using the Agency's discharge data query tool in Florida Health Finder. Report intended to analyze patient acuity level and the implication of increasing hospital cost by providing non-urgent care in emergency departments. Recent reports have demonstrated that low acuity level patients are not utilizing the emergency department nearly as much as in prior years.

Florida Center Annual Report – s. 408.062(1)(j). An annual report is produced and data is available online through Florida Health Finder.

Health Flex Report – s. 408.909. The Health Flex Plan program was a pilot program established to benefit low-income families that were not eligible for public assistance programs and were not covered by private insurance. There were initially only three plans in limited service areas available for consumers. There is currently only one reaming Health Flex Plan with less than 300 members.

Cover Florida Report – s. 408.9091. There are currently no plans participating in the Cover Florida Health Care Access Program. The last participating health plan terminated its Cover Florida policies in January of 2015. With the establishment of the Affordable Care Act, Cover Florida polices essentially became moot.

Assisted living sanctions Report – s 429.19(9) requires the Agency to publish and disseminate an annual list of ALFs sanctioned or fined. Fine information of all ALFs is available on the Florida Health Finder website as required by 429.55(2), F.S.

Annual Expenditures – s. 408.063, F.S. The data used to generate the Expenditures Report is not available until several years after the reporting period. The Agency publishes the current year report utilizing the available data from three years prior, making it stale on the publishing date. An Agency data analytics staff member spends three weeks per year preparing the report. This staff member is highly utilized for high priority data analytical projects. The dashboard associated with this report received only 14 website hits in a year's time span.

Considerable Agency staff time can be spent preparing formal reports required however, information is routinely published online.

Health care clinic licensure exemptions - Section 400.9905, F.S.
There are currently over 14 exemptions listed in the health care clinic licensure laws. Many of these exemptions align with low risk indicators such as an entity already regulated by the Agency as a health care provider for licensure and/or federal certification purposes, a health care establishment or profession otherwise regulated by the Department of Health, a non-profit entity, or an entity with substantial financial commitment.

Comprehensive outpatient rehabilitation facilities (42 C.F.R. part 485, subpart B), outpatient physical therapy and speech-language pathology providers (42 C.F.R. part 485, subpart H), end stage renal diseases (42 C.F.R. part 494) and clinical laboratories are federally certified providers regulated by the Agency and qualify for an exemption from health care clinic licensure. Current health care clinic exemption law does not provide an exemption for federally certified community mental health center-partial hospitalization programs (42 C.F.R. part 485, subpart J), portable x-ray providers (42 C.F.R. part 486, subpart C) and rural health care clinics (42 C.F.R. part 491, subpart A), which are also regulated by the Agency.

During the 2019 Legislative session, proviso language created two additional exemptions from clinic licensure for entities owned be an insurance holding company with over $1 billion in annual sales and entities owned by a behavioral health provider in at least five states with $90 million in annual revenues from behavioral health. These exemptions are in effect until June 30, 2020.

Unless exempt, providers that meet the definition of health care clinic must obtain a license, and providers that participate in Medicaid must meet all applicable state laws. Medicaid recently initiated rule-making to add licensure as a health care clinic when required by law to be a pre-requisite to enrollment as a Medicaid provider. Over 20,000 providers have been identified as possibly requiring a health care clinic license to remain in Medicaid; some will likely meet an exemption, however an estimated 13,000 may require licensure to meet Medicaid requirements by December 2020. The Agency asked for 13 positions support this workload through a legislative budget request. The health care clinic laws were originally implemented to address Personal Injury Protect insurance exploitation. Medicaid has many program integrity protections in place to address abuse.

Health care clinic surety bonds – Section 400.991(3)(c), F.S.
Health care clinic law in s. 400.991(3)(c), F.S., states that as an alternative to submitting documentation of proof of financial ability to operate for initial or change of ownership licensure, a clinic applicant may file a surety bond. No health care clinics have utilized this law submit a surety bond in lieu of proof of financial ability to operate.

Definition of "urgent care center" – Section 400.9935(1)(I), F.S.

Health care clinic law states in s. 400.9935(1)(i), F.S., that all clinics must publish a schedule of charges for the services offered to patients. Current section references "urgent care center" for the purposes of posting charges but does not provide a definition. Urgent care center is defined in s. 395, Part I, F.S. Providers are often confused as to whether all health care clinics or only "urgent care centers" must post charges. The term "publish" is not defined.

Statutory reference to specific data collection rule – Section 408.061, F.S.
Section 408.061, F.S., related to data elements reported by providers to the Agency's Florida Center currently includes reference to an administrative rule 59E-7.012, Florida Administrative Code which was repealed and replaced with 59E-7.021-7.030, F.A.C.

Multiphasic health testing center licensure – Part I of Chapter 483, F.S., 408.33, 408.803
Multiphasic health testing centers, currently regulated under Part I of Chapter 483, F.S., are facilities where in addition to taking specimens from the human body for delivery to registered clinical laboratories for analysis, certain measurements such as height and weight determinations, blood pressure determinations, limited audio and visual tests, and electrocardiograms are also made. These additional services are not required to be provided by licensed personnel but can be provided by a medical assistant that is certified or registered through a national organization. These clinics would also fall under the definition of a health care clinic in Chapter 400, Part X, however, are exempt since they are already regulated by the Agency.

As of January 21, 2020, there are 187 multiphasic health testing centers licensed in Florida. Of these, 69 are owned and operated by Laboratory Corporation of America and 111 are owned and operated by Quest Diagnostics, including one out-of-state center. Both Laboratory Corporation of America and Quest Diagnostics also own and operate several clinical laboratories throughout the state that are regulated under the federal Clinical Laboratory Improvement Amendments (CLIA). The remaining 7 multiphasic health testing centers are owned by Professional Health Examiners, Inc. After reviewing online the services provided by ProHealth it appears these are basically walk-in clinics. Services are provided by licensed personnel under the direction of a medical director and the company does not bill insurance and thus would also be exempt from health care clinic licensure as would those centers owned and operated by clinical laboratories regulated under the federal CLIA.

The Agency assesses a biennial licensure fee and health care assessment fee. The Agency collects an estimated $89,071.84 annually ($178,143.68 biennially). There are 187 multiphasic health testing centers and half will renew each year. Licensure cost = $952.64 ($652.64 biennial license fee + $300.00 biennial health care facility assessment fee). $952.64 licensure fees X 93.5 providers/year = $89,071.84.

In the last eight years (since 2011), there have only been six fine cases imposed against multiphasic health testing centers. In this timeframe, only 10 complaints were received with none substantiated; 195 deficiencies have been cited since 2011.

Uniform licensing stature definitions – Section 408.803, F.S.
See information regarding low-risk providers

Provisional licenses – Section 408.806, F.S.

Section 408.806, F.S., allows the Agency the ability to issue a provisional license for all regulated provider types:

- Before passing a survey to receive an upgraded standard license in the cases of change of ownerships, or
- When the provider is in litigation with the Agency regarding the denying or revoking of a license

However, a provisional license for an assisted living facility may be issued in additional scenarios:

- When the provider is making an initial application for licensure (s. 429.11, F.S.)
- If the facility has been licensed for less than two years, the initial extended congregate care license must be provisional and may not exceed six months (s. 429.07(3)(b)(2), F.S.).

Background screening for health care providers and employees – Sections 408.809 and 409.907, F.S.
The law includes an expired date that allowed an employee who becomes disqualified from employment due to a law change that adds new disqualifying offenses to continue to work pending a request for an exemption from disqualification. This authority expired in 2014, however, each year disqualifying offenses can be changed affecting people who are currently employed.

Seven state agencies participate in the Care Providers Background Screening Clearinghouse authorized in Chapter 435. Language in s. 408.809(2) allows providers to provide proof of screening from agencies joining the Clearinghouse to meet screening requirements until such time as the specified agency is fully implemented in the Clearinghouse. All specified agencies are now fully implemented in the Clearinghouse. Section 408.809(5) references an obsolete rescreening schedule that has expired.

Background screening requirements for licensure and Medicaid enrollment largely align, however, language is not consistent related to the staff required to be screened. Some Medicaid managed care plans have screened all staff beyond those with access to clients. The number of employees affected by this change is indeterminable.

Comprehensive emergency management plan submission – Section 408.821, F.S.
Requirements for providers required to submit comprehensive emergency management plans (CEMP) to local emergency management officials and to the Agency varies by each provider's authorizing statute. Some provider types like assisted living, require plan approval by local emergency management officials prior to licensure, however some local jurisdictions will not review plans until the provider is licensed. This make it impossible for certain providers to comply with the law.

Medicaid Program Integrity hospital retrospective review program – Section 409.905(5)(a), F.S.
The Agency performs routine pre- and post-payment claim reviews to determine the appropriateness of historical, existing, and future provider reimbursement. Since Medicaid Program Integrity's inception, the Agency's claim review processes have recovered in excess of one billion dollars.

Medicaid Program Integrity (MPI) also conducts provider audits based on probable cause through the Alien Audit Program, which began in April 2010 under provisions of s. 409.913, F.S. The Alien Audit Program was developed after a 2009/2010 audit report from the Health and Human Services Office of Inspector General, mandated that the state return the federal share of erroneous payment for certain hospital claims related to Emergent Medicaid for Aliens.

Medicaid Program Integrity has recovered millions of dollars in the Alien Audit Program, yet the First District Court of Appeals ruled that s. 409.905(5)(a), F.S.,[1] precludes post-payment audits to determine the appropriateness of reimbursement, including whether prior authorization was obtained under false pretenses.[2] The decision relied on and obsolete reference limiting retroactive audits that applied to a program that no longer exists.

The entire Alien Audit Program, which began in 2010 and included 668 total closed cases, collected $57,056,455.79. The Agency lost $13,449,595.12 related to 42 cases that have been or will be closed at zero overpayment due to the First District Court of Appeals ruling. The cases are Lee Memorial Health System Gulf Coast Medical Center vs. AHCA, No. 1D16-1969 and No. ID16-3975, and Cape Memorial Hospital, Inc. d/b/a Cape Coral Hospital vs. AHCA, No 1D16-5310.

The Agency's position that there is no statute of limitations for retrospective reviews. The Centers for Medicare and Medicaid Services does not consider any time limit with respect to recoupment of the federal share of overpayments. However, because some laws limit record retention to five year, MPI generally limits to a five year look back period. The Agency has no distinction related to payment type (fee-for-service or managed care).

Federal regulation under 42 CFR § 456.23 requires that the Agency have a post-payment review process for all Medicaid services. Additionally, federal regulation under 42 CFR § 455.12 sets forth requirements of the State plan for the identification, investigation, and referral of suspected fraud and abuse cases, which includes compliance with the 42 CFR § 456.23 requirement to have a post-payment review process. Federal regulation under 42 CFR 455.16, states that one of the possible resolutions to an investigation is seeking recovery of payments made to the provider.

Medicaid Program Integrity's annual reports are available at on the Agency's website here: http://ahca.myflorida.com/MCHQ/MPI/.

The following illustrated MPI's recovery activities in recent fiscal years in millions:

	FY 2013-14	FY 2014-15	FY 2015-16	FY 2016-17	FY 2017-18
Audits	$21.2	$37.8	$19.5	$37.7	$19.9
Costs	$0.2	$0.4	$0.2	$0.3	$0.2

Costs may include legal fees, legal costs, and Agency costs. Legal fees are not broken out separately.

Medicaid recovery of cost of litigation– Section 409.913(23)(a), F.S.
The Division of Administrative Hearings (DOAH) ruled that s. 409.913(23)(a), F.S., does not authorize the Agency to recover full attorney's fees on Medicaid Program Integrity legal cases. The specific ruling came in DOAH case number 18-5986F involving Covenant Hospice. The case had an overpayment of $637,973.10 and sanction of $127,594.62 and the Agency was seeking fees and costs in the amount of $330,186.14 as of February 7, 2019. The Agency has the ability to collect the "costs" amount of the $330,186.14 but not the "fees" amount. While sympathetic to the Agency's position, the court felt it was not at liberty to rule in the Agency's favor due to the statutory limitation.

The Florida Department of Health (DOH) experienced a similar problem in their previous statute s. 456.624, F.S. (now renumbered 456.072, F.S.). The First District Court of Appeals ruled that DOH's previous statute did not state legal fees, therefore no fees could be collected. An example of case with this ruling is DOAH case number 1D02-4457 from 2004. As a result, the department made changes to allow for collection of fees in their current statute, s. 456.072(4), F.S.

2. EFFECT OF THE BILL:

[1] Cases #1D16-3975, #1D16-5310, #1D16-1969

[2] 409.905(5)(a) F.S. was also intended to eliminate a Medicaid or Department of Children and Families (not Medicaid Program Integrity) retrospective review program that had been replaced by a prior authorization process

Increasing the frequency of birth center reports to the Agency – Section 383.327, F.S.
Modifying annual birth center reporting in s. 383.327, F.S., will improve the currency and regulatory value of information reported such as the number of hospital transfers and infant and maternal deaths.

Listing Hospital Beds on the License – Section 395.003(4), F.S.
Elimination of language in s. 395.003(4), F.S., would allow specialty hospital beds to be correctly listed on the face of the hospital license. The correction is needed in correspondence to the repeal of certificate of need review requirements for hospitals.

Repeal an unenforceable annual assessment – Section 395.7015, F.S.
The proposed bill removes defunct and unenforceable language from the statute, which was ruled unconstitutional in 2001. The Agency has never collected assessments under s. 395.7015, F.S. All rules referencing the statute were repealed.

Health Care Provider Risk-Based Licensure Inspections - Sections 400.19, 400.605, 429.35, 429.905, 429.929
The bill removes references to fixed inspection timeframes from authorizing statutes for nursing homes, hospice, and adult day care centers. Amendments made to s. 408.811, F.S., will allow the Agency flexibility to make fewer visits to providers with a good regulatory history, allowing more time with providers with a problematic history. Because it is important to assure providers remain diligent in maintaining compliance with regulations and providing sufficient patient and resident protections, the proposal includes the continued ability for agency staff to enter any facility at any time and an expectation to verify the compliance of those with a good performance to assure providers can show they are following the law and protecting patients at any time.
Specific provider changes:
Nursing homes – the bill will remove the maximum of 15-months between nursing home inspections and defer to the inspection cycle in s. 408.811, F.S. The bill also modifies the requirement to impose a two-year period of six-month inspections for certain violations; instead, allowing one additional inspection and changes the fine from $6,000 for the two–year period to $3,000 for the extra inspection. If a facility is cited for a qualifying deficiency after the additional inspection, the penalty would be imposed again.
Hospice: s. 400.605, F.S., is amended to remove program specific language related to the frequency of inspections.
Assisted living facilities: s. 429.35(2), F.S., is amended to remove program specific language related to the frequency of inspections.
Adult day care centers: s. 429.905(2), F.S. and s. 429.929, F.S., require biennial licensure inspections. Chapter 408, Part II also requires biennial licensure inspections.

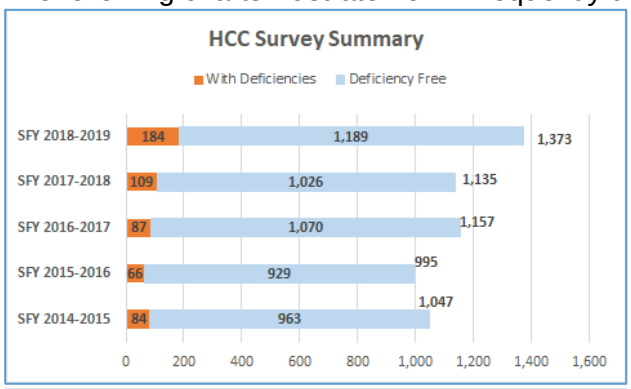
Low-Risk Provider Types - The bill defines specific provider types as low-risk: health care clinics (HCC), home medical equipment providers (HME), and nurse registries which do not provide residential care and generally have fewer deficiencies that other provider types. The agency may exempt a low-risk provider from licensure inspections based on an excellent regulatory history as defined by rule of deficiencies, sanctions, complaints and other regulatory actions.

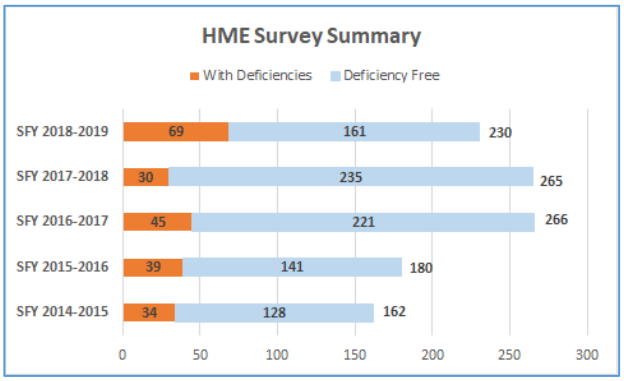
Low-Risk Providers – The Agency would conduct validation re-licensure inspections for 10 percent of exempt providers annually. This process enables less rigid regulatory oversight for high performing providers while maintaining the authority conduct an inspection at any time.

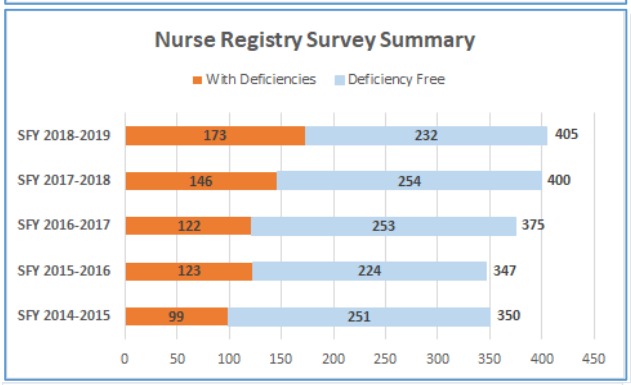
In the last two fiscal years (FY 2017-18 and FY 2018-19):

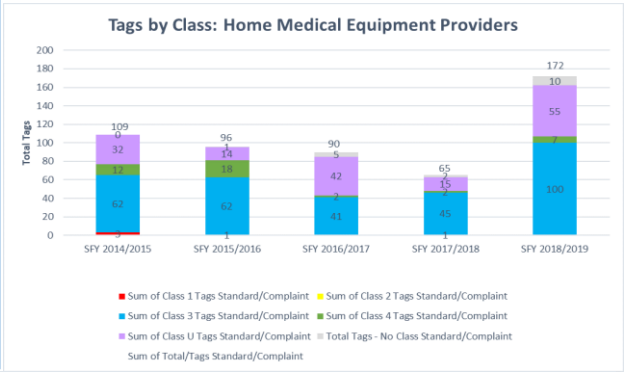
- Of the 1,150 current Active HME Providers
    - 654 HMEs were either Accredited or O2 exempt from relicensure surveys (this fluctuates)
    - 391 were surveyed, and 309 were deficiency free
- Of the 652 Active NR Providers
    - 589 were surveyed and 345 were deficiency free
- Of the 2,454 Active HCC Providers
    - 2,165 were surveyed and 1,920 were deficiency free

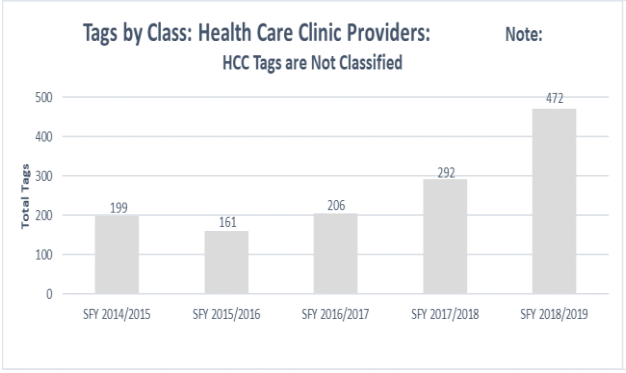
The following charts illustrate how infrequently deficiencies are cited on low-risk provider types.

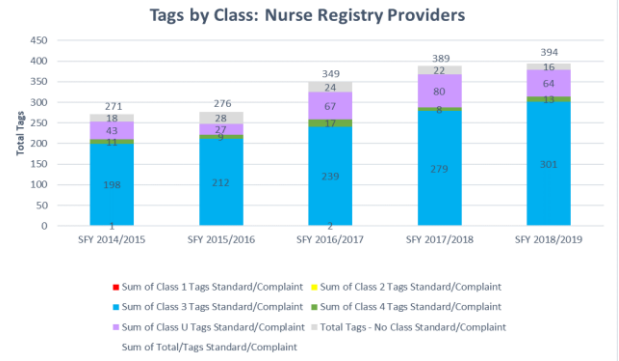












Extended Inspection Period- The Agency may develop rule criteria to inspect other licensed provider types less frequently for high performing providers including assisted living facilities and others. The Agency would still conduct a 10% sample review of those facilities that qualify for an extended cycle. Due to prescriptive federal inspection requirements, this flexibility would not be extended to nursing homes, hospitals or home health agencies, however the federal process does recognize accreditation for some of these programs where the agency conducts a sample of validation surveys after an accreditation inspection.

Once rules are promulgated, the Agency expects to shift resources to areas of need. See fiscal comments.

Clarifying the definitions and licensure requirements relating to home health agencies – Sections 400.462, 400.464, 400.492, 400.497, 400.506, 400.509, F.S.

The proposed bill revises the definition of a home health agency in ss. 400.462(12), F.S., to remove staffing services as a requirement of licensure and clarifies that the provision of home health services may be by direct or contract staff.

The bill replaces the term “organization” with “person or entity” to align with Chapter 408, Part II and address gaps related to “people”. The definition of “organization” in s. 400.462(22) is deleted and another home health agency license exemption is created in section s. 400.464(5) to address persons or entities that would not be subject to home health agency licensure under this definition. Sections 400.462, 400.464, 400.492 and

400.509 are amended to replace the term “organization” with “person or entity” or “licensee”, aligning the language with Chapter 408. Part II.

The bill also amends the definition of home health services in ss. 400.462(14), F.S., to remove the references to an organization in order to define what home health services are rather than who can provide them. The definition of nurse registry in ss. 400.462(21) is expanded to include entities, in addition to persons, that procure, offer, promise or attempt to secure contract for the provision of home health services.

Section 400.464 is amended to clarify that an exemption under this part is only applicable to an exemption as a home health agency and not an exemption as a nurse registry as both are included in Part III of Chapter 400. Section 400.464 creates an exemption from home health agency licensure for persons or entities providing skilled care services by only one type of health care professionals licensed either under part I of chapter 464 (nursing), part I, part III, or part V of chapter 468 (speech, occupational, or respiratory therapy), or chapter 486 (physical therapy). Skilled care services are currently defined in s. 400.462(29). This exemption indirectly exists within the current definition of “organization" which is being stricken. By adding this exemption under s. 400.464(5), a person or entity would be able to voluntarily apply to the Agency for a certificate of exemption from home health agency licensure as documentation of exempt status.

Language in section 400.471(2)(g) is amended to require applicants for change of ownership or license renewal to provide proof of accreditation and a survey demonstrating compliance with the applicable licensure requirements prior to the addition of skilled services.

Section 400.497 is amended to include rulemaking authority for additional services that a home health agency may offer. This change will allow other services be authorized as appropriate such as medical social work which is authorized in federal home health agency regulations.

Health care clinic exemptions – Section 400.9905, F.S.
Creating a health care clinic exemption for community mental health center-partial hospitalization programs certified under 42 C.F.R. part 485, subpart J, portable x-ray providers certified under 42 C.F.R. part 486, subpart C, and rural health care clinics certified under 42 C.F.R. part 491, subpart A aligns these programs with other federally certified programs. Approximately 200 providers will be eligible for an exemption. Certification requirements are more stringent than health care clinic licensure standards. The bill also codifies two exemptions that passed during the 2019 Legislative Session in proviso language for large entities owned or affiliated with an insurance company with over $1 billion on annual sales and a behavioral health provider in at least 5 states with over $90 million in annual revenues from behavioral health. The bill also creates an exemption for Medicaid providers from licensure which will eliminate the need for the 13 employees requested by the Agency’s legislative budget request.

Health care clinic surety bond – Section 400.991, F.S.

The bill repeals the ability for a clinic to submit a surety bond instead of providing proof of financial ability to operate. No clinics has utilized this option.

Health care clinic definition of “urgent care center” – Section 400.9935(1)(l), F.S.

The bill adds the definition of “urgent care center” from the hospital law [s. 395.002(29)(b)] to the health care clinic requirements related to posting charges. The bill also modifies the law to provide flexibility of how prices are posted by price level replacing the ability to post three price levels with any price levels. All health care clinics will continue to be required to publish these charges such as on a clinic’s website, in a document available at the clinic, in a scanned document which can be emailed upon request or in posted signage of undetermined size.

Deleting a reference to specific data collection rule – Section 408.061, F.S.

The bill removes a reference to an administrative rule. Rules are dynamic and should not be references in statute. Specific rules Data Collection 59E-7.011 to 7.020, F.A.C. were repealed and replaced with 59E-7.021-7.030, F.A.C.

Repeal multiphasic health testing center licensure – Part I of Chapter 483, F.S., 408.33, 408.803

Repealing multiphasic health testing center licensure in Part I of Chapter 483, F.S., would eliminate the additional regulation of entities that are already regulated or exempt from regulation under other state and/or federal laws. In addition to the repeal of the multiphasic licensure, the bill removed an exemption from health care clinic licensure. Therefore, if the provider did not meet a remaining exemption, those providing multiphasic services will be regulated under the health care clinic program. Based on information available to the Agency, it appears all 187 multiphasic health testing centers would be exempt from health care clinic licensure.

As the majority of multiphasic health testing centers operate as draw stations for the clinical laboratories regulated under the federal Clinical Laboratory Improvement Amendments (CLIA), should concerns arise regarding anything related to the specimen collection, these concerns could be addressed through the survey process for the main clinical laboratories. Based on information available online regarding the one non-clinical laboratory provider (ProHealth), it is unclear why a multiphasic health testing center license is actually required. This organization operates walk-in clinics (cash only), providing a wide range of services, under a medical director where services are provided by APRNs and PAs.

The deregulation of multiphasic health testing centers would result in a loss of revenue of $89,071.84 annually ($178,143.68 biennially). There are 187 multiphasic health testing centers and approximately half will renew each year. Licensure cost = $952.64 ($652.64 biennial license fee + $300.00 biennial health care facility assessment fee). $952.64 licensure fees X 93.5 providers/year = $89,071.84.

The repeal would also eliminate work duties and responsibilities associated with the licensure of multiphasic health testing centers. The staff currently assigned to this program are also assigned to other licensure and certification programs within the Laboratory and In-Home Services Unit. Because the multiphasic health testing center licensure program is relatively small, there would be no impact on the unit.

Expand the Agency's ability to issue a provisional license – Sections 408.806 and 429.11(6) F.S.

This provisional license authority for applicants making an initial application for licensure, currently only available for assisted living facilities, would now be authorized for all Agency regulated provider types in s. 408.806, F.S. The bill repeals the ALF provisional language in s. 429.11, F.S., since its now addressed in the uniform licensing requirements. This option would be helpful in cases such as a provider that fails to renew their license, allowing them to avoid an interruption in client services in a provisional status until all licensure requirements are met.

Background screening for health care provider license and Medicaid enrollment – Sections 408.809 and 409.907, F.S.

The bill removes an expired date that allowed an employee who becomes disqualified from employment due to a law change that adds new disqualifying offenses to continue to work pending a request for an exemption from disqualification. This will allow a person to keep their job if the law changes creating a new disqualifying offense, pending a review of an exemption from disqualification. The bill also removes several obsolete dates related to acceptance of prior screening results.

The bill will further align background screening requirements for licensure and Medicaid enrollment regarding staff screening by mirror the definition of employees and contractors required to be screened.

Update comprehensive emergency management plan requirements – Section 408.821, F.S.

Addition of CEMP requirements and violations for noncompliance in the Agency's uniform licensing statute, Chapter 408 Part II, will create consistency among Agency regulated provider types and ensure the timeframes for submission and review are consistent among all provider types. This change will also address the dilemma of initial licensure pending plan approval.

Repeal provision instructing the Agency to discontinue its Medicaid Program integrity hospital retrospective review program – Section 409.905(5)(a), F.S.

The directive in s. 409.905(5)(a), F.S., to discontinue an inpatient retrospective review program was intended by the Legislature to refer to a specific program conducted in the Division of Medicaid when the Division shifted to a prior authorization review. It is a misconception that this discontinuance was meant for retrospective reviews conducted by Medicaid Program Integrity. The proposed bill would eliminate the perceived contradiction that s. 409.905, F.S. supersedes s. 409.913, F.S., and allow Medicaid Program Integrity to continue retrospective reviews.

Clarify the authority to collect legal fees in Medicaid Program Integrity cases – Section 409.913(23)(a), F.S.
The bill would mirror Department of Health language to confirm the Agency's ability to collect all legal fees in defending case if the agency prevails. This would include cost of outside counsel.

Legislatively mandated reporting requirements

Report Name	Description of change	Authority	Location of Information Available. Comments
Hospice annual report	Repeal annual report. Retain requirement to report quality measures and consumer information.	s.400.60501(2), F.S.	Some report data elements no longer collected by DOEA. Hospice outcome and quality Information is published on FloridaHealthFinder.gov.
Annual e-Prescribing	Change annual legislative report to online report.	s. 408.0611, F.S.	Available anytime on the Agency's e-Prescribing dashboard, data is updated quarterly: http://fhin.net/eprescribing/dashboard/index.shtml
Emergency Department Utilization	Change annual legislative report to online report.	s. 408.062, F.S.	Report includes: Patient characteristics by age, ethnicity and gender Volume of Inpatient and Outpatient visits Volume by County Average charges for select conditions Most of the information is available anytime by using the Emergency Department Query Tool on the FloridaHealthFinder website: https://www.floridahealthfinder.gov/QueryTool/QTResults.aspx?T=E The query tool breaks out the inpatient and outpatient visits and shows the level of detail for a particular facility and is updated annually utilizing the same data source as the ED report.
Annual Expenditures	Repeal annual report due to diminished value as a result of 3-year lag in reporting information.	s. 408.063, F.S.	Report includes: Florida wage data from the Department of Economic Opportunity U.S. Census Bureau wage, expenditure, and population estimates National Health Expenditures data from CMS Florida Office of Insurance Regulation Managed Care HMO data Medicaid Payer data U.S. Bureau of Economic Analysis income data All data is publicly available on relevant government agency websites.
Florida Center Annual	Change annual legislative report to online report.	s. 408.062, F.S	Information is available on FloridaHealthFinder.gov; the status of data collection is updated bi-weekly. Information on

			quality measures is available at: https://www.florida healthfinder.gov/ CompareCare/ Glossary.aspx and https://www.floridahealthfinder.gov/Researchers/ Reference/Methodology /Methodology.aspx
Health Flex Program	Repeal annual report. The Health Flex Plan program was a pilot program established to benefit low-income families that were not eligible for public assistance programs and were not covered by private insurance. There were initially only three plans in limited service areas available for consumers. There is currently only one reaming Health Flex Plan with less than 300 members.	s. 408.909, F.S.	Report captures enrollment, financials, and any other possible statutory violation (none noted) for the one remaining plan. Information is available on the Agency page. http://ahca.myflorida.com/MCHQ/ Health_Facility_Regulation /Commercial_Managed _Care/health_flex_prog.shtml From 1/1/2016 to 1/1/2017, 2/6/2017 to 2/6/2018 and 1/16/2018 to 1/16/2019, the report received no website hits.
Cover Florida	Repeal annual report. There are currently no plans participating in the Cover Florida Health Care Access Program. The last participating health plan terminated its Cover Florida policies in January of 2015. With the establishment of the Affordable Care Act, Cover Florida polices essentially became moot.	s. 408.9091, F.S.	Report captures the health plans that initially offered the product, when they stopped offering the product and the counties of operation. Program as not been functionally since 2015. Any information available can be found on the Agency page. http://ahca.myflorida.com/ MCHQ/Health_Facility_Regulation /Commercial_Managed_Care/index.shtml From 1/1/2019 to 10/7/2019, there was only one website hit to the Cover Florida report. From 3/5/2018 to 3/5/2019 and from 3/1/2017 to 3/1/2018, the report received no website hits.
Assisted Living Facility Sanction	Repeal annual report. Published list once a year is static; more current information available on FloridaHealthFinder.gov	s. 429.19, F.S.	Readily available on assisted living facility profile pages on Florida Health Finder or can be requested from the Agency at any time. The ALF statute also requires a consumer information website where information is linked to FloridaHealthFinder.
Medicaid Program Integrity Annual Report	Change report due date to January 15 from January 1.	s. 409.913, F.S.	Current due date is on a holiday.

Repeal of multiphasic health testing center licensure – Part 1 of Chapter 483, F.S.
Repealing multiphasic health testing center licensure in Part 1 of Chapter 483, F.S., would eliminate the additional regulation of entities that are already regulated or exempt from regulation under other state and/or federal laws. Those entities include, among others, hospitals, ambulatory surgery centers, home health agencies, HMOs, clinical laboratories, governmental entities, and practitioners who treat their own patients. Currently, the entities subject to and exempt from multiphasic health testing center licensure are also exempted under the Health Care Clinic Act set forth in part X of Chapter 400, F.S.

The deregulation of multiphasic health testing centers would result in a loss of revenue of $89,071.84 annually ($178,143.68 biennially). There are 187 multiphasic health testing centers and half will renew each year. Licensure cost = $952.64 ($652.64 biennial license fee + $300.00 biennial health care facility assessment fee)
$952.64 licensure fees X 93.5 providers/year = $89,071.84.

The repeal would also eliminate work duties and responsibilities associated with the licensure of multiphasic health testing centers. The staff currently assigned to this program are also assigned to other licensure and certification programs within the Laboratory and In-Home Services Unit. Because the multiphasic health testing center licensure program is relatively small, there would be no impact on the unit.

Since 2011, there have only been six fine cases imposed against multiphasic health testing centers. In this timeframe, only 10 complaints were received with none substantiated and only 195 tags have been cited. For comparison, 84,159 tags were cited against nursing homes in the same timeframe.

3. DOES THE BILL DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES? Y ___ N _X__

If yes, explain:	
Is the change consistent with the agency's core mission?	Y _X__ N ___
Rule(s) impacted (provide references to F.A.C., etc.):	

4. WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?

Proponents and summary of position:	Unknown
Opponents and summary of position:	Unknown

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y __ N _X__

If yes, provide a description:	
Date Due:	
Bill Section Number(s):	

6. ARE THERE ANY GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSION, ETC.? REQUIRED BY THIS BILL? Y ___ N __X_

Board:	
Board Purpose:	
Who Appointments:	

Appointee Term:	
Changes:	
Bill Section Number(s):	

FISCAL ANALYSIS

1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT? Y __ N _X__

Revenues:	
Expenditures:	
Does the legislation increase local taxes or fees? If yes, explain.	
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	

2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT? Y _X_ N ___

Comments:	Exempting Medicaid providers from health care clinic law will result in a cost avoidance. The Agency previously asked for 13 employees in a legislative budget request to process additional health care clinic licensure applications for Medicaid providers which will no longer be needed. Because the Agency has to promulgate rules related to the risk-based licensure inspections, we are not able to determine at this time how many resources will be released to conduct other regulatory activities. The rule process takes six to nine months. The Agency's field operations managers and staff spend significant additional hours (in excess of 40 per week) to complete duties. The Agency's priority will be to reclassify positions to perform supervisory duties as resources are able to be shifted as a result of a reduction in inspections. The Medicaid Program Integrity retrospective alien audit case was an isolated example, however the Agency lost $13.5 million in revenue. Although the Agency cannot pinpoint an exact fiscal impact if this issue is not addressed, the Agency could face future litigation that puts millions of dollars of recoupment at risk. The Agency's tracking systems for Medicaid recovery does not distinguish legal costs in a case so we are unable to determine the future impact of the proposed change however the legal fee portion of the single case of over $330,000 was lost, which could be replicated in the future. A loss of $89,071.84 per year will occur in licensure fees from the repeal of multiphasic health testing center licensure.
Does the legislation contain a State Government appropriation?	No
If yes, was this appropriated last year?	N/A

3. DOES THE BILL HAVE A THE FISCAL IMPACT TO THE PRIVATE SECTOR? Y _X__N __

Revenues:	
Expenditures:	By excluding additional providers from health care clinic licensure, these providers will not be required to pay the $2,000 biennial clinic licensure fee.
Other:	

4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y __ N _X__

If yes, explain impact.	
Bill Section Number:	

TECHNOLOGY IMPACT

1. DOES THE BILL IMPACT THE AGENCY'S TECHNOLOGY SYSTEMS (I.E. IT SUPPORT, LICENSING SOFTWARE, DATA STORAGE, ETC.)? Y _X__ N ___

If yes, describe the anticipated impact to the agency including any fiscal impact.	

FEDERAL IMPACT

1. DOES THE BILL HAVE A FEDERAL IMPACT (I.E. FEDERAL COMPLIANCE, FEDERAL FUNDING, FEDERAL AGENCY INVOLVEMENT, ETC.)? Y ___ N _X__

If yes, describe the anticipated impact including any fiscal impact.	

ADDITIONAL COMMENTS

LEGAL – GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 1742
INTRODUCER:	Senator Mayfield
SUBJECT:	Home Medical Equipment Providers
DATE:	January 27, 2020 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Favorable**
2.			AHS	
3.			AP	

I. Summary:

SB 1742 amends s. 400.93, F.S., to exempt physicians licensed under chs. 458 and 459, F.S., as well as chiropractic physicians licensed under ch. 460, F.S., from the requirement to be licensed as a home medical equipment provider in order to sell or rent electrostimulation medical equipment and supplies to their own patients in the course of their practice.

The bill has an effective date of July 1, 2020.

II. Present Situation:

Home Medical Equipment Providers

Part VII of ch. 400, F.S., requires the Agency for Health Care Administration (AHCA) to license and regulate any person or entity that holds itself out to the public as performing any of the following functions:

- Providing home medical equipment[1] and services;[2]
- Accepting physician orders for home medical equipment and services; or
- Providing home medical equipment that typically requires home medical services.[3]

[1] Defined in s. 400.925, F.S., as any product as defined by the federal Food and Drug Administration's Drugs, Devices and Cosmetics Act, any products reimbursed under the Medicare Part B Durable Medical Equipment benefits, or any products reimbursed under the Florida Medicaid durable medical equipment program. Home medical equipment includes oxygen and related respiratory equipment; manual, motorized, or customized wheelchairs and related seating and positioning, but does not include prosthetics or orthotics or any splints, braces, or aids custom fabricated by a licensed health care practitioner; motorized scooters; personal transfer systems; and specialty beds, for use by a person with a medical need.

[2] Defined in s. 400.925, F.S., as equipment management and consumer instruction, including selection, delivery, set-up, and maintenance of equipment, and other related services for the use of home medical equipment in the consumer's regular or temporary place of residence.

[3] Section 400.93(1) and (2), F.S.

The following are exempt from the licensure requirement for home medical equipment providers:[4]

- Providers operated by the Department of Health (DOH) or the federal government;
- Nursing homes;
- Assisted living facilities;
- Home health agencies;
- Hospices;
- Intermediate care facilities;
- Transitional living facilities;
- Hospitals;
- Ambulatory surgical centers;
- Manufacturers and wholesale distributors when not sell directly to the consumer;
- Licensed health care practitioners who utilize home medical equipment in the course of their practice but do not sell or rent home medical equipment to their patients; and
- Pharmacies.

Currently, there are 1,167 licensed home medical equipment providers, including those providers that are located out of the state but hold a Florida license.[5]

Any person or entity applying for a license as a home medical equipment provider must provide the AHCA with:

- A report of the medical equipment that will be provided, indicating whether it will be provided directly or by contract;
- A report of the services that will provided, indicating whether the services will be provided directly or by contract;
- A list of the persons and entities with whom they contract;
- Documentation of accreditation, or an application for accreditation, from an organization recognized by the AHCA;[6]
- Proof of liability insurance; and
- A $300 application fee and a $400 inspection fee, unless exempt from inspection.[7]

As a requirement of licensure, home medical equipment providers must comply with a number of minimum standards including, but not limited to:

- Offering and providing home medical equipment and services, as necessary, to consumers who purchase or rent any equipment that requires such services;
- Providing at least one category of equipment directly from their own inventory;
- Responding to orders for other equipment from either their own inventory or from the inventory of other contracted companies;
- Maintaining trained personnel to coordinate orders and scheduling of equipment and service deliveries;

[4] Section 400.93(5), F.S.
[5] *See* AHCA, Florida Health Finder, *Home Health Care in Florida*, (printed list of home medical equipment providers on file with the Senate Committee on Health Policy).
[6] Accreditation must be achieved and maintained to maintain licensure.
[7] Section 400.931, F.S.

- Ensuring that their delivery personnel are appropriately trained;
- Ensuring that patients are aware of their service hours and emergency service procedures;
- Answering any questions or complaints a consumer has about an item or the use of an item;
- Maintaining and repairing, either directly or through contract, items rented to consumers;
- Maintaining a safe premises;
- Preparing and maintaining a comprehensive emergency management plan that must be updated annually and provide for continuing home medical equipment services for life-supporting or life-sustaining equipment during an emergency;
- Maintaining a prioritized list of patients who need continued services during an emergency;[8]
- Complying with AHCA rules on minimum qualifications for personnel, including ensuring that all personnel have the necessary training and background screening;[9] and
- Maintaining a record for each patient that includes the equipment and services the provider has provided and which must contain:
  - Any physician's order or certificate of medical necessity;
  - Signed and dated delivery slips;
  - Notes reflecting all services, maintenance performed, and equipment exchanges;
  - The date on which rental equipment was retrieved; and,
  - Any other appropriate information.[10]

Licensed home medical equipment providers are subject to periodic inspections, including biennial licensure inspections, inspections directed by the federal Centers for Medicare and Medicaid Services, and licensure complaint investigations. A home medical equipment provider may submit a survey or inspection by an accrediting organization in lieu of a licensure inspection if the provider's accreditation is not provisional and the AHCA receives a report from the accrediting organization. A copy of a valid medical oxygen retail establishment permit issued by the DOH may also be submitted in lieu of a licensure inspection.[11]

Electrostimulation Medical Equipment

Devices that provide electrical stimulation can be used medically to treat a number of symptoms and conditions. Electrical stimulators can provide direct, alternating, pulsed, and pulsed waveforms of energy to the human body through electrodes that may be indwelling, implanted in the skin, or used on the surface of the skin.[12] Such devices may be used to exercise muscles, demonstrate a muscular response to stimulation of a nerve, relieve pain, relieve incontinence, and provide test measurements.[13]

Functional electrical stimulation (FES), also known as therapeutic electrical stimulation (TES), is used to prevent or reverse muscular atrophy and bone loss by stimulating paralyzed limbs. FES is

[8] Section 400.934, F.S.
[9] AHCA, Rule 59A-25.004, F.A.C. All home medical equipment provider personnel are also subject to a level 2 background screening per s. 400.953, F.S.
[10] Section 400.94, F.S.
[11] Section 400.933, F.S.
[12] United Healthcare Medical Policy, *Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation*, p. 4, (January 1, 2020) https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/electrical-stimulation-treatment-pain-muscle-rehabilitation.pdf (last visited Jan. 23, 2020).
[13] Id.

designed to be used as a part of a self-administered, home-based rehabilitation program for the treatment of upper limb paralysis. An FES system consists of a custom-fitted device and control unit that allows the user to adjust the stimulation intensity and a training mode which can be gradually increased to avoid muscle fatigue.[14]

A second type of electrical stimulation is Transcutaneous Electrical Nerve Stimulation, or TENS. TENS is the application of electrical current through electrodes placed on the skin for pain control. It has been used to treat a variety of painful conditions, but there is "much controversy over which conditions to treat with TENS and the adequate parameters to use."[15] Despite this controversy, there is some clinical evidence that TENS is able to relieve certain types of pain and "experimental pain studies and clinical trials are beginning to refine parameters of stimulation to obtain the best pain relief."[16] For example, studies have shown that TENS increases the pressure and heat pain thresholds in people who are healthy and reduces mechanical and heat hyperalgesia in arthritic animals.[17]

Other types of electrical stimulation include interferential therapy (IFT) and neuromuscular electrical stimulation (NMES). IFT uses two alternating currents simultaneously applied to the affected area through electrodes and which is proposed to relieve musculoskeletal pain and increase healing in soft tissue injuries and bone fractures. NMES involves the application of electrical currents through the skin to cause muscle contractions and is used to promote the restoration of nerve supply, prevent or slow atrophy, relax muscle spasms, and to promote voluntary control of muscles in patients who have lost muscle function.[18]

III. Effect of Proposed Changes:

SB 1742 amends s. 400.93, F.S., to exempt physicians licensed under chs. 458 and 459, F.S., as well as chiropractic physicians licensed under ch. 460, F.S., from the requirement to be licensed as a home medical equipment provider in order to sell or rent electrostimulation medical equipment and supplies to their own patients in the course of their practice.

The bill has an effective date of July 1, 2020.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

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[14] *Supra* note 12.
[15] Effectiveness of Transcutaneous Electrical Nerve Stimulation for Treatment of Hyperalgesia and Pain, *Curr Rheumatol Rep. Dec 2008; 10(6): 492–499* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2746624/ (last visited Jan. 23, 2020).
[16] *Id.*
[17] Effects of Transcutaneous Electrical Nerve Stimulation on Pain, Pain Sensitivity, and Function in People With Knee Osteoarthritis: A Randomized Controlled Trial, *Physical Therapy 2012 Jul; 92(7): 898–910* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3386514/, (last visited Jan. 23, 2020).
[18] *Supra* note 12

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:

Physicians exempted under SB 1742 may see a positive fiscal impact due to no longer having to pay licensure and inspection fees or meet the licensure requirements of part VII of ch. 400, F.S.

C. Government Sector Impact:

The AHCA may experience a negative, but likely insignificant, fiscal impact due to fewer licensed home medical equipment providers.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 400.93 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Mayfield

17-01545-20 20201742__

A bill to be entitled

An act relating to home medical equipment providers; amending s. 400.93, F.S.; exempting allopathic, osteopathic, and chiropractic physicians who sell or rent electrostimulation medical equipment and supplies in the course of their practice from certain licensure requirements; providing an effective date.

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

Section 1. Paragraph (l) is added to subsection (5) of section 400.93, Florida Statutes, to read:

400.93 Licensure required; exemptions; unlawful acts; penalties.—

(5) The following are exempt from home medical equipment provider licensure, unless they have a separate company, corporation, or division that is in the business of providing home medical equipment and services for sale or rent to consumers at their regular or temporary place of residence pursuant to the provisions of this part:

(l) Physicians licensed under chapter 458 or chapter 459 and chiropractic physicians licensed under chapter 460 for the sale or rental of electrostimulation medical equipment and electrostimulation medical equipment supplies to their patients in the course of their practice.

Section 2. This act shall take effect July 1, 2020.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Subcommittee on Agriculture, Environment, and General Government, *Chair*
Children, Families, and Elder Affairs, *Vice Chair*
Appropriations
Environment and Natural Resources
Health Policy

SENATOR DEBBIE MAYFIELD
17th District

January 22, 2020

The Honorable Gayle Harrell
Chairwoman, Health Policy
530 Knott Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Re: SB 1742

Dear Chairwoman Harrell,

I am respectfully requesting Senate Bill 1742, a bill relating to Home Medical Equipment Providers, be placed on the agenda for your Health Policy.

I appreciate your consideration of this bill and I look forward to working with you and the Health Policy staff. If there are any questions or concerns, please do not hesitate to call my office at 850-487-5017.

Thank you,

Debbie Mayfield
State Senator, District 17

Cc: Allen Brown, Celia Georgiades

REPLY TO:
❒ 900 East Strawbridge Avenue, Melbourne, Florida 32901 (321) 409-2025 FAX: (888) 263-3815
❒ 1801 27th Street, Vero Beach, Florida 32960 (772) 226-1970
❒ 322 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5017

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)

1-28-20
Meeting Date

SB 1742
Bill Number (if applicable)

Topic TENS Unit Dispensing

Amendment Barcode (if applicable)

Name JACK HEBERT

Job Title GOVT AFFAIRS DIR

Address 2655 ULMERTON RD #276 Phone 7275603323
Street

CLEARWATER FL 33762 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 ASS'N

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

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 926
INTRODUCER:	Senator Harrell
SUBJECT:	Health Care Practitioner Licensure
DATE:	January 27, 2020
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Kibbey	Brown	HP	**Favorable**
2.			AHS	
3.			AP	

I. Summary:

SB 926 authorizes Florida to participate in the Interstate Medical Licensure Compact (IMLC or Compact) for the licensure of physicians and osteopathic physicians. The bill allows a physician who is licensed through the Compact and whose licensed is suspended or revoked through the Compact as a result of disciplinary action taken against the physician's license in another state, to have a formal hearing before the Florida Division of Administrative Hearings.

The bill also amends health care practitioner licensure, certification, and registration provisions in chapter 456 to remove prohibitions and penalties for applicants and practitioners who have failed to repay their student loans or who are listed on the listed on the U.S. Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

The bill has an indeterminate fiscal impact on state revenues and state expenditures.

The bill takes effect on July 1, 2021.

II. Present Situation:

Occupational Licensure Compacts

Interstate compacts are authorized under the U.S. Constitution, Article I, Section 10, cl. 3.[1] Compacts that affect a power delegated to the federal government or that affect or alter the

[1] "No state shall, without the Consent of Congress…enter into any Agreement or Compact with another State, or with a foreign Power[.]" *see* U.S. CONST. art. I, s. 10, cl. 3. While the language of the provision says congressional approval is required, not all compacts require congressional approval.

political balance within the federal system require the consent of Congress.[2] There are currently more than 200 compacts between the states, including 50 national compacts, of which six are for health professions.[3, 4]

The licensing of professions is predominantly a state responsibility as each state has developed its own regulations, oversight boards, and requirements for dozens of professions and occupations. More than 25 percent of individuals within the American workforce are currently in a profession that requires a professional license.[5]

In September 2018, the Federal Trade Commission (FTC) looked at the issue of state-by-state occupational licensure and its unintended consequences. In particular, the FTC noted that state-by-state licensing can have a particularly hard effect on those in the military and their spouses who are required to move frequently, those who provide services across state lines, or deliver services through telehealth.[6] The FTC also suggested that improved licensed portability would enhance competition, choice, and access for consumers, especially where services may be in short supply.[7]

Interstate Medical Licensure Compact

The Interstate Medical Licensure Compact provides an expedited pathway for medical and osteopathic physicians to qualify to practice medicine across state lines within a Licensure Compact. Currently, 29 states, the District of Columbia and the Territory of Guam which cover 43 medical and osteopathic boards participate in the Compact.[8]

The Interstate Medical Licensure Compact Commission (Commission) is created in Section 11 of the Compact and serves as the administrative arm of the Compact and member states. Each member state of the Compact has two voting representatives on the Commission. If a state has

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[2] This issue was settled in *Virginia v. Tennessee*, 148 U.S. 503 (1893). *See also Interstate Compacts & Agencies (1998),* William Kevin Voit, Sr. Editor and Gary Nitting, Council of State Governments, pg. 7, *available at* http://www.csg.org/knowledgecenter/docs/ncic/CompactsAgencies98.pdf (last visited Jan. 22, 2020)

[3] Ann O'M. Bowman and Neal D. Woods, *Why States Join Interstate Compacts,* The Council of State Governments (March 2017) p. 19 and 20, http://knowledgecenter.csg.org/kc/system/files/Bowman%202017.pdf, (last visited Jan. 22, 2020).

[4] Federal Trade Commission, *Policy Perspectives: Options to Enhance Occupational License Portability* (September 2018), p. 9, *available at* https://www.ftc.gov/system/files/documents/reports/options-enhance-occupational-license-portability/license_portability_policy_paper.pdf (last visited Jan. 22, 2020). The six health professions are nurses, medical, emergency medical services, physical therapy, psychology, and advanced registered nurse practitioners. The only two compacts currently operational are the Enhanced Nurse Compact and the physicians compacts as the others are awaiting the completion of an administrative structure.

[5] Albert Downs and Iris Hentze, *License Overload? Lawmakers are questioning whether we've gone too far with occupational and professional licensing* (April 1, 2018), STATE LEGISLATURES MAGAZINE, *ncsl.org,* http://www.ncsl.org/bookstore/state-legislatures-magazine/occupational-licensing-can-balance-safety-and-employment-opportunities.aspx (last visited Jan. 22, 2020).

[6] Federal Trade Commission, *Policy Perspectives, Options to Enhance Occupational License Portability* (September 2018), *available at* https://www.ftc.gov/system/files/documents/reports/options-enhance-occupational-license-portability/license_portability_policy_paper.pdf (last visited Jan. 22, 2020).

[7] *Id*.

[8] Interstate Medical Licensure Compact, *The IMLC,* https://imlcc.org/ (last visited Jan. 22, 2020).

separate regulatory boards for allopathic and osteopathic, then the representation is split between the two boards.[9]

Approximately 80 percent of physicians meet the eligibility guidelines for licensure through the Compact.[10] The providers' applications are expedited by using the information previously submitted in their State of Principal Licensure (SPL). The physician can then select in which states to practice in after a fresh background check is completed.

To qualify for consideration, the physician must:

- Hold a full, unrestricted medical license from a Compact member state and meet one of the following additional qualifications:
  - The physician's primary residence is in the SPL.
  - The physician's practice of medicine occurs in the SPL for at least 25 percent of the time.
  - The physician's employer is located in the SPL.
  - The physician uses the SPL as his or her state of residence for U.S. federal income tax purposes.

Additionally, the physician must maintain his or her licensure from the SPL at all times. A physician may change his or her SPL after the original qualification. Other requirements for eligibility for a Compact license include:

- Graduation from an accredited medical school, or a school listed in the International Medical Education Directory.
- Successful completion of graduate medical education from a school which has received accreditation from Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association (AOA).
- Passage – in no more than three attempts – of each component of the U.S. Medical Licensing Exam (USMLE) or the Comprehensive Osteopathic Medical Licensing Exam (COMLEX-USA) or equivalent.
- Holding a current specialty certification or time-unlimited certification by an American Board of Medical Specialties (ABMS) or American Osteopathic Association/Bureau of Osteopathic Specialists (AOABOS) board.
- Not having any history of disciplinary actions as to their medical license.
- Not having a criminal history.
- Not having any history of controlled substance actions as to their medical license.
- Not currently under investigation.[11]

The Commission charges an application fee of $700, which an applicant pays directly to the Commission. Each state's fee for licensure is separate from the Commission's application fee. The individual state fees currently vary from a low of $75 in Alabama and Wisconsin to a high of $790 in Maryland.[12]

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[9] Interstate Medical Licensure Compact, Section 11, (d), p. 11, https://imlcc.org/wp-content/uploads/2018/04/IMLC-Compact-Law.pdf (last visited Jan. 22, 2020).
[10] Interstate Medical Licensure Compact, *The IMLC*, https://imlcc.org/ (last visited Jan. 22, 2020).
[11] Interstate Medical Licensure Compact, *Do I Qualify*, https://imlcc.org/do-i-qualify/ (last visited Jan. 22, 2020).
[12] Interstate Medical Licensure Compact, *What Does It Cost?* https://imlcc.org/what-does-it-cost/ (last visited Jan. 22, 2020).

Regulation of Physicians in Florida

Licensing of Florida Physicians

The regulation of the practices of medicine and osteopathic medicine in Florida fall under chapters 458 and 459, F.S., respectively. The practice acts for both professions establish the regulatory boards, a variety of licenses, the application process with eligibility requirements, and financial responsibilities for the practicing physicians.

The boards have the authority to establish, by rule, standards of practice and standards of care for particular settings.[13] Such standards may include education and training, medication including anesthetics, assistance of and delegation to other personnel, sterilization, performance of complex or multiple procedures, records, informed consent, and policy and procedures manuals.[14]

The current licensure application fee for a medical doctor is $350 and is non-refundable.[15] Applications must be completed within one year. If a license is approved, the initial license fee is $355.[16] The entire process typically takes from two to six months from the time the application is received.[17]

For osteopathic physicians, the current application fee is non-refundable at $200, and if approved, the initial licensure fee is $305.[18] The same application validity provision of one year applies and the processing time of two to six months is the range of time that applicants should anticipate for a decision.[19] If an applicant is licensed in another state, the applicant may request that Florida "endorse" those exam scores and demonstrate that the license was issued based on those exam scores. The applicant must also show that the exam was substantially similar to any exam that Florida allows for licensure.[20]

The general requirements for licensure under both practice acts are very similar with the obvious differences found in the educational backgrounds of the applicants. However, the practice acts are not identical in their licensure offerings as shown in the table below, which compares some of the contents of the two practice acts. Where the practice acts share the most similarities are the qualifications for licensure. Both the Board of Medicine and the Board of Osteopathic Medicine require their respective applicants to meet these minimum qualifications:

- Complete an application form as designated by the appropriate regulatory board.
- Be at least 21 years of age.

[13] Sections 458.331(1)(v) and 459.015(1)(z), F.S.
[14] *Id.*
[15] Florida Board of Medicine, *Medical Doctor - Fees,* https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted (last visited Jan. 22, 2020).
[16] *Id.*
[17] Florida Board of Medicine, *Medical Doctor Unrestricted - Process,* https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted/ (last visited Jan. 22, 2020).
[18] Florida Board of Osteopathic Medicine, *Osteopathic Medicine Full Licensure - Fees,* https://floridasosteopathicmedicine.gov/licensing/osteopathic-medicine-full-licensure/ (last visited Jan. 22, 2020).
[19] Florida Board of Osteopathic Medicine, *Osteopathic Medicine Full Licensure - Process,* https://floridasosteopathicmedicine.gov/licensing/osteopathic-medicine-full-licensure/ (last visited Jan. 22, 2020).
[20] Florida Board of Osteopathic Medicine, *Osteopathic Medicine Full Licensure - Requirements,* https://floridasosteopathicmedicine.gov/licensing/osteopathic-medicine-full-licensure/ (last visited Jan. 22, 2020).

- Be of good moral character.
- Have completed at least two years (medical) or three years (osteopathic) of pre-professional post-secondary education.
- Have not previously committed any act that would constitute a violation of chapter 458 or chapter 459, as applicable, or lead to regulatory discipline.
- Have not had an application for a license to practice medicine or osteopathic medicine denied or a license revoked, suspended or otherwise acted upon in another jurisdiction by another licensing authority.
- Must submit a set of fingerprints to the DOH for a criminal background check.
- Demonstrate that he or she is a graduate of a medical college recognized and approved by the applicant's respective professional association.
- Demonstrate that she or he has successfully completed a resident internship (osteopathic medicine) or supervised clinical training (medical) of not less than 12 months in a hospital approved for this purpose by the applicant's respective professional association.
- Demonstrate that he or she has obtained a passing score, as established by the applicant's appropriate regulatory board, on all parts of the designated professional examination conducted by the regulatory board's approved medical examiners, no more than five years before making application to this state; or, if holding a valid active license in another state, that the initial licensure in the other state occurred no more than five years after the applicant obtained a passing score on the required examination.[21]

Statutory References for Practice Acts - Licensure Medical and Osteopathic Physicians: Ch. 458 and 459, F.S.		
Issue	**Medical Physicians**	**Osteopathic Physicians**
Regulatory Board	Board of Medicine s. 458.307, F.S.	Board of Osteopathic Medicine s. 459.004, F.S.
Rulemaking Authority	s. 458.309., F.S.	s. 459.005, F.S.
General Requirements for Licensure	s. 458.311, F.S.	s. 459.0055, F.S.
Licensure Types		
Restricted License	s. 458.310, F.S.	No provision
Restricted License Certain foreign physicians	s. 458.3115, F.S.	No provision
Licensure by Endorsement	s. 458.313, F.S.	No provision
Temporary Certificate (Approved Cancer Centers)	s. 458.3135, F.S.	No provision
Temporary Certificate (Training Programs)	s. 458.3137, F.S.	No provision
Medical Faculty Certificate	s. 458.3145, F.S.	s. 459.0077, F.S.
Temporary Certificate Areas of Critical Need	s. 458.315, F.S.	s. 459.0076, F.S.

[21] *See* ss. 458.311, F.S. and 459.0055, F.S.

Statutory References for Practice Acts - Licensure Medical and Osteopathic Physicians: Ch. 458 and 459, F.S.		
Issue	**Medical Physicians**	**Osteopathic Physicians**
Temporary Certificate Areas of Critical Need – Active Duty Military & Veterans	s. 458.3151, F.S.	s. 459.00761, F.S.
Public Health Certificate	s. 458.316, F.S.	No provision
Public Psychiatry Certificate	s. 458.3165, F.S.	No provision
Limited Licenses	s. 458.317, F.S.	s. 459.0075, F.S.
Expert Witness	s. 458.3175, F.S.	s. 459.0066, F.S.
License Renewal	s. 458.319, F.S. $500/max/biennial renewal	s. 459.008, F.S.
Financial Responsibility *Condition of Licensure*	s. 458.320, F.S.	s. 459.0085, F.S.
Penalty for Violations	s. 458.327, F.S.	s. 459.013, F.S.

In Florida, to practice medicine an individual must become a licensed medical doctor through licensure by examination[22] or licensure by endorsement.[23] Florida does not recognize another state's medical license or provide licensure reciprocity.[24] Licensure by endorsement requires the medical physician to meet the following requirements:

- Be a graduate of an allopathic U.S. medical school recognized and approved by the U.S. Office of Education and completed at least one year of residency training;
- Be a graduate of an allopathic international medical school and have a valid Educational Commission for Foreign Medical Graduates (ECFMG) certificate and completed an approved residency of at least two years in one specialty area; or
- Be a graduate who has completed the formal requirements of an international medical school except the internship or social service requirements, passed parts I and II of the National Board of Medical Examiners (NBME) or ECFMG equivalent examination, and completed an academic year of supervised clinical training (5th pathway) and completed an approved residency of at least two years in one specialty area.
- And both of the following:
    - Passed all parts of a national examination (the NBME; the Federation Licensing Examination offered by the Federation of State Medical Boards of the United States, Inc.; or the United States Medical Licensing Exam); and
    - Be licensed in another jurisdiction and actively practiced medicine in another jurisdiction for at least two of the immediately preceding four years; or passed a board-approved clinical competency examination within the year preceding filing of the application or;

[22] Section 458.311, F.S.
[23] Section 458.313, F.S.
[24] Notwithstanding this lack of reciprocity, physicians and other health care practitioners licensed out-of-state who meet certain requirements may register with the DOH under s. 456.47(4), F.S., and provide services to patients within Florida via telehealth, which is defined as "the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide health care services, including, but not limited to, assessment, diagnosis, consultation, treatment, and monitoring of a patient; transfer of medical data; patient and professional health-related education; public health services; and health administration." The term does not include audio-only telephone calls, e-mail messages, or facsimile transmissions.

successfully completed a board approved postgraduate training program within two years preceding filing of the application.[25]

Financial Responsibility

Florida-licensed allopathic physicians are required to maintain professional liability insurance or other financial responsibility to cover potential claims for medical malpractice as a condition of licensure, with specified exemptions.[26] Physicians who perform surgeries in a certain setting or have hospital privileges must maintain professional liability insurance or other financial responsibility to cover an amount not less than $250,000 per claim.[27] Physicians without hospital privileges must carry sufficient insurance or other financial responsibility in coverage amounts of not less than $100,000 per claim.[28] Certain physicians who are exempted from the requirement to carry professional liability insurance or other financial responsibility must provide notice to their patients.[29]

Florida-licensed osteopathic physicians have similar financial responsibility requirements as allopathic physicians[30]. With specified exceptions, the DOH must suspend, on an emergency basis, any licensed allopathic or osteopathic physician who fails to satisfy a medical malpractice claim against him or her within specified time frames.[31]

Disciplinary Process: Fines and Sanctions

Chapter 456, F.S., contains the general regulatory provisions for health care professions and occupations under the Division of Medical Quality Assurance (MQA) in the DOH. Section 456.072, F.S., specifies acts that constitute grounds for which disciplinary actions may be taken against a health care practitioner. Section 458.331, F.S., identifies acts that constitute grounds for which disciplinary actions may be taken against a medical physician and s. 459.015, F.S., identifies acts specific to an osteopathic physician. Some parts of the review process are public and some are confidential.[32]

Complaints and allegations are received by the MQA unit for determination of legal sufficiency and investigation. A determination of legal sufficiency is made if the ultimate facts show that a violation has occurred.[33] The complainant is notified by letter as to the whether the complaint will be investigated and if any additional information is needed. Complaints which involve an immediate threat to public safety are given the highest priority.

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[25] Florida Board of Medicine, *Medical Doctor-Unrestricted; Licensure by Endorsement,* https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted/ (last visited Jan. 22, 2020).
[26] Section 458.320, F.S.
[27] Section 458.320(2), F.S.
[28] Section 458.320(1), F.S.
[29] Section 458.320(5)(f) and (g), F.S.
[30] Section 459.0085, F.S.
[31] Sections 458.320(8) and 459.0085(9), F.S.
[32] Fla. Department of Health, Division of Medical Quality Assurance, *Enforcement Process*, (last updated Nov. 2019) http://www.floridahealth.gov/licensing-and-regulation/enforcement/_documents/enforcement-process-chart.pdf). (last visited Jan. 23, 2020).
[33] Fla. Department of Health, *Consumer Services – Administrative Complaint Process,* http://www.floridahealth.gov/licensing-and-regulation/enforcement/admin-complaint-process/consumer-services.html (last visited Jan. 23, 2020).

The DOH is responsible for reviewing each report to determine if discipline against the provider is warranted.[34] Authorization for the discipline of allopathic and osteopathic physicians can be found in state law and administrative rule.[35] If held liable for one of the offenses, the fines and sanctions by category and by offense are based on whether it is the physician's first, second, or third offense.[36] The boards may issue a written notice of noncompliance for the first occurrence of a single minor violation.[37] The amount of fines assessed can vary depending on the severity of the situation, such as improper use of a substance to concealment of a material fact. A penalty may come in the form of a reprimand, a licensure suspension, or revocation followed by some designated period of probation if there is an opportunity for licensure reinstatement. Other sanctions may include supplemental continuing education requirements and require proof of completion before the license can be reinstated.

Health Care Practitioners – Defaults on Student Loans

Section 456.072(1)(k), F.S., requires the suspension of a health care practitioner's license when the licensee is in default on a student loan that is guaranteed by the state or federal government. The suspension remains in effect until the licensee enters into a new payment agreement. That agreement is followed by a mandatory probation for the duration of the student loan and a fine in the amount of 10 percent of the defaulted loan amount. These fines are deposited into the Medical Quality Assurance Trust Fund.

Section 456.0721, F.S., requires the DOH to obtain information from the federal government on health care practitioners who are in default on guaranteed student loans. The DOH must annually report to the Legislature data on licensees in default.

Section 456.074 (4), F.S., requires the DOH to issue an emergency order suspending the license of any licensee who, after notice from the DOH, fails to provide proof within 45 days that new payment terms have been agreed to by parties to the loan.

In State Fiscal Year 2017-2018, the DOH reported 850 student loan defaults.[38] During this same time, 76 investigations were completed, and 26 emergency suspension orders were filed.[39] In State Fiscal Year 2018-2019, the DOH reported 87 student loan defaults.[40] During this same time, 250 investigations were completed, and 121 emergency suspension orders were filed.[41]

The Office of Inspector General's List of Excluded Individuals and Entities

Paragraphs 456.0635(2)(e) and (3)(e), F.S. require the DOH to refuse to issue or renew a license, registration, or certification to a candidate or applicant if the candidate or licensee is currently

[34] *See* ss. 458.351(5) and 459.026(5), F.S.
[35] *See s*s. 458.307 and 459.004, F.S., for the regulatory boards, and ss. 64B8-8 and 64B15-19, F.A.C., for administrative rules relating to disciplinary procedures.
[36] *Id*.
[37] Sections 64B8-8.011 and 64B15-19.0065, F.A.C. A minor violation is deemed to not endanger the public health, safety, and welfare and does not demonstrate a serious inability to practice.
[38] Department of Health, *House Bill 77 Agency Analysis* (on file with the Senate Committee on Health Policy).
[39] *Id*.
[40] *Id*.
[41] *Id*.

listed on the U.S. Department of Health and Human Services Office of the Inspector General's List of Excluded Individuals and Entities (LEIE).

The Office of Inspector General (OIG) has the authority to exclude individuals and entities from federally funded health care under the authority of sections 1128 and 1156 of the Social Security Act. Exclusions are imposed for a number of reasons:[42]

- Mandatory exclusions: OIG is required by law to exclude from participation in all federal health care programs individuals and entities convicted of the following types of criminal offenses: Medicare or Medicaid fraud, as well as any other offenses related to the delivery of items or services under Medicare, Medicaid, SCHIP, or other State health care programs; patient abuse or neglect; felony convictions for other health care-related fraud, theft, or other financial misconduct; and felony convictions relating to unlawful manufacture, distribution, prescription, or dispensing of controlled substances.
- Permissive exclusions: OIG has discretion to exclude individuals and entities on a number of grounds, including (but not limited to) misdemeanor convictions related to health care fraud other than Medicare or a state health program, fraud in a program (other than a health care program) funded by any federal, state or local government agency; misdemeanor convictions relating to the unlawful manufacture, distribution, prescription, or dispensing of controlled substances; suspension, revocation, or surrender of a license to provide health care for reasons bearing on professional competence, professional performance, or financial integrity; provision of unnecessary or substandard services; submission of false or fraudulent claims to a Federal health care program; engaging in unlawful kickback arrangements; defaulting on health education loan or scholarship obligations; and controlling a sanctioned entity as an owner, officer, or managing employee. [emphasis added]

Section 1128(b)(14) of the Social Security Act and 42 U.S.C. s. 1320a-7(b)(14), provide that a default on a health education loan or scholarship obligation is permissive grounds for being placed on the LEIE and that such exclusion shall last until the default or obligation is resolved. If a candidate or applicant is placed on the LEIE for a default on such a loan, the DOH would be obligated to deny that person's application for initial license or renewal of an existing license.

Sovereign Immunity

Sovereign immunity generally bars lawsuits against the state or its political subdivisions for torts committed by an officer, employee, or agent of such governments unless the immunity is expressly waived. The Florida Constitution recognizes that the concept of sovereign immunity applies to the state, although the state may waive its immunity through an enactment of general law. [43]

In 1973, the Legislature enacted s. 768.28, F.S., a partial waiver of sovereign immunity, allowing individuals to sue state government and its subdivisions.[44] According to subsection (1), individuals may sue the government under circumstances where a private person "would be liable to the claimant, in accordance with the general laws of [the] state . . ." Section 768.28(5),

[42]Office of Inspector General, *Background Information*, https://oig.hhs.gov/exclusions/background.asp (last visited Jan. 23, 2020).
[43] FLA. CONST. art. X, s. 13.
[44] Chapter 73-313, L.O.F., codified at s. 768.28, F.S.

F.S., imposes a $200,000 limit on the government's liability to a single person, and a $300,000 total limit on liability for claims arising out of a single incident.

OPPAGA Report 19-07[45]

Chapter 2019-138, Law of Florida, directed the Office of Program Policy Analysis and Government Accountability (OPPAGA) to analyze the Interstate Medical Licensure Compact (which is reflected in SB 926 as section 7) and develop recommendations addressing Florida's prospective entrance into the Compact. On October 1, 2019, OPPAGA published Report No. 19-07. To avoid legal conflicts, the OPPAGA recommended in the report that the Legislature:

- Repeal Florida's initial licensure provisions that fall outside of the Compact's licensure provisions. Florida does not license persons who are listed on the LEIE. The Compact has no comparable requirement. (Addressed in sections 3-6 of SB 926.)
- Enact statutory language providing physicians who practice in Florida whose licenses were revoked in their State of Principal License (SPL) an opportunity to challenge the reason for the revocation or suspension in Florida. (Addressed in section 8 of SB 926.)
- Enact statutory language clarifying that the Compact pays claims or judgments arising from the Commission's employment-related actions in the state. (Addressed in section 10 of SB 926.)
- Provide an exception from public meeting requirements to allow closed meetings of the Commission. (Addressed in linked SB 928.)
- Provide an exception from public records requirements to exempt application records received by the Commission from disclosure. (Addressed in linked SB 928.)
- Set a Compact implementation date to ensure that the DOH would have adequate time to make required changes to rule, forms, and technological infrastructure in order to process licenses through the Compact. (SB 926 has an effective date of July 1, 2021.)

III. Effect of Proposed Changes:

Section 1 creates section 458.3129, F.S., to provide that an allopathic physician licensed to practice medicine through the Interstate Medical Licensure Compact (Compact) is deemed to be licensed under chapter 458, F.S.

Section 2 creates section 459.3074, F.S., to provide that an osteopathic physician licensed to practice medicine through the Compact is deemed to be licensed under chapter 459, F.S. (The bill's first two sections are needed to authorize physicians licensed through the Compact to practice in Florida under the Florida Statutes.)

Federal List of Excluded Individuals and Entities / Student Loans

Section 3 amends section 456.0635, F.S., to remove the requirement that each board within the jurisdiction of the DOH, or the DOH itself if there is no board, prohibit a candidate from being examined for or issued, or having renewed a license, certificate, or registration to practice a health care profession if he or she is listed on the U.S. Department of Health and Human

[45] Office of Program Policy Analysis and Gov't Accountability, Florida Legislature, *Florida's Participation in the Interstate Medical Licensure Compact Would Require Statutory Changes to Avoid Legal Conflicts*, Report No. 19-07, (Oct. 1, 2019) *available at* http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/1907rpt.pdf (last visited Jan. 23, 2020).

Services Office of Inspector General's List of Excluded Individuals and Entities. Many of the mandatory and permissive exclusions included on the List of Excluded Individuals and Entities are banned from the initial licensure, certification, or registration or renewal of licensure, certification, or registration in other provisions of the Florida Statutes.[46]

Section 4 amends section 456.072, F.S. to remove a provision classifying the failure to repay a student loan issued or guaranteed by the state or federal government in accordance with the terms of the loan as a failure to perform a statutory or legal obligation and removes penalties.

Section 5 repeals section 456.0721, F.S. to remove provisions requiring the DOH to obtain information from the federal government on health care practitioners who are in default on guaranteed student loans. This also removes a provision requiring the DOH to annually report to the Legislature data on licensees in default.

Section 6 amends section 456.074, F.S. to remove the requirement, and related provisions, that the DOH immediately suspend the licenses of certain health care practitioners for failing to provide proof of new payment terms for defaulted student loans within a specified timeframe.

Interstate Medical Licensure Compact

Section 7 creates the Compact as s. 456.4501, F.S., which enters Florida into the Compact. The Compact has 24 sections that establish the Compact's administration and components and prescribe how the Commission will oversee the Compact and conduct its business. The table below describes new statutory language, by Compact section, which creates the components of the Compact.

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
1	Provides the purpose of the Compact Establishes prevailing standard of care	The purpose of the Interstate Medical Licensure Compact (compact) is to provide a streamlined, comprehensive process that allows physicians to become licensed in multiple states. It allows physicians to become licensed without changing a state's Medical Practice Act(s). The Compact also adopts the prevailing standard of care based on where the patient is located at the time of the patient-provider encounter. Jurisdiction for disciplinary action or any other adverse actions against a physician's license is retained in the jurisdiction where the license is issued to the physician.
2	Definitions Establishes standard definitions for	Definitions are provided for: - Bylaws: means those Bylaws established by the Commission pursuant to Section 11 for governance, direction, and control of its action and conduct. - Commissioner: means the voting representative appointed by each member board pursuant to Section 11 whereby each member state

[46] *See* s. 456.0635, F.S. *See also* Office of Inspector General, *Exclusion Authorities,* https://oig.hhs.gov/exclusions/authorities.asp (last visited Jan. 23, 2020).

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
	operation of the Compact and the Commission.	appoints two members to the Commission. If the member state has two medical boards, the two representatives should be split between the two boards. - Conviction: means a finding by a court that an individual is guilty of a criminal offense through adjudication, or entry of a plea of guilt or no contest to the charge by the offender. A conviction also means evidence of an entry of a conviction of a criminal offense by the court shall be considered final for the purposes of disciplinary action by a member board. - Expedited license: means a full and unrestricted medical license granted by a member state to an eligible physician through the process set forth in the Compact. - Interstate Commission: means the interstate commission created pursuant to Section 11. - License: means authorization by a state for a physician to engage in the practice of medicine, which would be unlawful without the authorization. - Medical Practice Act: means laws and regulations governing the practice of allopathic and osteopathic medicine within a member state. (In Florida, the Medical Practice Act for allopathic medicine is under ch. 458, F.S., and for osteopathic medicine, under ch. 459, F.S.) - Member Board: means a state agency in a member state that acts in the sovereign interests of the state by protecting the public through licensure, regulation, and education of physicians as directed by the state government. (The Florida Board of Medicine and the Florida Board of Osteopathic Medicine are responsible for the licensure, regulation, and education of physicians in Florida.) - Member State: means a state that has enacted the Compact. - Practice of medicine: means the diagnosis, treatment, prevention, cure, or relieving of a human disease, ailment, defect, complaint, or other physical, or mental condition, by attendance, advise, device, diagnostic test, or other means, or offering, undertaking, attempting to do, or holding oneself out as able to do, any of these acts. - Physician means: any persons who is a graduate of medical school accredited by the Liaison Committee on Medical Education, the Commission on Osteopathic College Accreditation, or a medical school listed in the International Medical Education Directory or its equivalent; passed each component of the USMLE or the COMPLEX-USA within three attempts, or any of its predecessor examinations accepted by a state medical board as an equivalent examination for licensure purposes; successfully completed graduate medical education approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association; holds specialty certification or time-unlimited specialty certificate recognized by the American Board of Medical Specialties or the American Osteopathic Association's Board of Osteopathic Specialties; however, the times unlimited specialty certificate does not have to be maintained once the physician is initially determined through the expedited Compact process; possess a full and unrestricted license to engage in the practice

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
		of medicine issued by a member board; has never been convicted received adjudication, community supervision, or deferred disposition for any offense by a court of appropriate jurisdiction; has never held a license authorizing the practice of medicine subjected to discipline by a licensing agency in any state, federal, or foreign jurisdiction, excluding any action related to non-payment of fees related to a license; has never had a controlled substance license or permit suspended or revoked by a state or the United States Drug Enforcement Administration; and is not under active investigation by a licensing agency or law enforcement authority in any state, federal, or foreign jurisdiction. - Offense means: A felony, high court misdemeanor, or crime of moral turpitude. - Rule means: A written statement by the Commission promulgated pursuant to Section 12 of the Compact that is of general applicability, implements, interprets, or prescribes a policy or provision of the Compact, or an organizational, procedural, or practice requirement of the Commission, and has the force and effect of statutory law in a member state, if the rule is not inconsistent with the laws of the member state. The term includes the amendment, repeal, or suspension of an existing rule. - State means: Any state, commonwealth, district, or territory of the United States. - State of Principal License means: A member state where a physician holds a license to practice medicine and which has been designated as such by the physician for purposes of registration and participation in the Compact.
3	Eligibility Provides minimum requirements to receive an expedited license	To be eligible to participate and receive an expedited license, a physician must meet the requirements of Section 2 (definition of physician). A physician who does not meet the requirements of Section 2 may obtain a license to practice medicine in a member state outside of the Compact if the individual complies with all of the laws and requirements to practice medicine in that state.
4	State of Principal License (SPL) Defines a SPL	The Compact requires participating physicians to designate a State of Principal License (SPL) for purposes of registration for expedited licensure if the physician possesses a full and unrestricted license to practice medicine in that state. The SPL must be a state where: - The physician has his/her primary residence, or - The physician has at least 25 percent of his/her practice, or - The state where the physician's employer is located. If no state qualifies for one of the above options, then the state of residence as designated on physician's federal income taxes. A SPL may be re-designated at any time as long as the physician possesses a full and unrestricted license to practice medicine in that state. The Commission is authorized to develop rules to facilitate the re-designation process.

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
5	Application and Issuance of Expedited Licensure *Qualifications* *Commission rulemaking provisions*	Section 5 of the Compact establishes the process for the issuance of the expedited license. A physician must file an application with the member of the state selected as the SPL. The SPL will evaluate the application to determine whether the physician is eligible for the expedited licensure process and issue a letter of qualification, either verifying or denying eligibility, to the Commission. - Static Qualifications: Include verification of medical education, graduate medical education, results of any medical or licensing examinations and any other qualifications set by the Commission through rule. - Performance of Criminal Background Checks by the member board through FBI, with the exception of federal employees who have suitability determined in accordance with U.S. 5 CFR section 731.202. - Appeals on eligibility determinations are handled through the member state. - Upon completion of eligibility verification process with member state, applicants suitable for an expedited license are directed to complete the registration process with the Commission, including the payment of any fees. - After receipt of registration and payment of fees, the physician receives his/her expedited license. The license authorizes the physician to practice medicine in the issuing state consistent with the Medical Practice Act and all applicable laws and regulations of the issuing member board and member state. - An expedited license shall be valid for a period consistent with the member state licensure period and in the same manner as required for other physicians holding a full and unrestricted license. - An expedited license obtained through the Compact shall be terminated if a physician fails to monitor a license in the SPL for a non-disciplinary reason, without re-designation of a new SPL. - The Commission is authorized to develop rules relating to the application process, including fees and issuing the expedited license.
6	Fees for Expedited Licensure *Rulemaking authority*	A member state is authorized to charge a fee for an expedited license that is issued or renewed through the Compact. (In Florida, DOH is already authorized under current law to charge fees for physician licensure.) The Commission is authorized is develop rules relating to fees for expedited licenses. The rules are not permitted to limit the authority of the member states, the regulating authority of the member states, or to impose and determine the amount of the fee charged by the member states.

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
7	Renewal and Continued Participation *Renewal license process created* *Continuing education required for renewal with member state* *Fees collected, if any, by member state.* *Rulemaking authority.*	A physician with an expedited license in a member state must complete a renewal process with the Commission if the physician: - Maintains a full and unrestricted license in a SPL. - Has not been convicted, received adjudication, deferred adjudication, community supervision, or deferred disposition for any offense by a court of appropriate jurisdiction. - Has not had a license authorizing the practice of medicine subject to discipline by a licensing agency in any state, federal, or foreign jurisdiction, excluding any action relating to non-payment of fees related to a license. - Has not had a controlled substance license or permit suspended or revoked by a state or the United State Drug Enforcement Administration. Physicians are required to comply with all continuing education and professional development requirements for renewal of a license issued by a member state. The Commission shall collect any renewal fees charged for the renewal of a license and distribute the fees to the appropriate member board. Upon payment of fees, a physician's license shall be renewed. Any information collected during the renewal process shall also be shared with all member boards. The Commission is authorized to develop rules to address the renewal of licenses.
8	Coordinated Information Systems *Authorized to create database of all applicants* *By request, may share data* *Rulemaking authority*	The Commission is required to establish a database of all licensed physicians who have applied for licensure. Member boards are required to report disciplinary or investigatory actions as required by Commission rule. Member boards may also report any non-public complaint, disciplinary, or investigatory information not required to be reported to the Commission. Upon request, member boards shall share complaint or disciplinary information about physicians to another member board. All information provided to the Commission or distributed by the member boards shall be confidential, filed under seal, and used only for investigatory or disciplinary matters. The Commission is authorized to develop rules for mandated or discretionary sharing of information by member boards.
9	Joint Investigations *Permits joint investigations between the*	Licensure and disciplinary records of physicians are deemed investigative. A member board may participate with other member boards in joint investigations of physicians licensed by the member boards in

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
	state and the member boards	addition to the authority granted by the member board and its respective Medical Practice Act or other respective state law. Member boards may share any investigative, litigation, or compliance materials in furtherance of any joint or individual investigation initiated under the Compact. Any member state may investigate actual or alleged violations of the statutes authorizing the practice of medicine in any other member state in which a physician holds a license to practice medicine.
10	Disciplinary Actions *Discipline by a member state has reciprocal actions* *Licensure actions specific actions to reinstate*	Any disciplinary action taken by any member board against a physician licensed through the Compact shall be deemed unprofessional conduct which may be subject to discipline by other member boards, in addition to any violation of the Medical Practice Act or regulations in that State. If the physician's license is revoked, surrendered, or relinquished in lieu of discipline in the SPL, or suspended, then all licenses issued to that physician by member boards shall be automatically placed, without any further action necessary by any member board, on the same status. If the SPL subsequently reinstates the physician's license, a license issued to the physician by any other member board shall remain encumbered until that respective board takes action to specifically reinstate the license in a manner consistent with the Medical Practice Act in that state. If a disciplinary action is taken against the physician in a member state that is the physician's SPL, any other member state may deem the action conclusive as to matter of law and fact decided, and: - Impose the same or lesser sanction or sanctions against the physician so long as such sanctions are consistent with the Medical Practice Act of that state; or - Pursue separate disciplinary action against the physician under the Medical Practice Act, regardless of the action taken in other member states. If a license granted to a physician by a member board is revoked, surrendered, or relinquished in lieu of discipline, or suspended, then any license issued to the physician by any other member board or boards shall be suspended, automatically, and without further action necessary by the other board(s), for ninety (90) days upon entry of the order by the disciplining board, to permit the member board(s) to investigate the basis for the action under the Medical Practice Act of that state. A member board may terminate the automatic suspension of the license it issued prior to the completion of the 90-day suspension period in a manner consistent with the Medical Practice Act of that state.

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
11	Interstate Medical Licensure Compact Commission *Recognizes creation of Commission and state's representative with 2 Commissioners, one from each regulatory board* *Availability of Commission meetings, except for certain topics* *Availability of public data from the Commission* *Public notice required* *Creates an executive committee to act on behalf of the Commission*	The member states create the Interstate Medical Licensure Compact Commission as a joint agency of the member states and administration of the Compact. The Commission has all the duties, powers, and responsibilities set forth in the Compact, plus any other powers conferred upon it by the member states through the Compact. Each member state has two (2) two voting representatives appointed by each member state to serve as Commissioners. For states with separate regulatory boards for allopathic and osteopathic regulatory boards, the member state shall appoint one representative from each member board. A Commissioner shall be: - An allopathic or osteopathic physician appointed to a member board. - Executive director, executive secretary, or similar executive or a member board, or - Member of the public appointed to a member board. The Commission shall meet at least once per calendar year and at least a portion of the meeting shall be a business meeting that includes the election of officers. The Chair may call additional meeting and shall call for all meeting upon the request of a majority of the member states. Meetings are permitted via telecommunication according to the Bylaws. Each Commissioner is entitled to one vote. A majority of Commissioners shall constitute a quorum, unless a larger quorum is required by the Bylaws of the Commission. A Commissioner shall not delegate a vote to another Commissioner. In the absence of its Commissioner, a member state may delegate voting authority for a specified meeting to another person from that state who meets the requirements of being a Commissioner. The Commission shall provide public notice of all meetings and all meetings shall be open to the public. A meeting may be closed to the public, in full or in portion, when it determines by a 2/3 vote of the Commissioners present, that an issue or matter would likely to: - Relate solely to the internal personnel practices and procedures of the Interstate Commission. - Discuss matters specifically exempted from disclosure by federal statute; - Discuss trade secrets, commercial, or financial information that is privileged or confidential; - Involve accusing a person of a crime, or formally censuring a person;

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Section	**Title**	**Description**
		- Discuss information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy; - Discuss investigative records compiled for law enforcement purposes; or - Specifically relate to the participation in a civil action or other legal proceeding. The Commission shall make its information and official records, to the extent, not otherwise designated in the Compact or by its rules, available to the public for inspection. An executive committee is established which has the authority to act on behalf of the Commission, with the exception of rulemaking, when the Commission is not in session. The executive committee shall oversee the administration of the Compact, including enforcement and compliance with the Compact, its bylaws and rules, and other such duties as necessary. The Commission may establish other committees for governance and administration of the Compact.
12	Powers and Duties of the Interstate Commission *Recognizes creation of the Commission*	The Commission shall have the duties and the powers to: - Oversee and administer the Compact. - Promulgate rules, which are binding. - Issue advisory opinions upon the request of member states concerning the meaning or interpretation of the Compact or its bylaws, rules, and actions. - Enforce compliance with the Compact, provisions, the rules, and the bylaws. - Establish and appoint committees, including the executive committee, which has the power to act on behalf of the Interstate Commission. - Pay, or provide for the payment of Commission expenses. - Establish and maintain one or more offices. - Borrow, accept, hire, or contract for services of personnel. - Purchase and maintain insurance and bonds. - Employ an executive director with power to employ, select, or appoint employees, agents, or consultants, determine their duties, and fix their compensation. - Establish personnel policies and programs. - Accept donations and grants of money, equipment, supplies, materials, and services, and to receive, utilize and dispose of it consistent with conflict of interest policies as established by the Commission. - Lease, purchase, accept contributions, or donation of, or otherwise own, hold, improve or use, any property, real, personal, or mixed. - Establish a budget and make expenditures. - Adopt a seal and bylaws governing the management and operation of the Commission. - Report annually to the legislatures and governors of the members concerning the activities of the Commission during the preceding year,

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
		including reports of financial audits and any recommendations that may have been adopted by the Commission. - Coordinate education, training, and public awareness regarding the Compact, its implementation and operation. - Maintain records in accordance with bylaws. - Seek and obtain trademarks, copyrights, and patents. - Perform such functions as may be necessary or appropriate to achieve the purpose of the Compact.
13	Finance Powers *Provides for annual assessment* *Requires rule for any assessment* *No pledging credit without authorization* *Yearly audits*	The Compact authorizes an annual assessment levied on each member state to cover the costs of operations and activities of the Commission and its staff. The assessment must be sufficient to cover the amount not provided by other sources and needed to cover the annual budget approved each year by the Commission. The Compact requires that the assessment be memorialized by rule binding all the member states. The Commission is not authorized to pledge the credit of any of the member states, except by, and with the authority of, the member states. The Compact requires yearly financial audits conducted by a certified or licensed public accountant and the report is to be included in the Commission's annual report.
14	Organization and Operation of the Interstate Commission *Annual officer election* *No officer remuneration* *Liability protection for actions within scope of duties and responsibilities only for officers,*	The Compact creates a requirement for the Commission to adopt bylaws by a two-thirds (2/3) vote within twelve months of the first meeting which has already occurred. The first Bylaws were adopted in October 2015.[47] A Chair, Vice Chair, and Treasurer shall be elected or appointed each year by the Commission. Officers serve without remuneration. Officers and employees are immune from suit and liability, either personally or in their professional capacity, for a claim for damage to or loss of property or personal injury or other civil liability cause or arising out of, or relating to, an actual or alleged act, error or omission that occurred with the scope of Commission employment, duties, or responsibilities, provided such person should not be protected from suit or liability for damage or loss, injury or liability caused by the intentional or willful and wanton conduct of such a person.

[47] Interstate Medical Licensure Compact, *Annual Report 2017,* https://imlcc.org/wp-content/uploads/2018/03/IMLCC-Annual-Report-2017-1.pdf (last visited Jan. 22, 2020).

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
	employees, and agents	The liability of the executive director and Commission employees or representatives of the Commission, acting within the scope of their employment, may not exceed the limits set forth under the state's Constitution and laws for state officials, employees, and agents. The Compact provides that the Commission is considered an instrumentality of the state for this purpose. The Compact provides that the Commission shall defend the executive director, its employees, and subject to the approval of the state's attorney general or other appropriate legal counsel, shall defend in any civil action seeking to impose liability within scope of duties. The Compact provides that employees and representatives of the Commission shall be held harmless in the amount of any settlement or fees, including attorney fees and costs, that occurred within the scope of employment or responsibilities and not a result of willful or wanton misconduct.
15	Rulemaking Functions of the Interstate Commission *Promulgate reasonable rules* *Judicial review at U.S. Federal District Court*	The Commission is required to promulgate reasonable rules in order to implement and operate the Compact and the Commission. The Compact adds that any attempt to exercise rulemaking beyond the scope of the Compact renders the action invalid. The rules should substantially conform to the "Model State Administrative Procedures Act" of 2010 and subsequent amendments thereto. The Compact allows for judicial review of any promulgated rule. A petition may be filed thirty (30) days after a rule has been promulgated in the U.S. District Court in Washington, D.C., or the federal court where the Commission is located.[48] The Compact requests deference to the Commission's action consistent with state law.
16	Oversight of Interstate Contract *Enforcement* *Service of process*	The Compact is the responsibility of each state's own executive, legislative, and judicial branch to oversee and enforce. All courts are to take judicial notice of the Compact and any adopted administrative rules in a proceeding involving Compact subject matter. The Compact provides that the Commission is entitled to receive service of process in any proceeding and shall have standing in any proceeding. Failure to serve the Commission shall render a judgment null and void as to the Commission, the Compact, or promulgated rule.

[48] The Interstate Medical Licensure Compact Commission is currently headquartered in Littleton, Colorado. *See* Interstate Medical License Commission, Facts about the IMLCC, https://imlcc.org/facts-about-the-imlcc/ (last visited Jan. 22, 2020).

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
17	Enforcement of Interstate Contract	The Compact provides the Commission reasonable discretion to enforce the provisions and rules of the Compact, including when and where to initiate legal action. The Commission is permitted to seek a range of remedies.
18	Default Procedures	The Compact provides a number of reasons a member state may default on the Compact, including failure to perform required duties and responsibilities and the options available to the Commission. The Compact requires the Commission to promulgate rules to address how physician licenses are affected by the termination of a member state from the Compact. The rules must also ensure that a member state does not bear any costs when a state has been found to be in default. The Compact provides an appeal process for the terminating state and procedures for attorney's fees and costs.
19	Dispute Resolution	The Compact authorizes the Commission to use dispute resolution tools to resolve disputes between states, such as mediation and binding dispute resolution. The Commission shall promulgate rules for the dispute resolution process.
20	Member States, Effective Date and Amendment	The Compact allows any state to become a member state and that the Compact is binding upon the legislative enactment of the Compact by no less than seven (7) states.[49]
21	Withdrawal	A member state may withdraw from the Compact through repeal of this section of law which inserted the Compact into state statute. Any repeal of the Compact through repeal of the state law cannot take effect until one (1) year after the effective date of such an action and written notice has been given by the withdrawing state to the governor of each other member state. The Compact provision also requires that upon introduction of any repeal legislation, that the withdrawing state immediately notify the Chairperson of the Commission of the legislation. The Compact provides that it is the Commission's responsibility to notify the other member states within 60 (sixty) days of its receipt of information about legislation that would repeal that state's participation in the Compact. The withdrawing state would be responsible for any dues, obligations, or liabilities incurred through

[49] The Compact is in force now. The Commission was seated for the first time in October 2015 and issued its first letters of qualification to physicians in April 2017. *See* Interstate Medical Licensure Compact, https://imlcc.org/faqs/ (last visited Jan. 22, 2020).

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
		the date of withdrawal. Reinstatement is an option under the Compact. The Compact authorizes the Commission to develop rules to address the impact of the withdrawal of a member state on licenses.
22	Dissolution	When the membership of the Compact is reduced to one, the Compact shall be dissolved. Once dissolved, the Compact shall be null and void. Once concluded, any surplus funds of the Commission shall be distributed in accordance with the bylaws.
23	Severability and Construction	If any part of this Compact is not enforceable, the remaining provisions are still enforceable. The provisions of the Compact are to be liberally construed. and nothing is to be construed so as to prohibit the applicability of other interstate compacts to which states might be members.
24	Binding Effect of Compact and Other Laws	This Compact does not prohibit the enforcement of other laws which are not in conflict with this Compact. All laws which are in a member state which are inconsistent with this Compact are superseded to the point of the contact. The actions of the Commission are binding on the member states, including all promulgated rules and the adopted bylaws of the Commission. All agreements between the Commission and the member state are binding in accordance with their terms. In the event that any provision of this Compact exceeds Florida's constitutional limits imposed on the legislature of any member state, such provision shall be ineffective to the extent that the conflict of the constitutional provision in question in that member state.

Section 8 creates section 456.4502, F.S. to require a formal hearing be held before the Division of Administrative Hearings if there are any disputed issues of material fact when the licenses of certain physicians and osteopathic physicians are suspended or revoked by this state under the Compact; requiring the DOH to notify the division of a petition for a formal hearing within a specified timeframe; requiring the administrative law judge to issue a recommended order; requiring the Board of Medicine or the Board of Osteopathic Medicine, as applicable, to determine and issue final orders in certain cases; providing the DOH with standing to seek judicial review of any final order of the boards;

Section 9 creates section 456.4504, F.S., to authorize the DOH to adopt rules to implement the Compact.

Section 10 creates section 456.4502, F.S., to designate the representative appointed from the Board of Medicine and the representative appointed from the Board of Osteopathic Medicine, when serving as commissioners of the Commission and any administrator, officer, executive director, employee, or representative of the Commission, when acting within the scope of their employment, duties, or responsibilities in this state, are considered agents of the state, for the purpose of applying sovereign immunity and waivers of sovereign immunity. This section also requires the Commission to pay certain claims or judgments and authorizes the Commission to maintain insurance coverage to pay such claims or judgments.

Section 11 provides an effective date of July 1, 2021.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

The Interstate Commission requires most of its meetings to be open to the public. The notice requirements vary depending on the purpose of the meeting, however. Rulemaking hearings, where rules are proposed in a manner substantially similar to the model state administrative procedure act of 2010, are submitted to the Bylaws and Rules Committee for review and action. Prior to final consideration by the Commission, the final proposed rule must be publicly noticed on the Commission's website or other agreed upon distribution site at least 30 days prior to the meeting at which the vote is scheduled.[50] A reason for the proposed rule action will also be posted.[51] The public must also be provided a reasonable opportunity to provide public comment, orally or in writing, for proposed rules. A committee of the Commission may propose a rule at any time by a majority vote of that committee.

The written procedure states for every proposed rule action that there will also be instruction on how interested parties may attend the scheduled public hearing, may submit their intent to attend the public hearing and submit any written comments.[52] A transcript of these meetings are not made unless one is specifically requested and then the requestor is responsible for the cost the transcription.[53]

Not later than 30 days after its adoption, any interested party may petition for judicial review of the rule in the United States District Court for the District of Columbia or in the

[50] Interstate Medical Licensure Commission, *Rule on Rulemaking* (Adopted June 24, 2016), *Rule 1.4(c),* https://imlcc.org/wp-content/uploads/2018/02/IMLCC-Rule-Chapter-1-Rule-on-Rulemaking-Adopted-June-24-2016.pdf (last visited Jan. 23, 2020).
[51] *Id.*, Rule 1.4(b).
[52] *Id.*, Rule 1.4(d).
[53] *Id.*, Rule 1.4(e).

federal court where the Commission's headquarters are currently located. The Commission's mailing address currently is in Littleton, Colorado.[54]

The Compact also permits the Commission, with a two-thirds vote of the Commissioners present, to meet in closed, nonpublic meetings if the Commission must address any matters that:

- Relate solely to the internal personnel practices and procedures of the Interstate Commission.
- Specifically exempted from disclosure by federal statute;
- Discuss trade secrets, commercial, or financial information that is privileged or confidential;
- Involve accusing a person of a crime, or formally censuring a person;
- Discuss information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy;
- Discuss investigative records compiled for law enforcement purposes; or
- Specifically relate to the participation in a civil action or other legal proceeding.[55]

The rulemaking process, its timelines and public involvement process, plus the closure of public meetings for some of these detailed reasons, may be inconsistent with Florida law on public meetings.

While the provisions of the Compact and its administrative rules and corporate bylaws require minutes to be kept of some of these closed sessions, it is not clear that it is applicable to all closed sessions and it does require an interested party to request a transcriber in some cases to be present and to expend personal funds to ensure the availability of minutes. A third party may or may not be as likely either to fully describe all matters discussed and provide an accurate summary of actions taken, including a record of any roll call votes.[56]

According to the Commission's Bylaws, the public notice for a regular meeting of the Commission is at least 10 days prior to the meeting according to the Compact and the notice will be posted on the Commission's website or distributed through another website designated by the Commission for interested parties to receive notice who have requested to receive such notices.[57]

C. Trust Funds Restrictions:

None.

[54] Interstate Medical License Commission, Facts about the IMLCC, https://imlcc.org/facts-about-the-imlcc/ (last visited Jan. 22, 2020).
[55] Interstate Medical License Compact Bylaws, *Section 11 – Interstate Medical License Compact Commission, Section (h)-(l)*, https://imlcc.org/wp-content/uploads/2018/04/IMLC-Compact-Law.pdf (last visited Jan. 22, 2020).
[56] *Id.*
[57] *Id.*

D. State Tax or Fee Increases:

Article VII, Section 19, of the State Constitution requires that a new state tax or fee, as well as an increased state tax or fee, must be approved by two-thirds of the membership of each house of the Legislature and must be contained in a separate bill that contains no other subject. Article VII, Section 19(d)(1) of the State Constitution defines "fee" to mean "any charge or payment required by law, including any fee for service, fee or cost for licenses, and charge for service."

The bill authorizes the Compact to assess and collect fees from allopathic and osteopathic physicians who elect to participate in the expedited licensure process.

For physicians who elect this license, a non-refundable service fee of $700 for the letter of qualification is charged to the applicant by the Commission when the initial application is submitted to the Commission. Of that $700, $300 is remitted to the applicant's home state or state of principal licensure and the remaining $400 is sent to the Commission's general fund.

Every time the applicant requests that a letter of qualification be disseminated to one or more of the member states that participate in the Compact after the initial dissemination of the letter for the expedited license, the cost to the registrant is $100. Of this amount, one hundred percent is sent to the Commission's General Fund.

For each expedited license that is renewed through the Compact, a non-refundable fee of $25 shall be assessed to the physician and paid to the Commission General Fund. The Commission receives 100 percent of these funds.

E. Other Constitutional Issues:

The Compact authorizes Compact administrators to develop rules that member states must adopt, which is potentially an unlawful delegation of legislative authority. If enacted into law, the state will bind itself to rules not yet promulgated and adopted by the Commission. The Florida Supreme Court has held that while it is within the province of the Legislature to adopt federal statutes enacted by Congress and rules promulgated by federal administrative bodies that are in existence at the time the Legislature acts, it is an unconstitutional delegation of legislative authority to prospectively adopt federal statutes not yet enacted by Congress and rules not yet promulgated by federal administrative bodies.[58,59] Under this holding, the constitutionality of the bill's adoption of prospective rules might be questioned, and there does not appear to be Florida case law that squarely addresses this issue in the context of interstate compacts.

[58] *Freimuth v. State*, 272 So.2d 473, 476 (Fla. 1972) (quoting *Fla. Ind. Comm'n v. State ex rel Orange State Oil Co.,* 155 Fla. 772 (1945).

[59] This prohibition is based on the separation of powers doctrine, set forth in Article II, Section 3 of the Florida Constitution, which has been construed in Florida to require the Legislature, when delegating the administration of legislative programs, to establish the minimum standards and guidelines ascertainable by reference to the enactment creating the program. *See Avatar Development Corp. v. State*, 723 So.2d 199 (Fla. 1998).

The most recent case Florida courts have had to address this issue was in *Department of Children and Family Services v. L.G.*, involving the Interstate Compact for the Placement of Children (ICPC).[60] The First District Court of Appeal considered an argument that the regulations adopted by the Association of Administrators of the ICPC were binding and that the lower court's order permitting a mother and child to relocate to another state was in violation of the ICPC. The court denied the appeal and held that the Association's regulations did not apply as they conflicted with the ICPC and the regulations did not apply to the facts of the case.

The court also references language in the ICPC that confers to its compact administrators the "power to promulgate rules and regulations to carry out more effectively the terms and provisions of this compact."[61] The court states that "the precise legal effect of the ICPC administrators' regulations in Florida is unclear," but noted that it did not need to address the question to decide the case.[62] However, in a footnote, the court said:

> Any regulations promulgated before Florida adopted the ICPC did not, of course, reflect the vote of a Florida compact administrator, and no such regulations were ever themselves enacted into law in Florida. When the Legislature did adopt the ICPC, it did not (and could not) enact as the law of Florida or adopt prospectively regulations then yet to be promulgated by an entity not even covered by the Florida Administrative Procedure Act. *See Freimuth v. State,* 272 So.2d 473, 476 (Fla.1972); *Fla. Indus. Comm'n v. State ex rel. Orange State Oil Co.,* 155 Fla. 772, 21 So.2d 599, 603 (1945) ("[I]t is within the province of the legislature to approve and adopt the provisions of federal statutes, and all of the administrative rules made by a federal administrative body, that are in existence and in effect at the time the legislature acts, but it would be an unconstitutional delegation of legislative power for the legislature to adopt in advance any federal act or the ruling of any federal administrative body that Congress or such administrative body might see fit to adopt in the future."); *Brazil v. Div. of Admin.*, 347 So.2d 755, 757–58 (Fla. 1st DCA 1977), *disapproved on other grounds by LaPointe Outdoor Adver. v. Fla. Dep't of Transp.,* 398 So.2d 1370, 1370 (Fla.1981). The ICPC compact administrators stand on the same footing as federal government administrators in this regard.[63]

In accordance with that footnote, the bill's delegation of rule-making authority to the Commission is similar to the delegation to the ICPC administrators, and thus could constitute an unlawful delegation of legislative authority. The referenced case, however, does not appear to be binding as precedent since the court's footnote discussion is dicta.[64]

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[60] 801 So.2d 1047 (Fla. 1st DCA 2001).
[61] Id at 1052.
[62] *Id.*
[63] *Id.*
[64] Dicta are statements of a court that are not essential to the determination of the case before it and are not a part of the law of the case. Dicta has no biding legal effect and is without force as judicial precedent. 12A FLA JUR. 2D *Courts and Judges* s. 191 (2015).

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 926 could lead to more licensed allopathic physicians and osteopathic physicians practicing in Florida. The fiscal result to the private sector is indeterminate.

C. Government Sector Impact:

The DOH Division of Medical Quality Assurance (MQA) will see a recurring decrease in revenue due to the loss of the mandated 10 percent fine on student loan default cases that is removed under the bill.[65] The MQA will also experience a recurring reduction in workload and cost due to fewer investigations and prosecutions to conduct from student loan default cases.[66] The MQA will incur non-recurring costs associated with rulemaking, which current budget authority is adequate to absorb.[67]

As a member state of the Compact, the state will see an increased volume in the number of licensure applications at the MQA, Board of Medicine, and Board of Osteopathic Medicine. Applicants for the expedited licensure process must have a designated State of Principal License (SPL) where the physician has acquired his full and unrestricted license to practice medicine, is in good standing, practices medicine at least 25 percent of the time, is the physician's primary state of residence or is the location of the physician's employer. Applications for an expedited license with a member board through the Commission would first go through a Florida eligibility vetting process to issue a letter of qualification or to deny a letter of qualification.

The DOH could experience an indeterminate increase in administrative costs from:

- Processing applications from out-of-state physicians for expedited licensure under the Compact;
- Conducting a fresh background screening for Florida physicians wishing to apply for licensure in other member Compact states:
- Participation in joint investigations and disciplinary actions related to physicians located within member states of the Commission; and
- Information technology costs related to information sharing between the DOH and the Commission.

The Commission is authorized to levy an annual assessment on member states to offset the Commission's administrative and information technology costs. The cost of the annual assessment is indeterminate because the amount of the assessment is contingent

[65] Department of Health, *House Bill 77 Agency Analysis* (on file with the Senate Committee on Health Policy).
[66] *Id.*
[67] *Id.*

on the formula developed by the Commission and is proportional to the number of participating member states.

The state could experience a need for additional resources at the DOH to handle an increase in physician applications for expedited licensure under the Compact, as well as additional revenue from application fees. The resulting overall impact is indeterminate.

The DOH may incur non-recurring costs associated with rulemaking to implement the Compact if rulemaking is necessary.

The Florida Department of Law Enforcement (FDLE) may also experience an indeterminate negative fiscal impact from criminal history records checks and fingerprint retention that could result from the passage of the Compact.[68] The FDLE has indicated that the impact of this bill alone does not necessitate additional FTE or other resources.[69]

The bill may somewhat increase the caseload at the Division of Administrative Hearings. The number of disciplined physicians who would pursue this legal path to recover their licenses is indeterminate.

Overall, the bill has an indeterminate fiscal impact on state revenues and state expenditures.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 456.0653, 456.072, and 768.28.

This bill creates the following sections of the Florida Statutes: 458.3129, 459.074, 456.4501, 456.4502, and 456.4504.

This bill repeals section 456.0721 of the Florida Statutes.

[68] Florida Department of Law Enforcement *Senate Bill 926 Agency Analysis* (Nov. 25, 2019) (on file with Senate Committee on Health Policy).
[69] *Id.*

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Harrell

25-01035C-20 2020926__

A bill to be entitled

An act relating to health care practitioner licensure; creating s. 458.3129, F.S.; establishing that a physician licensed under the Interstate Medical Licensure Compact is deemed to be licensed under chapter 458; creating s. 459.074, F.S.; establishing that an osteopathic physician licensed under the Interstate Medical Licensure Compact is deemed to be licensed under chapter 459; amending s. 456.0635, F.S.; removing the requirement that each board within the jurisdiction of the Department of Health, or the department if there is no board, prohibit a candidate from being examined for or issued, or having renewed a license, certificate, or registration to practice a health care profession if he or she is listed on a specified federal list of excluded individuals and entities; amending s. 456.072, F.S.; deleting a provision classifying the failure to repay a student loan issued or guaranteed by the state or federal government in accordance with the terms of the loan as a failure to perform a statutory or legal obligation; removing penalties; repealing s. 456.0721, F.S., relating to investigations of health care practitioners in default on student loan or scholarship obligations; amending s. 456.074, F.S.; deleting the requirement, and related provisions, that the department immediately suspend the licenses of certain health care practitioners for failing to provide proof of new payment terms for defaulted

student loans within a specified timeframe; creating s. 456.4501, F.S.; implementing the Interstate Medical Licensure Compact in this state; providing for an interstate medical licensure process; providing requirements for multistate practice; creating s. 456.4502, F.S.; establishing that a formal hearing before the Division of Administrative Hearings must be held if there are any disputed issues of material fact when the licenses of certain physicians and osteopathic physicians are suspended or revoked by this state under the compact; requiring the department to notify the division of a petition for a formal hearing within a specified timeframe; requiring the administrative law judge to issue a recommended order; requiring the Board of Medicine or the Board of Osteopathic Medicine, as applicable, to determine and issue final orders in certain cases; providing the department with standing to seek judicial review of any final order of the boards; creating s. 456.4504, F.S.; authorizing the department to adopt rules; amending s. 768.28, F.S.; designating the state commissioners of the Interstate Medical Licensure Compact Commission and other members or employees of the commission as state agents for the purpose of applying sovereign immunity and waivers of sovereign immunity; requiring the commission to pay certain claims or judgments; authorizing the commission to maintain insurance coverage to pay such claims or judgments; providing an effective date.

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

Section 1. Section 458.3129, Florida Statutes, is created to read:

458.3129 Interstate Medical Licensure Compact.—A physician licensed to practice medicine under s. 456.4501 is deemed to also be licensed under this chapter.

Section 2. Section 459.074, Florida Statutes, is created to read:

459.074 Interstate Medical Licensure Compact.—A physician licensed to practice osteopathic medicine under s. 456.4501 is deemed to also be licensed under this chapter.

Section 3. Subsection (2) and paragraph (e) of subsection (3) of section 456.0635, Florida Statutes, are amended to read:

456.0635 Health care fraud; disqualification for license, certificate, or registration.—

(2) Each board within the jurisdiction of the department, or the department if there is no board, shall refuse to admit a candidate to any examination and refuse to issue a license, certificate, or registration to any applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the candidate or applicant:

(a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, unless the candidate or applicant has successfully completed a pretrial diversion or drug court program for that felony and provides

proof that the plea has been withdrawn or the charges have been dismissed. Any such conviction or plea shall exclude the applicant or candidate from licensure, examination, certification, or registration unless the sentence and any subsequent period of probation for such conviction or plea ended:

1. For felonies of the first or second degree, more than 15 years before the date of application.

2. For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

3. For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application;

(b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application;

(c) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the candidate or applicant has been in good standing with the Florida Medicaid program for the most recent 5 years; or

(d) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the candidate or applicant has been in good standing with a state Medicaid program for the most recent 5 years and the termination occurred at least 20 years before the date of the application~~; or~~

~~(e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities~~.

This subsection does not apply to an applicant for initial licensure, certification, or registration who was arrested or charged with a felony specified in paragraph (a) or paragraph (b) before July 1, 2009.

(3) The department shall refuse to renew a license, certificate, or registration of any applicant if the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant:

~~(e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.~~

This subsection does not apply to an applicant for renewal of licensure, certification, or registration who was arrested or charged with a felony specified in paragraph (a) or paragraph (b) before July 1, 2009.

Section 4. Paragraph (k) of subsection (1) of section 456.072, Florida Statutes, is amended to read:

456.072 Grounds for discipline; penalties; enforcement.—

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(k) Failing to perform any statutory or legal obligation placed upon a licensee. ~~For purposes of this section, failing to repay a student loan issued or guaranteed by the state or the~~

~~Federal Government in accordance with the terms of the loan or failing to comply with service scholarship obligations shall be considered a failure to perform a statutory or legal obligation, and the minimum disciplinary action imposed shall be a suspension of the license until new payment terms are agreed upon or the scholarship obligation is resumed, followed by probation for the duration of the student loan or remaining scholarship obligation period, and a fine equal to 10 percent of the defaulted loan amount. Fines collected shall be deposited into the Medical Quality Assurance Trust Fund.~~

Section 5. Section 456.0721, Florida Statutes, is repealed.

Section 6. Subsection (4) of section 456.074, Florida Statutes, is amended to read:

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

~~(4) Upon receipt of information that a Florida-licensed health care practitioner has defaulted on a student loan issued or guaranteed by the state or the Federal Government, the department shall notify the licensee by certified mail that he or she shall be subject to immediate suspension of license unless, within 45 days after the date of mailing, the licensee provides proof that new payment terms have been agreed upon by all parties to the loan. The department shall issue an emergency order suspending the license of any licensee who, after 45 days following the date of mailing from the department, has failed to provide such proof. Production of such proof shall not prohibit the department from proceeding with disciplinary action against the licensee pursuant to s. 456.073.~~

Section 7. Section 456.4501, Florida Statutes, is created

to read:

456.4501 Interstate Medical Licensure Compact.—The Interstate Medical Licensure Compact is hereby enacted into law and entered into by this state with all other jurisdictions legally joining therein in the form substantially as follows:

SECTION 1

PURPOSE

In order to strengthen access to health care, and in recognition of the advances in the delivery of health care, the member states of the Interstate Medical Licensure Compact have allied in common purpose to develop a comprehensive process that complements the existing licensing and regulatory authority of state medical boards, provides a streamlined process that allows physicians to become licensed in multiple states, thereby enhancing the portability of a medical license and ensuring the safety of patients. The Compact creates another pathway for licensure and does not otherwise change a state's existing Medical Practice Act. The Compact also adopts the prevailing standard for licensure and affirms that the practice of medicine occurs where the patient is located at the time of the physician-patient encounter, and therefore, requires the physician to be under the jurisdiction of the state medical board where the patient is located. State medical boards that participate in the Compact retain the jurisdiction to impose an adverse action against a license to practice medicine in that state issued to a physician through the procedures in the Compact.

SECTION 2

DEFINITIONS

In this compact:

(a) "Bylaws" means those bylaws established by the Interstate Commission pursuant to Section 11 for its governance, or for directing and controlling its actions and conduct.

(b) "Commissioner" means the voting representative appointed by each member board pursuant to Section 11.

(c) "Conviction" means a finding by a court that an individual is guilty of a criminal offense through adjudication, or entry of a plea of guilt or no contest to the charge by the offender. Evidence of an entry of a conviction of a criminal offense by the court shall be considered final for purposes of disciplinary action by a member board.

(d) "Expedited License" means a full and unrestricted medical license granted by a member state to an eligible physician through the process set forth in the Compact.

(e) "Interstate Commission" means the interstate commission created pursuant to Section 11.

(f) "License" means authorization by a state for a physician to engage in the practice of medicine, which would be unlawful without the authorization.

(g) "Medical Practice Act" means laws and regulations governing the practice of allopathic and osteopathic medicine within a member state.

(h) "Member Board" means a state agency in a member state that acts in the sovereign interests of the state by protecting

the public through licensure, regulation, and education of physicians as directed by the state government.

(i) "Member State" means a state that has enacted the Compact.

(j) "Practice of medicine" means the diagnosis, treatment, prevention, cure, or relieving of a human disease, ailment, defect, complaint, or other physical or mental condition, by attendance, advice, device, diagnostic test, or other means, or offering, undertaking, attempting to do, or holding oneself out as able to do, any of these acts.

(k) "Physician" means any person who:

(1) Is a graduate of a medical school accredited by the Liaison Committee on Medical Education, the Commission on Osteopathic College Accreditation, or a medical school listed in the International Medical Education Directory or its equivalent;

(2) Passed each component of the United States Medical Licensing Examination (USMLE) or the Comprehensive Osteopathic Medical Licensing Examination (COMLEX-USA) within three attempts, or any of its predecessor examinations accepted by a state medical board as an equivalent examination for licensure purposes;

(3) Successfully completed graduate medical education approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association;

(4) Holds specialty certification or a time-unlimited specialty certificate recognized by the American Board of Medical Specialties or the American Osteopathic Association's Bureau of Osteopathic Specialists; however, the specialty certification or a time-unlimited specialty certificate does not

have to be maintained once a physician is initially determined to be eligible for expedited licensure through the Compact;

(5) Possesses a full and unrestricted license to engage in the practice of medicine issued by a member board;

(6) Has never been convicted, received adjudication, deferred adjudication, community supervision, or deferred disposition for any offense by a court of appropriate jurisdiction;

(7) Has never held a license authorizing the practice of medicine subjected to discipline by a licensing agency in any state, federal, or foreign jurisdiction, excluding any action related to non-payment of fees related to a license;

(8) Has never had a controlled substance license or permit suspended or revoked by a state or the United States Drug Enforcement Administration; and

(9) Is not under active investigation by a licensing agency or law enforcement authority in any state, federal, or foreign jurisdiction.

(l) "Offense" means a felony, high court misdemeanor, or crime of moral turpitude.

(m) "Rule" means a written statement by the Interstate Commission promulgated pursuant to Section 12 of the Compact that is of general applicability, implements, interprets, or prescribes a policy or provision of the Compact, or an organizational, procedural, or practice requirement of the Interstate Commission, and has the force and effect of statutory law in a member state, if the rule is not inconsistent with the laws of the member state. The term includes the amendment, repeal, or suspension of an existing rule.

(n) "State" means any state, commonwealth, district, or territory of the United States.

(o) "State of Principal License" means a member state where a physician holds a license to practice medicine and which has been designated as such by the physician for purposes of registration and participation in the Compact.

SECTION 3

ELIGIBILITY

(a) A physician must meet the eligibility requirements as defined in Section 2(k) to receive an expedited license under the terms and provisions of the Compact.

(b) A physician who does not meet the requirements of Section 2(k) may obtain a license to practice medicine in a member state if the individual complies with all laws and requirements, other than the Compact, relating to the issuance of a license to practice medicine in that state.

SECTION 4

DESIGNATION OF STATE OF PRINCIPAL LICENSE

(a) A physician shall designate a member state as the state of principal license for purposes of registration for expedited licensure through the Compact if the physician possesses a full and unrestricted license to practice medicine in that state, and the state is:

(1) The state of primary residence for the physician, or

(2) The state where at least 25% of the practice of

medicine occurs, or

(3) The location of the physician's employer, or

(4) If no state qualifies under subsection (1), subsection (2), or subsection (3), the state designated as state of residence for purpose of federal income tax.

(b) A physician may redesignate a member state as state of principal license at any time, as long as the state meets the requirements in subsection (a).

(c) The Interstate Commission is authorized to develop rules to facilitate redesignation of another member state as the state of principal license.

SECTION 5

APPLICATION AND ISSUANCE OF EXPEDITED LICENSURE

(a) A physician seeking licensure through the Compact shall file an application for an expedited license with the member board of the state selected by the physician as the state of principal license.

(b) Upon receipt of an application for an expedited license, the member board within the state selected as the state of principal license shall evaluate whether the physician is eligible for expedited licensure and issue a letter of qualification, verifying or denying the physician's eligibility, to the Interstate Commission.

(1) Static qualifications, which include verification of medical education, graduate medical education, results of any medical or licensing examination, and other qualifications as determined by the Interstate Commission through rule, shall not

be subject to additional primary source verification where already primary source verified by the state of principal license.

(2) The member board within the state selected as the state of principal license shall, in the course of verifying eligibility, perform a criminal background check of an applicant, including the use of the results of fingerprint or other biometric data checks compliant with the requirements of the Federal Bureau of Investigation, with the exception of federal employees who have suitability determination in accordance with U.S. 5 C.F.R. s. 731.202.

(3) Appeal on the determination of eligibility shall be made to the member state where the application was filed and shall be subject to the law of that state.

(c) Upon verification in subsection (b), physicians eligible for an expedited license shall complete the registration process established by the Interstate Commission to receive a license in a member state selected pursuant to subsection (a), including the payment of any applicable fees.

(d) After receiving verification of eligibility under subsection (b) and any fees under subsection (c), a member board shall issue an expedited license to the physician. This license shall authorize the physician to practice medicine in the issuing state consistent with the Medical Practice Act and all applicable laws and regulations of the issuing member board and member state.

(e) An expedited license shall be valid for a period consistent with the licensure period in the member state and in the same manner as required for other physicians holding a full

and unrestricted license within the member state.

(f) An expedited license obtained through the Compact shall be terminated if a physician fails to maintain a license in the state of principal licensure for a non-disciplinary reason, without redesignation of a new state of principal licensure.

(g) The Interstate Commission is authorized to develop rules regarding the application process, including payment of any applicable fees, and the issuance of an expedited license.

SECTION 6

FEES FOR EXPEDITED LICENSURE

(a) A member state issuing an expedited license authorizing the practice of medicine in that state, or the regulating authority of the member state, may impose a fee for a license issued or renewed through the Compact.

(b) The Interstate Commission is authorized to develop rules regarding fees for expedited licenses. However, those rules shall not limit the authority of a member state, or the regulating authority of the member state, to impose and determine the amount of a fee under subsection (a).

SECTION 7

RENEWAL AND CONTINUED PARTICIPATION

(a) A physician seeking to renew an expedited license granted in a member state shall complete a renewal process with the Interstate Commission if the physician:

(1) Maintains a full and unrestricted license in a state of

principal license;

(2) Has not been convicted, received adjudication, deferred adjudication, community supervision, or deferred disposition for any offense by a court of appropriate jurisdiction;

(3) Has not had a license authorizing the practice of medicine subject to discipline by a licensing agency in any state, federal, or foreign jurisdiction, excluding any action related to non-payment of fees related to a license; and

(4) Has not had a controlled substance license or permit suspended or revoked by a state or the United States Drug Enforcement Administration.

(b) Physicians shall comply with all continuing professional development or continuing medical education requirements for renewal of a license issued by a member state.

(c) The Interstate Commission shall collect any renewal fees charged for the renewal of a license and distribute the fees to the applicable member board.

(d) Upon receipt of any renewal fees collected in subsection (c), a member board shall renew the physician's license.

(e) Physician information collected by the Interstate Commission during the renewal process will be distributed to all member boards.

(f) The Interstate Commission is authorized to develop rules to address renewal of licenses obtained through the Compact.

SECTION 8

COORDINATED INFORMATION SYSTEM

(a) The Interstate Commission shall establish a database of all physicians licensed, or who have applied for licensure, under Section 5.

(b) Notwithstanding any other provision of law, member boards shall report to the Interstate Commission any public action or complaints against a licensed physician who has applied or received an expedited license through the Compact.

(c) Member boards shall report disciplinary or investigatory information determined as necessary and proper by rule of the Interstate Commission.

(d) Member boards may report any non-public complaint, disciplinary, or investigatory information not required by subsection (c) to the Interstate Commission.

(e) Member boards shall share complaint or disciplinary information about a physician upon request of another member board.

(f) All information provided to the Interstate Commission or distributed by member boards shall be confidential, filed under seal, and used only for investigatory or disciplinary matters.

(g) The Interstate Commission is authorized to develop rules for mandated or discretionary sharing of information by member boards.

SECTION 9

JOINT INVESTIGATIONS

(a) Licensure and disciplinary records of physicians are

deemed investigative.

(b) In addition to the authority granted to a member board by its respective Medical Practice Act or other applicable state law, a member board may participate with other member boards in joint investigations of physicians licensed by the member boards.

(c) A subpoena issued by a member state shall be enforceable in other member states.

(d) Member boards may share any investigative, litigation, or compliance materials in furtherance of any joint or individual investigation initiated under the Compact.

(e) Any member state may investigate actual or alleged violations of the statutes authorizing the practice of medicine in any other member state in which a physician holds a license to practice medicine.

SECTION 10

DISCIPLINARY ACTIONS

(a) Any disciplinary action taken by any member board against a physician licensed through the Compact shall be deemed unprofessional conduct which may be subject to discipline by other member boards, in addition to any violation of the Medical Practice Act or regulations in that state.

(b) If a license granted to a physician by the member board in the state of principal license is revoked, surrendered or relinquished in lieu of discipline, or suspended, then all licenses issued to the physician by member boards shall automatically be placed, without further action necessary by any

member board, on the same status. If the member board in the state of principal license subsequently reinstates the physician's license, a license issued to the physician by any other member board shall remain encumbered until that respective member board takes action to reinstate the license in a manner consistent with the Medical Practice Act of that state.

(c) If disciplinary action is taken against a physician by a member board not in the state of principal license, any other member board may deem the action conclusive as to matter of law and fact decided, and:

(1) Impose the same or lesser sanction(s) against the physician so long as such sanctions are consistent with the Medical Practice Act of that state; or

(2) Pursue separate disciplinary action against the physician under its respective Medical Practice Act, regardless of the action taken in other member states.

(d) If a license granted to a physician by a member board is revoked, surrendered or relinquished in lieu of discipline, or suspended, then any license(s) issued to the physician by any other member board(s) shall be suspended, automatically and immediately without further action necessary by the other member board(s), for ninety (90) days upon entry of the order by the disciplining board, to permit the member board(s) to investigate the basis for the action under the Medical Practice Act of that state. A member board may terminate the automatic suspension of the license it issued prior to the completion of the ninety (90) day suspension period in a manner consistent with the Medical Practice Act of that state.

SECTION 11

INTERSTATE MEDICAL LICENSURE COMPACT COMMISSION

(a) The member states hereby create the "Interstate Medical Licensure Compact Commission."

(b) The purpose of the Interstate Commission is the administration of the Interstate Medical Licensure Compact, which is a discretionary state function.

(c) The Interstate Commission shall be a body corporate and joint agency of the member states and shall have all the responsibilities, powers, and duties set forth in the Compact, and such additional powers as may be conferred upon it by a subsequent concurrent action of the respective legislatures of the member states in accordance with the terms of the Compact.

(d) The Interstate Commission shall consist of two voting representatives appointed by each member state who shall serve as Commissioners. In states where allopathic and osteopathic physicians are regulated by separate member boards, or if the licensing and disciplinary authority is split between multiple member boards within a member state, the member state shall appoint one representative from each member board. A Commissioner shall be a(n):

(1) Allopathic or osteopathic physician appointed to a member board;

(2) Executive director, executive secretary, or similar executive of a member board; or

(3) Member of the public appointed to a member board.

(e) The Interstate Commission shall meet at least once each calendar year. A portion of this meeting shall be a business

meeting to address such matters as may properly come before the Commission, including the election of officers. The chairperson may call additional meetings and shall call for a meeting upon the request of a majority of the member states.

(f) The bylaws may provide for meetings of the Interstate Commission to be conducted by telecommunication or electronic communication.

(g) Each Commissioner participating at a meeting of the Interstate Commission is entitled to one vote. A majority of Commissioners shall constitute a quorum for the transaction of business, unless a larger quorum is required by the bylaws of the Interstate Commission. A Commissioner shall not delegate a vote to another Commissioner. In the absence of its Commissioner, a member state may delegate voting authority for a specified meeting to another person from that state who shall meet the requirements of subsection (d).

(h) The Interstate Commission shall provide public notice of all meetings and all meetings shall be open to the public. The Interstate Commission may close a meeting, in full or in portion, where it determines by a two-thirds vote of the Commissioners present that an open meeting would be likely to:

(1) Relate solely to the internal personnel practices and procedures of the Interstate Commission;

(2) Discuss matters specifically exempted from disclosure by federal statute;

(3) Discuss trade secrets, commercial, or financial information that is privileged or confidential;

(4) Involve accusing a person of a crime, or formally censuring a person;

(5) Discuss information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy;

(6) Discuss investigative records compiled for law enforcement purposes; or

(7) Specifically relate to the participation in a civil action or other legal proceeding.

(i) The Interstate Commission shall keep minutes which shall fully describe all matters discussed in a meeting and shall provide a full and accurate summary of actions taken, including record of any roll call votes.

(j) The Interstate Commission shall make its information and official records, to the extent not otherwise designated in the Compact or by its rules, available to the public for inspection.

(k) The Interstate Commission shall establish an executive committee, which shall include officers, members, and others as determined by the bylaws. The executive committee shall have the power to act on behalf of the Interstate Commission, with the exception of rulemaking, during periods when the Interstate Commission is not in session. When acting on behalf of the Interstate Commission, the executive committee shall oversee the administration of the Compact including enforcement and compliance with the provisions of the Compact, its bylaws and rules, and other such duties as necessary.

(l) The Interstate Commission may establish other committees for governance and administration of the Compact.

SECTION 12

POWERS AND DUTIES OF THE INTERSTATE COMMISSION

The Interstate Commission shall have the duty and power to:

(a) Oversee and maintain the administration of the Compact;

(b) Promulgate rules which shall be binding to the extent and in the manner provided for in the Compact;

(c) Issue, upon the request of a member state or member board, advisory opinions concerning the meaning or interpretation of the Compact, its bylaws, rules, and actions;

(d) Enforce compliance with Compact provisions, the rules promulgated by the Interstate Commission, and the bylaws, using all necessary and proper means, including but not limited to the use of judicial process;

(e) Establish and appoint committees including, but not limited to, an executive committee as required by Section 11, which shall have the power to act on behalf of the Interstate Commission in carrying out its powers and duties;

(f) Pay, or provide for the payment of the expenses related to the establishment, organization, and ongoing activities of the Interstate Commission;

(g) Establish and maintain one or more offices;

(h) Borrow, accept, hire, or contract for services of personnel;

(i) Purchase and maintain insurance and bonds;

(j) Employ an executive director who shall have such powers to employ, select or appoint employees, agents, or consultants, and to determine their qualifications, define their duties, and fix their compensation;

(k) Establish personnel policies and programs relating to

conflicts of interest, rates of compensation, and qualifications of personnel;

(l) Accept donations and grants of money, equipment, supplies, materials and services, and to receive, utilize, and dispose of it in a manner consistent with the conflict of interest policies established by the Interstate Commission;

(m) Lease, purchase, accept contributions or donations of, or otherwise to own, hold, improve or use, any property, real, personal, or mixed;

(n) Sell, convey, mortgage, pledge, lease, exchange, abandon, or otherwise dispose of any property, real, personal, or mixed;

(o) Establish a budget and make expenditures;

(p) Adopt a seal and bylaws governing the management and operation of the Interstate Commission;

(q) Report annually to the legislatures and governors of the member states concerning the activities of the Interstate Commission during the preceding year. Such reports shall also include reports of financial audits and any recommendations that may have been adopted by the Interstate Commission;

(r) Coordinate education, training, and public awareness regarding the Compact, its implementation, and its operation;

(s) Maintain records in accordance with the bylaws;

(t) Seek and obtain trademarks, copyrights, and patents; and

(u) Perform such functions as may be necessary or appropriate to achieve the purposes of the Compact.

SECTION 13

FINANCE POWERS

(a) The Interstate Commission may levy on and collect an annual assessment from each member state to cover the cost of the operations and activities of the Interstate Commission and its staff. The total assessment, subject to appropriation, must be sufficient to cover the annual budget approved each year for which revenue is not provided by other sources. The aggregate annual assessment amount shall be allocated upon a formula to be determined by the Interstate Commission, which shall promulgate a rule binding upon all member states.

(b) The Interstate Commission shall not incur obligations of any kind prior to securing the funds adequate to meet the same.

(c) The Interstate Commission shall not pledge the credit of any of the member states, except by, and with the authority of, the member state.

(d) The Interstate Commission shall be subject to a yearly financial audit conducted by a certified or licensed public accountant and the report of the audit shall be included in the annual report of the Interstate Commission.

SECTION 14

ORGANIZATION AND OPERATION OF THE INTERSTATE COMMISSION

(a) The Interstate Commission shall, by a majority of Commissioners present and voting, adopt bylaws to govern its conduct as may be necessary or appropriate to carry out the purposes of the Compact within twelve (12) months of the first

Interstate Commission meeting.

(b) The Interstate Commission shall elect or appoint annually from among its Commissioners a chairperson, a vice-chairperson, and a treasurer, each of whom shall have such authority and duties as may be specified in the bylaws. The chairperson, or in the chairperson's absence or disability, the vice-chairperson, shall preside at all meetings of the Interstate Commission.

(c) Officers selected in subsection (b) shall serve without remuneration from the Interstate Commission.

(d) The officers and employees of the Interstate Commission shall be immune from suit and liability, either personally or in their official capacity, for a claim for damage to or loss of property or personal injury or other civil liability caused or arising out of, or relating to, an actual or alleged act, error, or omission that occurred, or that such person had a reasonable basis for believing occurred, within the scope of Interstate Commission employment, duties, or responsibilities; provided that such person shall not be protected from suit or liability for damage, loss, injury, or liability caused by the intentional or willful and wanton misconduct of such person.

(1) The liability of the executive director and employees of the Interstate Commission or representatives of the Interstate Commission, acting within the scope of such person's employment or duties for acts, errors, or omissions occurring within such person's state, may not exceed the limits of liability set forth under the constitution and laws of that state for state officials, employees, and agents. The Interstate Commission is considered to be an instrumentality of the states

for the purposes of any such action. Nothing in this subsection shall be construed to protect such person from suit or liability for damage, loss, injury, or liability caused by the intentional or willful and wanton misconduct of such person.

(2) The Interstate Commission shall defend the executive director, its employees, and subject to the approval of the attorney general or other appropriate legal counsel of the member state represented by an Interstate Commission representative, shall defend such Interstate Commission representative in any civil action seeking to impose liability arising out of an actual or alleged act, error or omission that occurred within the scope of Interstate Commission employment, duties or responsibilities, or that the defendant had a reasonable basis for believing occurred within the scope of Interstate Commission employment, duties, or responsibilities, provided that the actual or alleged act, error, or omission did not result from intentional or willful and wanton misconduct on the part of such person.

(3) To the extent not covered by the state involved, member state, or the Interstate Commission, the representatives or employees of the Interstate Commission shall be held harmless in the amount of a settlement or judgment, including attorney's fees and costs, obtained against such persons arising out of an actual or alleged act, error, or omission that occurred within the scope of Interstate Commission employment, duties, or responsibilities, or that such persons had a reasonable basis for believing occurred within the scope of Interstate Commission employment, duties, or responsibilities, provided that the actual or alleged act, error, or omission did not result from

intentional or willful and wanton misconduct on the part of such persons.

SECTION 15

RULEMAKING FUNCTIONS OF THE INTERSTATE COMMISSION

(a) The Interstate Commission shall promulgate reasonable rules in order to effectively and efficiently achieve the purposes of the Compact. Notwithstanding the foregoing, in the event the Interstate Commission exercises its rulemaking authority in a manner that is beyond the scope of the purposes of the Compact, or the powers granted hereunder, then such an action by the Interstate Commission shall be invalid and have no force or effect.

(b) Rules deemed appropriate for the operations of the Interstate Commission shall be made pursuant to a rulemaking process that substantially conforms to the "Model State Administrative Procedure Act" of 2010, and subsequent amendments thereto.

(c) Not later than thirty (30) days after a rule is promulgated, any person may file a petition for judicial review of the rule in the United States District Court for the District of Columbia or the federal district where the Interstate Commission has its principal offices, provided that the filing of such a petition shall not stay or otherwise prevent the rule from becoming effective unless the court finds that the petitioner has a substantial likelihood of success. The court shall give deference to the actions of the Interstate Commission consistent with applicable law and shall not find the rule to be

unlawful if the rule represents a reasonable exercise of the authority granted to the Interstate Commission.

SECTION 16

OVERSIGHT OF INTERSTATE COMPACT

(a) The executive, legislative, and judicial branches of state government in each member state shall enforce the Compact and shall take all actions necessary and appropriate to effectuate the Compact's purposes and intent. The provisions of the Compact and the rules promulgated hereunder shall have standing as statutory law but shall not override existing state authority to regulate the practice of medicine.

(b) All courts shall take judicial notice of the Compact and the rules in any judicial or administrative proceeding in a member state pertaining to the subject matter of the Compact which may affect the powers, responsibilities or actions of the Interstate Commission.

(c) The Interstate Commission shall be entitled to receive all service of process in any such proceeding, and shall have standing to intervene in the proceeding for all purposes. Failure to provide service of process to the Interstate Commission shall render a judgment or order void as to the Interstate Commission, the Compact, or promulgated rules.

SECTION 17

ENFORCEMENT OF INTERSTATE COMPACT

(a) The Interstate Commission, in the reasonable exercise

of its discretion, shall enforce the provisions and rules of the Compact.

(b) The Interstate Commission may, by majority vote of the Commissioners, initiate legal action in the United States District Court for the District of Columbia, or, at the discretion of the Interstate Commission, in the federal district where the Interstate Commission has its principal offices, to enforce compliance with the provisions of the Compact, and its promulgated rules and bylaws, against a member state in default. The relief sought may include both injunctive relief and damages. In the event judicial enforcement is necessary, the prevailing party shall be awarded all costs of such litigation including reasonable attorney's fees.

(c) The remedies herein shall not be the exclusive remedies of the Interstate Commission. The Interstate Commission may avail itself of any other remedies available under state law or the regulation of a profession.

SECTION 18

DEFAULT PROCEDURES

(a) The grounds for default include, but are not limited to, failure of a member state to perform such obligations or responsibilities imposed upon it by the Compact, or the rules and bylaws of the Interstate Commission promulgated under the Compact.

(b) If the Interstate Commission determines that a member state has defaulted in the performance of its obligations or responsibilities under the Compact, or the bylaws or promulgated

rules, the Interstate Commission shall:

(1) Provide written notice to the defaulting state and other member states, of the nature of the default, the means of curing the default, and any action taken by the Interstate Commission. The Interstate Commission shall specify the conditions by which the defaulting state must cure its default; and

(2) Provide remedial training and specific technical assistance regarding the default.

(c) If the defaulting state fails to cure the default, the defaulting state shall be terminated from the Compact upon an affirmative vote of a majority of the Commissioners and all rights, privileges, and benefits conferred by the Compact shall terminate on the effective date of termination. A cure of the default does not relieve the offending state of obligations or liabilities incurred during the period of the default.

(d) Termination of membership in the Compact shall be imposed only after all other means of securing compliance have been exhausted. Notice of intent to terminate shall be given by the Interstate Commission to the governor, the majority and minority leaders of the defaulting state's legislature, and each of the member states.

(e) The Interstate Commission shall establish rules and procedures to address licenses and physicians that are materially impacted by the termination of a member state, or the withdrawal of a member state.

(f) The member state which has been terminated is responsible for all dues, obligations, and liabilities incurred through the effective date of termination including obligations,

the performance of which extends beyond the effective date of termination.

(g) The Interstate Commission shall not bear any costs relating to any state that has been found to be in default or which has been terminated from the Compact, unless otherwise mutually agreed upon in writing between the Interstate Commission and the defaulting state.

(h) The defaulting state may appeal the action of the Interstate Commission by petitioning the United States District Court for the District of Columbia or the federal district where the Interstate Commission has its principal offices. The prevailing party shall be awarded all costs of such litigation including reasonable attorney's fees.

SECTION 19

DISPUTE RESOLUTION

(a) The Interstate Commission shall attempt, upon the request of a member state, to resolve disputes which are subject to the Compact and which may arise among member states or member boards.

(b) The Interstate Commission shall promulgate rules providing for both mediation and binding dispute resolution as appropriate.

SECTION 20

MEMBER STATES, EFFECTIVE DATE AND AMENDMENT

(a) Any state is eligible to become a member state of the

Compact.

(b) The Compact shall become effective and binding upon legislative enactment of the Compact into law by no less than seven (7) states. Thereafter, it shall become effective and binding on a state upon enactment of the Compact into law by that state.

(c) The governors of non-member states, or their designees, shall be invited to participate in the activities of the Interstate Commission on a non-voting basis prior to adoption of the Compact by all states.

(d) The Interstate Commission may propose amendments to the Compact for enactment by the member states. No amendment shall become effective and binding upon the Interstate Commission and the member states unless and until it is enacted into law by unanimous consent of the member states.

SECTION 21

WITHDRAWAL

(a) Once effective, the Compact shall continue in force and remain binding upon each and every member state; provided that a member state may withdraw from the Compact by specifically repealing the statute which enacted the Compact into law.

(b) Withdrawal from the Compact shall be by the enactment of a statute repealing the same, but shall not take effect until one (1) year after the effective date of such statute and until written notice of the withdrawal has been given by the withdrawing state to the governor of each other member state.

(c) The withdrawing state shall immediately notify the

chairperson of the Interstate Commission in writing upon the introduction of legislation repealing the Compact in the withdrawing state.

(d) The Interstate Commission shall notify the other member states of the withdrawing state's intent to withdraw within sixty (60) days of its receipt of notice provided under subsection (c).

(e) The withdrawing state is responsible for all dues, obligations and liabilities incurred through the effective date of withdrawal, including obligations, the performance of which extend beyond the effective date of withdrawal.

(f) Reinstatement following withdrawal of a member state shall occur upon the withdrawing state reenacting the Compact or upon such later date as determined by the Interstate Commission.

(g) The Interstate Commission is authorized to develop rules to address the impact of the withdrawal of a member state on licenses granted in other member states to physicians who designated the withdrawing member state as the state of principal license.

SECTION 22

DISSOLUTION

(a) The Compact shall dissolve effective upon the date of the withdrawal or default of the member state which reduces the membership in the Compact to one (1) member state.

(b) Upon the dissolution of the Compact, the Compact becomes null and void and shall be of no further force or effect, and the business and affairs of the Interstate

Commission shall be concluded and surplus funds shall be distributed in accordance with the bylaws.

SECTION 23

SEVERABILITY AND CONSTRUCTION

(a) The provisions of the Compact shall be severable, and if any phrase, clause, sentence, or provision is deemed unenforceable, the remaining provisions of the Compact shall be enforceable.

(b) The provisions of the Compact shall be liberally construed to effectuate its purposes.

(c) Nothing in the Compact shall be construed to prohibit the applicability of other interstate compacts to which the states are members.

SECTION 24

BINDING EFFECT OF COMPACT AND OTHER LAWS

(a) Nothing herein prevents the enforcement of any other law of a member state that is not inconsistent with the Compact.

(b) All laws in a member state in conflict with the Compact are superseded to the extent of the conflict.

(c) All lawful actions of the Interstate Commission, including all rules and bylaws promulgated by the Commission, are binding upon the member states.

(d) All agreements between the Interstate Commission and the member states are binding in accordance with their terms.

(e) In the event any provision of the Compact exceeds the

constitutional limits imposed on the legislature of any member state, such provision shall be ineffective to the extent of the conflict with the constitutional provision in question in that member state.

Section 8. Section 456.4502, Florida Statutes, is created to read:

456.4502 Interstate Medical Licensure Compact; disciplinary proceedings.—A physician licensed pursuant to chapter 458, chapter 459, or s. 456.4501 whose license is suspended or revoked by this state pursuant to the Interstate Medical Licensure Compact as a result of disciplinary action taken against the physician's license in another state shall be granted a formal hearing before an administrative law judge from the Division of Administrative Hearings held pursuant to chapter 120 if there are any disputed issues of material fact. In such proceedings:

(a) Notwithstanding s. 120.569(2), the department shall notify the division within 45 days after receipt of a petition or request for a formal hearing.

(b) The determination of whether the physician has violated the laws and rules regulating the practice of medicine or osteopathic medicine, as applicable, including a determination of the reasonable standard of care, is a conclusion of law that is to be determined by appropriate board, and is not a finding of fact to be determined by an administrative law judge.

(c) The administrative law judge shall issue a recommended order pursuant to chapter 120.

(d) The Board of Medicine or the Board of Osteopathic Medicine, as applicable, shall determine and issue the final

order in each disciplinary case. Such order shall constitute final agency action.

(e) Any consent order or agreed-upon settlement is subject to the approval of the department.

(f) The department shall have standing to seek judicial review of any final order of the board, pursuant to s. 120.68.

Section 9. Section 456.4504, Florida Statutes, is created to read:

456.4504 Interstate Medical Licensure Compact Rules.—The department may adopt rules to implement the Interstate Medical Licensure Compact.

Section 10. Paragraph (h) is added to subsection (10) of section 768.28, Florida Statutes, to read:

768.28 Waiver of sovereign immunity in tort actions; recovery limits; limitation on attorney fees; statute of limitations; exclusions; indemnification; risk management programs.—

(10)

(h) For the purposes of this section, the representative appointed from the Board of Medicine and the representative appointed from the Board of Osteopathic Medicine, when serving as commissioners of the Interstate Medical Licensure Compact Commission pursuant to s. 456.4501, and any administrator, officer, executive director, employee, or representative of the Interstate Medical Licensure Compact Commission, when acting within the scope of their employment, duties, or responsibilities in this state, are considered agents of the state. The commission shall pay any claims or judgments pursuant to this section and may maintain insurance coverage to pay any

such claims or judgments.

Section 11. This act shall take effect July 1, 2021.

THE FLORIDA SENATE

APPEARANCE RECORD

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

11/28/2028
Meeting Date

926
Bill Number (if applicable)

Topic HEALTH CARE PRACTITIONER LICENSURE

Amendment Barcode (if applicable)

Name Layne Smith

Job Title Gov. Relations Director

Address 4500 San Pablo Road
Street

Jacksonville FL 32224
City *State* *Zip*

Phone 904-953-7334

Email Smith.layne@mayo.edu

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Mayo Clinic

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

1/28/20
Meeting Date

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

926
Bill Number (if applicable)

Topic Health Care Practitioner Licensure

Amendment Barcode (if applicable)

Name Jared Willis

Job Title Dir. of Govt Relations

Address 2544 Blairstone Pines
Street

Phone 850-284-1996

Tallahassee FL 33301
City *State* *Zip*

Email

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Osteopathic Medical 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)

1/28/20
Meeting Date

SB 926
Bill Number (if applicable)

Topic Health Care Practitioner Licensure

Amendment Barcode (if applicable)

Name Ronald Gilfillen

Job Title Medical Doctor

Address 1430 Piedmont Dr. E.
Street

Tallahassee FL 32308
City *State* *Zip*

Phone 850 224-6496

Email ronaldgilfillen@att.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Medical Association (President)

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)

2020 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Florida Department of Health

BILL INFORMATION	
BILL NUMBER:	77
BILL TITLE:	Student Loans and Scholarship Obligations of Health Care Practitioners
BILL SPONSOR:	Goff-Marcil
EFFECTIVE DATE:	7/1/2020

COMMITTEES OF REFERENCE
1) Click or tap here to enter text.
2) Click or tap here to enter text.
3) Click or tap here to enter text.
4) Click or tap here to enter text.
5) Click or tap here to enter text.

CURRENT COMMITTEE
Click or tap here to enter text.

SIMILAR BILLS	
BILL NUMBER:	Click or tap here to enter text.
SPONSOR:	Click or tap here to enter text.

PREVIOUS LEGISLATION	
BILL NUMBER:	Click or tap here to enter text.
SPONSOR:	Click or tap here to enter text.
YEAR:	Click or tap here to enter text.
LAST ACTION:	Click or tap here to enter text.

IDENTICAL BILLS	
BILL NUMBER:	Click or tap here to enter text.
SPONSOR:	Click or tap here to enter text.

Is this bill part of an agency package?
No

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	Click or tap here to enter text.
LEAD AGENCY ANALYST:	Click or tap here to enter text.
ADDITIONAL ANALYST(S):	Click or tap here to enter text.
LEGAL ANALYST:	Click or tap here to enter text.
FISCAL ANALYST:	Click or tap here to enter text.

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

The bill deletes the authority for taking disciplinary action against health care practitioners who are in default on a student loan guaranteed by the state or federal government.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

Section 456.072(1)(k), F.S., requires the suspension of licenses when the licensee is in default on a student loan which is guaranteed by the state or federal government. The suspension remains in effect until the licensee enters into a new payment agreement. Discipline is then mandated which includes a fine in the amount of 10% of the defaulted loan amount and probation for the duration of the student loan.

Section 456.0721, F.S., requires the Department of Health to obtain information from the federal government on health care practitioners who are in default on guaranteed student loans. The Department must annually report to the Legislature data on licensees in default.

Section 456.074 (4), F.S., requires the Department of Health to issue an emergency order suspending the license of any licensee who, after notice from the Department, fails to provide proof within 45 days that new payment terms have been agreed to by parties to the loan.

In FY17-18, the Department reported 850 student loan defaults. During this same time, 76 investigations were completed, and 26 emergency suspension orders were filed.

In FY18-19, the Department reported 87 student loan defaults. During this same time, 250 investigations were completed, and 121 emergency suspension orders were filed.

2. EFFECT OF THE BILL:

Section 456.072(1)(k), F.S., relating to grounds for discipline, is amended to delete the provisions about student loan defaults as grounds for discipline for failing to perform a legal or statutory obligation.

Section 456.0721,F.S., relating to practitioners in default on student loans, is repealed.

Section 456.074(4), F.S., is amended to delete the provisions related to notice and an emergency order suspending a license if the licensee does not show proof of new payment terms.

The bill would take effect on July 1, 2020.

3. DOES THE BILL DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES? Y☐ N☒

If yes, explain:	

Is the change consistent with the agency's core mission?	Y☒ N☐
Rule(s) impacted (provide references to F.A.C., etc.):	

4. WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?

Proponents and summary of position:	Unknown
Opponents and summary of position:	Unknown

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y☐ N☒

If yes, provide a description:	Click or tap here to enter text.
Date Due:	Click or tap here to enter text.
Bill Section Number(s):	N/A

6. ARE THERE ANY NEW GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSIONS, ETC. REQUIRED BY THIS BILL? Y☐ N☒

Board:	Click or tap here to enter text.
Board Purpose:	Click or tap here to enter text.
Who Appoints:	Click or tap here to enter text.
Changes:	N/A
Bill Section Number(s):	N/A

FISCAL ANALYSIS

1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT? Y☐ N☒

Revenues:	None
Expenditures:	None
Does the legislation increase local taxes or fees? If yes, explain.	No
If yes, does the legislation provide for a local	N/A

referendum or local governing body public vote prior to implementation of the tax or fee increase?	

2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT? Y☒ N☐

Revenues:	DOH/MQA will experience a recurring decrease in revenue due to the loss of the mandated 10% fine imposed on student loan default cases.
Expenditures:	DOH/MQA will experience a recurring reduction in workload and cost due to fewer investigations and prosecutions to conduct. The Compliance Management Unit would no longer have to track licensees on probation due to board imposed discipline. DOH/MQA will incur non-recurring costs associated with rulemaking, which current budget authority is adequate to absorb.
Does the legislation contain a State Government appropriation?	No
If yes, was this appropriated last year?	N/A

3. DOES THE BILL HAVE A FISCAL IMPACT TO THE PRIVATE SECTOR? Y☒ N☐

Revenues:	Unknown
Expenditures:	The health care workforce would no longer be subject to the mandatory 10% fine for student loans in default.
Other:	The health care workforce would no longer be impacted by licensees being suspended due to student loan defaults.

4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y☐ N☐

If yes, explain impact.	The mandatory 10% fine due to student loans in default would be repealed
Bill Section Number:	Section 2

TECHNOLOGY IMPACT

1. DOES THE BILL IMPACT THE AGENCY'S TECHNOLOGY SYSTEMS (I.E. IT SUPPORT, LICENSING SOFTWARE, DATA STORAGE, ETC.)? Y☐ N☒

If yes, describe the anticipated impact to the agency including any fiscal impact.	N/A

FEDERAL IMPACT

1. DOES THE BILL HAVE A FEDERAL IMPACT (I.E. FEDERAL COMPLIANCE, FEDERAL FUNDING, FEDERAL AGENCY INVOLVEMENT, ETC.)? Y☐ N☒

If yes, describe the anticipated impact including any fiscal impact.	Click or tap here to enter text.

ADDITIONAL COMMENTS

LEGAL - GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	Lines 29-34 deletes minimum disciplinary actions for defaulting on a student loan but a reference to fines collected as a result of a default remains on lines 34-35. Recommend clarification by deleting this reference. The proposed legislation as drafted presents a conflict with s. 456.0635(2)(e), 456.0635(3)(e), Fla. Stat. These sections require the department to refuse to issue or renew a license to a candidate or applicant if the candidate or licensee is currently listed on the United States Department of Health and Human Services Office of the Inspector General's List of Excluded Individuals and Entities (LEIE). Section 1128(b)(14) of the Social Security Act and 42 USC1320a-7(b)(14), provides that a default on a health education loan or scholarship obligation is permissive grounds for being placed on the LEIE and that such exclusion shall last until the default or obligation is resolved. If a candidate or applicant is placed on the LEIE for a default on such a loan the department would be obligated to deny that person's application for initial license or renewal of an existing license.

2020 FDLE LEGISLATIVE BILL ANALYSIS

BILL INFORMATION	
BILL NUMBER:	SB 926
BILL TITLE:	Health Care Practitioner Licensure
BILL SPONSOR:	Senator Harrell
EFFECTIVE DATE:	July 1, 2020

COMMITTEES OF REFERENCE
1)
2)
3)
4)
5)

CURRENT COMMITTEE

SIMILAR BILLS	
BILL NUMBER:	
SPONSOR:	

IDENTICAL BILLS	
BILL NUMBER:	
SPONSOR:	

PREVIOUS LEGISLATION	
BILL NUMBER:	
SPONSOR:	
YEAR:	
LAST ACTION:	

Is this bill part of an agency package?
No

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	November 25, 2019
LEAD AGENCY ANALYST:	Charles Schaeffer
ADDITIONAL ANALYST(S):	Tracy Townsend, Becky Bezemek
LEGAL ANALYST:	Jason Jones, Weston Petkovsek
FISCAL ANALYST:	Cynthia Barr

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

Establishing that a physician licensed under the Interstate Medical Licensure Compact is deemed to be licensed under Chapter 458, FS; establishing that an osteopathic physician licensed under the Interstate Medical Licensure Compact is deemed to be licensed under Chapter 459, FS; deleting a provision classifying the failure to repay a student loan issued or guaranteed by the state or federal government in accordance with the terms of the loan as a failure to perform a statutory or legal obligation; implementing the Interstate Medical Licensure Compact in this state.

2. SUBSTANTIVE BILL ANALYSIS

1. **PRESENT SITUATION:** Currently, physicians in Florida are required to obtain a professional license through the Florida Department of Health (DOH). State law requires for these professionals' fingerprints be retained in the Care Provider Background Screening Clearinghouse (Clearinghouse).

2. **EFFECT OF THE BILL:** Florida would join the Interstate Medical Licensure Compact, allowing physicians who obtain a medical license in their initial home state receive expedited licensing when transferring their primary location of practice to another state. The bill requires state and national criminal history record checks for applicants and the subsequent sharing of information with other participating states.

3. **DOES THE LEGISLATION DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES OR PROCEDURES? Y ☐ N ☒**

If yes, explain:	
What is the expected impact to the agency's core mission?	**Y ☐ N ☐**
Rule(s) impacted (provide references to F.A.C., etc.):	

4. **WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?**

List any known proponents and opponents:	
Provide a summary of the proponents' and opponents' positions:	

5. **ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y ☐ N ☒**

If yes, provide a description:	
Date Due:	
Bill Section Number:	

6. **ARE THERE ANY NEW GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSION, ETC. REQURIED BY THIS BILL? Y ☐ N ☒**

Board:	
Board Purpose:	

Who Appointments:	
Appointee Term:	
Changes:	
Bill Section Number(s):	

FISCAL ANALYSIS

1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT? Y ☐ N ☒

Revenues:	
Expenditures:	
Does the legislation increase local taxes or fees?	
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	

2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT? Y ☐ N ☐

Revenues:	Unknown. The department has contacted the DOH for an anticipated number of new criminal history record checks that could result from the passage of this bill and is awaiting a response. The total fiscal revenue for the state portion of a state and national criminal history record check with five years of fingerprint retention within the Clearinghouse is $48. These fees go into FDLE's Operating Trust Fund. Of this total amount, the cost for state level criminal history record checks is $24. Since persons screened pursuant to this bill will be entered in the Clearinghouse, $24 for five years of state fingerprint retention will be paid up front. When FDLE begins participation in the federal retention program, there will be no fees required by the FBI for federal fingerprint retention.
Expenditures:	
Does the legislation contain a State Government appropriation?	
If yes, was this appropriated last year?	

3. DOES THE BILL HAVE A FISCAL IMPACT TO THE PRIVATE SECTOR? Y ☐ N ☐

Revenues:	Unknown. The department has contacted the DOH for an anticipated number new criminal history record checks that could expect as a result from the passage of this bill and is awaiting a response.

	The total fiscal impact to the private sector for state and national criminal history record checks with five years of Clearinghouse retention is $61.25. Of this total amount, the cost for a state and national criminal history record check is $37.25; the cost for the national portion of the criminal history record check is $13.25 and the cost for the state portion is $24, which goes into FDLE's Operating Trust Fund. Since persons screened pursuant to this bill will be entered in the Clearinghouse, $24 for five years of state fingerprint retention will be paid up front and will go into FDLE's Operating Trust Fund. When FDLE begins participation in the federal retention program, there will be no fees required by the FBI for federal fingerprint retention.
Expenditures:	
Other:	

4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y ☐ N ☒

Does the bill increase taxes, fees or fines?	
Does the bill decrease taxes, fees or fines?	
What is the impact of the increase or decrease?	
Bill Section Number:	

TECHNOLOGY IMPACT

1. DOES THE LEGISLATION IMPACTTHE AGENCY'S TECHNOLOGY SYSTEMS (I.E., IT SUPPORT, LICENSING, SOFTWARE, DATA STORAGE, ETC.)? Y ☒ N ☐

If yes, describe the anticipated impact to the agency including any fiscal impact.	Unknown. The department would need to know the estimated number of individuals falling under the scope of this bill to access the impact.

FEDERAL IMPACT

1. DOES THE LEGISLATION HAVE A FEDERAL IMPACT (I.E., FEDERAL COMPLIANCE, FEDERAL FUNDING, FEDERAL AGECY INVOLVEMENT, ETC.)? Y ☐ N ☒

If yes, describe the anticipated impact including any fiscal impact.	

LEGAL - GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments and recommended action:	No additional comments.

ADDITIONAL COMMENTS

- Lines 345-351: The department's understanding of this passage is that "static qualifications", such as results of medical and licensure examinations, may not be subjected to "additional primary source verification where already primary source verified". This language may be construed to prohibit state and national criminal history record checks and the subsequent retention of fingerprints for future arrest hit notifications required under Section 456.0135, FS.

- Per section 456.0135, FS, all applicants licensed under Chapters 458 and 459, FS, are to be entered in the Care Provider Background Screening Clearinghouse established in Section 435.12, FS. Under this bill and in conjunction with existing state law, multi-state licenses issued to applicants outside of Florida would be ineligible for retention in the Clearinghouse. Significantly, it would be in violation of state law for a physician, subject to the licensing requirements of Chapters 458 and 459, FS, to work in Florida if his or her fingerprints were not entered and retained in the Clearinghouse, per the requirements of Sections 456.0135 and 435.12, FS.

- Sections 5 and 8: The department contacted DOH for clarification on the anticipated contents of the "letter of qualification" and is awaiting a response. Dissemination of criminal history record information (CHRI) is authorized and obtained under a specific state statute and would be used solely for in-state purposes and cannot be disseminated outside the receiving governmental department or related governmental agency. Therefore, any subsequent arrests of in-state licensed physicians, whose fingerprints are retained under the Clearinghouse, may not be disclosed to the Interstate Medical Licensure Compact or its Coordinated Information System. If the intent is not to permit the sharing of CHRI, an express declaration to that effect is needed. Federal regulation outlines the dissemination of criminal history record information (CHRI) in 28 CFR part 20.33.

  § 20.33 Dissemination of criminal history record information.

  (a) Criminal history record information contained in the III System and the FIRS may be made available:

  (1) To criminal justice agencies for criminal justice purposes, which purposes include the screening of employees or applicants for employment hired by criminal justice agencies;

  (2) To federal agencies authorized to receive it pursuant to federal statute or Executive order;

  (3) For use in connection with licensing or employment, pursuant to Public Law 92-544, 86 Stat. 1115, or other federal legislation, and for other uses for which dissemination is authorized by federal law. Refer to § 50.12 of this chapter for dissemination guidelines relating to requests processed under this paragraph;

  (4) For issuance of press releases and publicity designed to effect the apprehension of wanted persons in connection with serious or significant offenses;

  (5) To criminal justice agencies for the conduct of background checks under the National Instant Criminal Background Check System (NICS);

  (6) To noncriminal justice governmental agencies performing criminal justice dispatching functions or data processing/ information services for criminal justice agencies; and

  (7) To private contractors pursuant to a specific agreement with an agency identified in paragraphs (a)(1) or (a)(6) of this section and for the purpose of providing services for the administration of criminal justice pursuant to that agreement. The agreement must incorporate a security addendum approved by the Attorney General of the United States, which shall specifically authorize access to criminal history record information, limit the use of the information to the purposes for which it is provided, ensure the security and confidentiality of the information consistent with these regulations, provide for sanctions, and contain such other provisions as the Attorney General may require. The power and authority of the Attorney General hereunder shall be exercised by the FBI Director (or the Director's designee).

  (b) The exchange of criminal history record information authorized by paragraph (a) of this section is subject to cancellation if dissemination is made outside the receiving departments, related agencies, or service providers identified in paragraphs (a)(6) and (a)(7) of this section.

(c) Nothing in these regulations prevents a criminal justice agency from disclosing to the public factual information concerning the status of an investigation, the apprehension, arrest, release, or prosecution of an individual, the adjudication of charges, or the correctional status of an individual, which is reasonably contemporaneous with the event to which the information relates.

(d) Criminal history records received from the III System or the FIRS shall be used only for the purpose requested and a current record should be requested when needed for a subsequent authorized use.

- Additionally, there is a risk that a state participating in the Compact, which also participates in the National Fingerprint File (NFF) Program, would have arrest records not currently indexed with the FBI. This means NFF states may have arrest records which would not appear on a national criminal history record check. Twenty states currently participate in the NFF.

- Sections 23 and 24: FDLE recommends if the intent of the Compact's authority is to be overruled by pre-existing member state law(s), the proposed language within Sections 23 and 24 be modified to jointly state as such. Currently, Section 23 attests to the Compact's unenforceable authorities being bypassed whereas Section 24 explicitly calls for the overruling of pre-existing member state laws that are in conflict with the Compact's authority.

- While the impact of this bill does not necessitate additional FTE or other resources, this bill in combination with additional criminal history record check bills could rise to the level requiring additional staffing and other resources.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 928
INTRODUCER:	Senator Harrell
SUBJECT:	Public Records and Meetings/Interstate Medical Licensure Compact
DATE:	January 29, 2020 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Kibbey	Brown	HP	**Fav/CS**
2.			GO	
3.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 928 exempts from public record inspection and copying requirements the personal identifying information of a physician, other than the physician's name, licensure status, or licensure number, obtained from the coordinated information system under the Interstate Medical Licensure Compact, as defined in s. 456.4501, F.S.,[1] and held by the Department of Health (DOH) or the Board (the Board of Medicine or the Board of Osteopathic Medicine).[2] This information is not exempt from public records requirements under the bill if the state originally reporting the information to the coordinated information system authorizes disclosure of such information by law.

The bill exempts from public meeting requirements a meeting or a portion of the meeting of the Interstate Medical Licensure Commission established under the Interstate Medical Licensure Compact. The exemption applies when matters specifically exempted from disclosure by state or federal law are discussed. The bill provides that recordings, minutes, and records generated from those meetings are also exempt from requirements to disclose such public records.

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

The bill provides an effective date of the same date that SB 926 or similar legislation takes effect. SB 926, the substantive bill authorizing Florida's participation in the Interstate Medical Licensure Compact, has an effective date of July 1, 2021.

[1] Section 456.4501, F.S., is created in SB 926 and establishes the state's participation in the Interstate Medical Licensure Compact and the coordinated information system.

[2] Section 456.001, F.S.

The bill provides for the repeal of the exemption on October 2, 2025, unless reviewed and reenacted by the Legislature. It also provides statements of public necessity for the public records and public meetings exemptions as required by the State Constitution.

The bill creates a new public records exemption; therefore, a two-thirds vote of the members present and voting in each house of the Legislature is required for final passage.

II. Present Situation:

Access to Public Records - Generally

The Florida Constitution provides that the public has the right to inspect or copy records made or received in connection with official governmental business.[3] The right to inspect or copy applies to the official business of any public body, officer, or employee of the state, including all three branches of state government, local governmental entities, and any person acting on behalf of the government.[4]

Additional requirements and exemptions related to public records are found in various statutes and rules, depending on the branch of government involved. For instance, s. 11.0431, F.S., provides public access requirements for legislative records. Relevant exemptions are codified in s. 11.0431(2)-(3), F.S., and the statutory provisions are adopted in the rules of each house of the legislature.[5] Florida Rule of Judicial Administration 2.420 governs public access to judicial branch records.[6] Lastly, ch. 119, F.S., provides requirements for public records held by executive agencies.

Executive Agency Records – The Public Records Act

Chapter 119, F.S., known as the Public Records Act, provides that all state, county and municipal records are open for personal inspection and copying by any person, and that providing access to public records is a duty of each agency.[7]

A public record includes virtually any document or recording, regardless of its physical form or how it may be transmitted.[8] The Florida Supreme Court has interpreted the statutory definition of

[3] FLA. CONST. art. I, s. 24(a).
[4] *Id*.
[5] *See* Rule 1.48, *Rules and Manual of the Florida Senate*, (2018-2020) and Rule 14.1, *Rules of the Florida House of Representatives*, Edition 2, (2018-2020)
[6] *State v. Wooten*, 260 So. 3d 1060 (Fla. 4th DCA 2018).
[7] Section 119.01(1), F.S. Section 119.011(2), F.S., defines "agency" as "any state, county, district, authority, or municipal officer, department, division, board, bureau, commission, or other separate unit of government created or established by law including, for the purposes of this chapter, the Commission on Ethics, the Public Service Commission, and the Office of Public Counsel, and any other public or private agency, person, partnership, corporation, or business entity acting on behalf of any public agency."
[8] Section 119.011(12), F.S., defines "public record" to mean "all documents, papers, letters, maps, books, tapes, photographs, films, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connection with the transaction of official business by any agency."

"public record" to include "material prepared in connection with official agency business which is intended to perpetuate, communicate, or formalize knowledge of some type."[9]

The Florida Statutes specify conditions under which public access to public records must be provided. The Public Records Act guarantees every person's right to inspect and copy any public record at any reasonable time, under reasonable conditions, and under supervision by the custodian of the public record.[10] A violation of the Public Records Act may result in civil or criminal liability.[11]

The Legislature may exempt public records from public access requirements by passing a general law by a two-thirds vote of both the House and the Senate.[12] The exemption must state with specificity the public necessity justifying the exemption and must be no broader than necessary to accomplish the stated purpose of the exemption.[13]

General exemptions from the public records requirements are contained in the Public Records Act.[14] Specific exemptions often are placed in the substantive statutes relating to a particular agency or program.[15]

When creating a public records exemption, the Legislature may provide that a record is "exempt" or "confidential and exempt." Custodians of records designated as "exempt" are not prohibited from disclosing the record; rather, the exemption means that the custodian cannot be compelled to disclose the record.[16] Custodians of records designated as "confidential and exempt" may not disclose the record except under circumstances specifically defined by the Legislature.[17]

Open Government Sunset Review Act

The Open Government Sunset Review Act[18] (the Act) prescribes a legislative review process for newly created or substantially amended[19] public records or open meetings exemptions, with specified exceptions.[20] It requires the automatic repeal of such exemption on October 2nd of the

[9] *Shevin v. Byron, Harless, Schaffer, Reid and Assoc., Inc*., 379 So. 2d 633, 640 (Fla. 1980).
[10] Section 119.07(1)(a), F.S.
[11] Section 119.10, F.S. Public records laws are found throughout the Florida Statutes, as are the penalties for violating those laws.
[12] FLA. CONST. art. I, s. 24(c).
[13] *Id*. *See, e.g., Halifax Hosp. Medical Center v. News-Journal Corp.*, 724 So. 2d 567 (Fla. 1999) (holding that a public meetings exemption was unconstitutional because the statement of public necessity did not define important terms and did not justify the breadth of the exemption); *Baker County Press, Inc. v. Baker County Medical Services, Inc.*, 870 So. 2d 189 (Fla. 1st DCA 2004) (holding that a statutory provision written to bring another party within an existing public records exemption is unconstitutional without a public necessity statement).
[14] *See, e.g.*, s. 119.071(1)(a), F.S. (exempting from public disclosure examination questions and answer sheets of examinations administered by a governmental agency for the purpose of licensure).
[15] *See, e.g.*, s. 213.053(2)(a), F.S., (exempting from public disclosure information contained in tax returns received by the Department of Revenue).
[16] *See Williams v. City of Minneola*, 575 So. 2d 683, 687 (Fla. 5th DCA 1991).
[17] *WFTV, Inc. v. The School Board of Seminole*, 874 So. 2d 48 (Fla. 5th DCA 2004).
[18] Section 119.15, F.S.
[19] An exemption is considered to be substantially amended if it is expanded to include more records or information or to include meetings as well as records. Section 119.15(4)(b), F.S.
[20] Section 119.15(2)(a) and (b), F.S., provide that exemptions that are required by federal law or are applicable solely to the Legislature or the State Court System are not subject to the Open Government Sunset Review Act.

fifth year after creation or substantial amendment, unless the Legislature reenacts the exemption.[21]

Open Meetings Law

The State Constitution provides that the public has a right to access governmental meetings.[22] Each collegial body must provide notice of its meetings to the public and permit the public to attend any meeting at which official acts are taken or at which public business is transacted or discussed.[23] This applies to the meetings of any collegial body of the executive branch of state government, counties, municipalities, school districts or special districts.[24]

Public policy regarding access to government meetings also is addressed in the Florida Statutes. Section 286.011, F.S., which is also known as the "Government in the Sunshine Law,"[25] or the "Sunshine Law,"[26] requires all meetings of any board or commission of any state or local agency or authority at which official acts are to be taken be open to the public.[27] The board or commission must provide the public reasonable notice of such meetings.[28] Public meetings may not be held at any location that discriminates on the basis of sex, age, race, creed, color, origin or economic status or which operates in a manner that unreasonably restricts the public's access to the facility.[29] Minutes of a public meeting must be promptly recorded and open to public inspection.[30] Failure to abide by public meetings requirements will invalidate any resolution, rule or formal action adopted at a meeting.[31] A public officer or member of a governmental entity who violates the Sunshine Law is subject to civil and criminal penalties.[32]

The Legislature may create an exemption to public meetings requirements by passing a general law by at least a two-thirds vote of both the Senate and the House of Representatives.[33] The exemption must explicitly lay out the public necessity justifying the exemption, and must be no broader than necessary to accomplish the stated purpose of the exemption.[34] A statutory exemption which does not meet these two criteria may be unconstitutional and may not be judicially saved.[35]

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[21] Section 119.15(3), F.S.
[22] FLA CONST. art. I, s. 24(b).
[23] *Id*.
[24] FLA CONST. art. I, s. 24(b). Meetings of the Legislature are governed by Article III, section 4(e) of the Florida Constitution, which states: "The rules of procedure of each house shall further provide that all prearranged gatherings, between more than two members of the legislature, or between the governor, the president of the senate, or the speaker of the house of representatives, the purpose of which is to agree upon formal legislative action that will be taken at a subsequent time, or at which formal legislative action is taken, regarding pending legislation or amendments, shall be reasonably open to the public."
[25] *Times Pub. Co. v. Williams*, 222 So. 2d 470, 472 (Fla. 2d DCA 1969).
[26] *Board of Public Instruction of Broward County v. Doran*, 224 So. 2d 693, 695 (Fla. 1969).
[27] Section 286.011(1)-(2), F.S.
[28] *Id*.
[29] Section 286.011(6), F.S.
[30] Section 286.011(2), F.S.
[31] Section 286.011(1), F.S.
[32] Section 286.011(3), F.S.
[33] FLA CONST., art. I, s. 24(c).
[34] *Id*.
[35] *Halifax Hosp. Medical Center v. New-Journal Corp.*, 724 So. 2d 567 (Fla. 1999). In *Halifax Hospital*, the Florida Supreme Court found that a public meetings exemption was unconstitutional because the statement of public necessity did not define

The following are general exemptions from the requirement that all meetings of any state agency or authority be open to the public:

- That portion of a meeting that would reveal a security or fire safety system plan; and
- Any portion of a team meeting at which negotiation strategies are discussed.[36]

Practitioner Profiles

Pursuant to s. 456.041, F.S., the DOH operates a database of Florida's health care practitioners, which includes physicians. The practitioner profile database is online and searchable.[37] The profile may include information that is public record and relates to the practitioner's profession.[38] Practitioners and the DOH are required to update profiles.[39] Information exempt from public disclosure and submitted by another governmental entity that the DOH uses for practitioner profiles, continues to maintain its exempt status.[40]

Interstate Medical Licensure Compact and Commission

Interstate Medical Licensure Compact

The Interstate Medical Licensure Compact (Compact) provides an expedited pathway for medical and osteopathic physicians to qualify to practice medicine across state lines within a licensure compact. Currently, 29 states, the District of Columbia and the Territory of Guam which cover 43 medical and osteopathic boards participate in the Compact.[41]

Approximately 80 percent of physicians meet the eligibility guidelines for licensure through the Compact.[42] The providers' applications are expedited by using the information previously submitted in their state of principal licensure (SPL). The physician can then seek expedited licensure in member states after a fresh background check is completed.

Interstate Medical Licensure Compact Commission

The Interstate Medical Licensure Compact Commission (Commission) is created in Section 11 of the Compact and serves as the administrative arm of the Compact and the member states. Each member state has two voting representatives on the Commission and, if the state has

important terms and did not justify the breadth of the exemption. *Id*. at 570. The Florida Supreme Court also declined to narrow the exemption in order to save it. *Id.* In *Baker County Press, Inc. v. Baker County Medical Services, Inc.*, 870 So. 2d 189 (Fla. 1st DCA 2004), the court found that the intent of a public records statute was to create a public records exemption. The *Baker County Press* court found that since the law did not contain a public necessity statement, it was unconstitutional. *Id*. at 196.

[36] Section 286.0113, F.S.

[37] Section 456.041(8), F.S.; Department of Health Practitioner Profile Search, https://appsmqa.doh.state.fl.us/MQASearchServices/HealthCareProviders/PractitionerProfileSearch (last visited Jan. 23, 2020).

[38] Section 456.041(7), F.S.

[39] Section 456.042, F.S.

[40] Section 456.046, F.S.

[41] Interstate Medical Licensure Compact, *The IMLC*, https://imlcc.org/ (last visited Jan. 23, 2020).

[42] *Id*.

separate regulatory boards for allopathic and osteopathic, then the representation is split between the two boards.[43]

The Commission meets at least once per calendar year in a publicly noticed meeting. The Compact also creates an Executive Committee that may act on behalf of the Commission, with the exception of rulemaking. Information, rules, and minutes of the Commission and the Executive Committee, with the exception of those areas that may be closed to the public, are available to the public for inspection.[44]

All or a portion of a Commission meeting may be closed to the public if a topic is likely to involve certain matters, based on a two-thirds vote of those Commission members present at the meeting. The areas covered by a closed meeting are:

- Personnel matters;
- Matters specifically exempted from disclosure by federal law;
- Trade secrets, commercial, or financial information that is privileged or confidential;
- Information that involves accusing a person of a crime or that formally censures a person;
- Information of a personal nature where disclosure would clearly constitute an unwarranted invasion of personal privacy;
- Investigative records compiled for law enforcement purposes; or
- Information that specifically relates to the Commission's participation in a civil action or other legal proceeding. [45]

III. Effect of Proposed Changes:

Section 1 creates s. 456.4502, F.S., to make a physician's personal identifying information, other than the physician's name, licensure status, or licensure number, obtained from the IMLC's coordinated information system, as defined in s. 456.4501, F.S., and held by the DOH or the Boards, exempt from public disclosure under s. 119.07(1), F.S., and s. 24(a), Art. I of the State Constitution. The personal identifying information is exempt from public disclosure under the bill unless the state that originally reported the information to the coordinated information system authorizes the disclosure of such information. Under such circumstances, the information may only be disclosed to the extent permitted by the reporting state's law.

The bill also creates an exemption from s. 286.011, F.S., and s. 24(b), Art. I, of the State Constitution for a meeting or any portion of a meeting of the Commission that is closed to the public by a two-thirds vote of the Commission members present. Such a meeting may be closed if Commission members believe that the meeting would likely:

- Relate solely to the internal personnel practices and procedures of the commission;
- Involve discussion of matters exempted from disclosure by federal statute;
- Involve discussion of trade secrets, commercial, or financial information that is privileged or confidential;

[43] Interstate Medical Licensure Compact, Section 11, (d), p. 11, https://imlcc.org/wp-content/uploads/2018/04/IMLC-Compact-Law.pdf (last visited Jan. 23, 2020).
[44] Interstate Medical Licensure Compact, Section 11(d), pg. 13, https://imlcc.org/wp-content/uploads/2018/04/IMLC-Compact-Law.pdf (last visited Jan. 23, 2020).
[45] *See Interstate Medical Licensure Compact*, Section 11(h), pp. 12-13, https://imlcc.org/wp-content/uploads/2018/04/IMLC-Compact-Law.pdf (last visited Jan. 23, 2020).

- Involve accusing a person of a crime or that formally censures a person;
- Involve discussion of information of a personal nature where disclosure would clearly constitute an unwarranted invasion of personal privacy;
- Involve discussion of investigative records compiled for law enforcement purposes; or
- Relate specifically to participation in a civil action or other legal proceeding.

Recordings, minutes, and records generated during an exempt meeting are exempt from s. 119.07(1), F.S., and s. 24(a), Art. I of the State Constitution.

These exemptions are subject to the Open Government Sunset Review Act and will stand repealed on October 2, 2024, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 2 provides, as required by the State Constitution, a statement of public necessity which provides that protection of the specified information is required under the Compact which the state must adopt in order to become a member state and a party to the Compact. Without the public records exemption, the state would be unable to effectively and efficiently function as a member of the Compact.

Additionally, the bill provides a statement of public necessity, as required by the Florida Constitution, for protecting any meeting or portion of a meeting of the Commission at which matters specifically exempted from disclosure by federal or state statute are discussed. These meetings or portions of meetings would be exempted from s. 286.011, F.S., and s. 24(b), Art. I. of the State Constitution. Without the public meeting exemption, the state will be prohibited from becoming a party to the Compact.

The bill includes a statement of public necessity by the Legislature that the recordings, minutes, and records generated during an exempt meeting of the Commission are exempt pursuant to s. 464.0096, F.S., and exempt from s. 119.07(1), F.S., and s. 24(a), Art. I of the State Constitution. Release of such information would negate the public meeting exemption.

Section 3 provides that the bill takes effect on the same date as SB 926 or similar legislation takes effect, if such legislation is adopted in the same legislative session or an extension thereof and becomes law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

Not applicable. The bill does not require counties or municipalities to take action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

B. Public Records/Open Meetings Issues:

Vote Requirement

Article I, section 24(c), of the State Constitution requires a two-thirds vote of the members present and voting for final passage of a bill creating or expanding an exemption to the public records requirements. This bill creates a public records exemption and a public meeting exemption; therefore, it requires a two-thirds vote.

Public Necessity Statement

Article I, section 24(c), of the State Constitution requires a bill creating or expanding an exemption to the public records requirements to state with specificity the public necessity justifying the exemption. Section 2 includes a public necessity statement that supports the exemptions.

Breadth of Exemption

Article I, section 24(c), of the State Constitution requires exemptions to the public records and public meetings requirements to be no broader than necessary to accomplish the stated purpose of the law. It is not clear if the public records exemption is broader than necessary to accomplish the purposes outlined in the public necessity statement. The exemption covers a physician's personal identifying information (excluding a physician's name, licensure status and license number) that is otherwise exempt in the physician's home state. In the context of the Compact, it is not clear what information would be considered "personal identifying information" for purposes of this exemption. Personal identifying information is used throughout the Florida Statutes and is not defined. It is not clear if a state would consider a physician's business address, certifications, or level of education to be personal identifying information. State laws are also subject to change, so it is not clear if this exemption is limited to state laws as currently enacted or in the future. Therefore, the breadth of the exemption is subject to change depending on when or how the DOH and the Boards interpret the laws of the physician's home state.

It is also unclear if the public meetings exemption is broader than necessary to accomplish the purposes outlined in the public necessity statement. The bill provides instances during which a public meeting may be closed. Some of those matters are already exempted under Florida's public meetings exemptions.[46] In addition, the bill provides that the Commission has the authority to vote on when it will close a meeting, so it is not clear exactly which meetings or portions of meetings will be closed. The bill provides the Commission with authority to close a meeting or a portion of a meeting by a two-thirds vote. This could be considered an overly broad exemption. Additionally, one of the seven reasons enumerated upon which the Commission may vote to close a meeting is when the meeting would likely involve a discussion of personal information that would constitute a clearly unwarranted invasion of personal privacy. This may conflict with article 1, section 23, of the State Constitution which provides:

[46] Meetings with attorneys on pending litigation are exempt under s. 286.011(8), F.S. Competitive solicitations team meetings and some negotiations are exempt under s. 286.0113(2), F.S. Meetings to determine if there is probable cause to find that a practitioner is subject to discipline are closed until 10 days after probable cause has been found pursuant to s. 456.073(4), F.S. These exemptions are provided as examples and not an exhaustive list of relevant public meetings exemptions.

> Every natural person has the right to be let alone and free from governmental intrusion into the person's private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided by law.
>
> Courts will look to the Legislature to balance these competing interests.[47]

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The private sector will be subject to the cost, to the extent imposed, associated with the DOH making redactions in response to public records request.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

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[47] *See Campus Communications, Inc. v. Earnhardt*, 821 So. 2d 388, 402-403 (Fla. 5th DCA 2002) ("Thus our function here has not been to weigh these two constitutional rights with respect to autopsy photographs and determine whether the right that helps ensure an open government freely accessible by every citizen is more significant or profound than the right that preserves individual liberty and privacy. Rather, our function has been to determine whether the Legislature has declared that the latter prevails over the former in a manner that is consistent with the constitutional provisions that bestow upon it the power to do so."); *see also Wallace v. Guzman*, 687 So. 2d 1351, 1354 (Fla. 3d DCA 1997) (noting "[t]he [L]egislature has balanced the private/public rights by creating the various exemptions from public disclosure contained in section 119.07, Florida Statutes (1995).").

VIII. Statutes Affected:

This bill creates section 456.4503 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on January 28, 2020:
The CS corrects a typographical error on line 81. The CS also revises the contingent effective date so that the bill will take effect on the same date that SB 926 or similar legislation takes effect if such legislation is adopted in the same legislative session or an extension thereof and becomes a law.

B. Amendments:

None.

By Senator Harrell

25-01036-20 2020928__

A bill to be entitled

An act relating to public records and meetings; creating s. 456.4503, F.S.; providing an exemption from public records requirements for certain information held by the Department of Health, the Board of Medicine, or the Board of Osteopathic Medicine, pursuant to the Interstate Medical Licensure Compact; providing an exemption from public meeting requirements for certain meetings or portions of certain meetings of the Interstate Medical Licensure Compact Commission; providing an exemption from public records requirements for recordings, minutes, and records generated during the closed portions of such meetings; providing for future legislative review and repeal of the exemptions; providing a statement of public necessity; providing a contingent effective date.

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

Section 1. Section 456.4503, Florida Statutes, is created to read:

456.4503 Interstate Medical Licensure Compact; public records and meetings exemptions.—

(1) A physician's personal identifying information, other than the physician's name, licensure status, or licensure number, obtained from the coordinated information system, as described in section 8 of s. 456.4501, and held by the department, the Board of Medicine, or the Board of Osteopathic

Medicine, is exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution unless the state that originally reported the information to the coordinated information system authorizes the disclosure of such information by law. If disclosure is so authorized, information may be disclosed only to the extent authorized by law by the reporting state.

(2)(a) A meeting or a portion of a meeting of the Interstate Medical Licensure Compact Commission, established in section 11 of s. 456.4501, is exempt from s. 286.011 and s. 24(b), Art. I of the State Constitution if the commission has determined that an open meeting would be likely to:

1. Relate solely to the internal personnel practices and procedures of the commission;

2. Discuss matters specifically exempted from disclosure by federal statute;

3. Discuss trade secrets or commercial or financial information that is privileged or confidential;

4. Involve accusing a person of a crime, or formally censuring a person;

5. Discuss information of a personal nature when disclosure would constitute a clearly unwarranted invasion of personal privacy;

6. Discuss investigative records compiled for law enforcement purposes; or

7. Specifically relate to the participation in a civil action or other legal proceeding.

(b) In keeping with the intent of the Interstate Medical Licensure Compact, recordings, minutes, and records generated during an exempt meeting or portion of such a meeting are exempt

from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(3) This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2025, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 2. (1) The Legislature finds that it is a public necessity that a physician's personal identifying information, other than the physician's name, licensure status, or licensure number, obtained from the coordinated information system, as described in section 8 of s. 456.4501, Florida Statutes, and held by the Department of Health, the Board of Medicine, or the Board of Osteopathic Medicine, be made exempt from s. 119.07(1), Florida Statutes, and s. 24(a), Article I of the State Constitution. Protection of such information is required under the Interstate Medical Licensure Compact, which the state must adopt in order to become a member state of the compact. Without the public records exemption, this state will be unable to effectively and efficiently implement and administer the compact.

(2)(a) The Legislature finds that it is a public necessity that any meeting of the Interstate Medical Licensure Compact Commission held as provided s. 456.4501 in which matters specifically exempted from disclosure by federal or state law are discussed be made exempt from s. 286.011, Florida Statutes, and s. 24(b), Article I of the State Constitution.

(b) The Interstate Medical Licensure Compact requires the closure of any meeting, or any portion of a meeting, of the Interstate Medical Licensure Compact Commission if two-thirds of

the commission members determine that certain sensitive and confidential subject matters may arise during the meeting and that the meeting should be closed to the public. In the absence of a public meeting exemption, this state would be prohibited from becoming a member state of the compact.

(3) The Legislature also finds that it is a public necessity that the recordings, minutes, and records generated during a meeting that is exempt pursuant to s. 456.4503(2), Florida Statutes, be made exempt from s. 119.07(1), Florida Statutes, and s. 24(a), Article I of the State Constitution. Release of such information would negate the public meeting exemption. As such, the Legislature finds that the public records exemption is a public necessity.

Section 3. This act shall take effect on the same date that SB ___ or similar legislation takes effect, if such legislation is adopted in the same legislative session or an extension thereof and becomes a law.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 1676
INTRODUCER:	Senator Albritton
SUBJECT:	Direct Care Workers
DATE:	January 27, 2020
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Pre-meeting**
2.			AHS	
3.			AP	

I. Summary:

SB 1676 expands the scope of practice and defines relevant terms for registered nurses (RNs), certified nursing assistants (CNAs), and home health aides practicing in a nursing home or with a home health agency. The bill authorizes:

- An RN to delegate specific tasks, including medication administration, to CNAs and home health aides if the nursing home or the home health agency authorizes the RN to delegate tasks; and provides grounds for disciplinary action for RNs delegating to unqualified persons;
- A CNA to perform any task delegated to him or her by an RN including the administration of prescription medication, except controlled substances, under specific circumstances;
- A home health aide to perform any task delegated to him or her by an RN including the administration of prescription medications, except controlled substances. under specific circumstances;
- That nonnursing staff providing eating assistance to nursing home residents may count toward nursing home minimum staffing standards;
- An unlicensed person, under certain circumstances, to assist a patient with the self-administration of medication, including intermittent positive pressure breathing treatments and nebulizers;
- The Agency for Health Care Administration (AHCA) to create the Excellence in Home Health Program (Program) for the purpose of awarding designations to home health agencies that meet specified criteria; and
- The AHCA to create the Home Care Services Registry (Registry) for home care workers to voluntarily register and provide specific information for the AHCA to provide to third parties

The bill becomes effective upon becoming a law.

II. Present Situation:

The Agency For Health Care Administration (AHCA)

The AHCA is created in s. 20.42, F.S. The AHCA is the chief health policy and planning entity for the state and its Division of Health Quality Assurance (HQA) is responsible for, among other things, health facility licensure, inspection, and regulatory enforcement. HQA is funded with more than $49 million in state and federal funds. It licenses or certifies and regulates 40 different types of health care providers, including hospitals, nursing homes, assisted living facilities, and home health agencies. In total, the AHCA licenses, certifies, regulates, or provides exemptions for more than 48,000 providers. [1]

Florida Nursing Homes

Nursing homes provide 24-hour-per-day nursing care, case management, health monitoring, personal care, nutritional meals and special diets, physical, occupational, and speech therapy, social activities, and respite care for those who are ill or physically infirm.[2] Nursing care is provided by licensed practical nurses and RNs. Personal care is provided by CNAs and can include help with bathing, dressing, eating, walking, and physical transfer (like moving from a bed to a chair).[3]

A nursing home may also provide services like dietary consultation, laboratory, X-ray, pharmacy services, laundry, and pet therapy visits. Some facilities may provide special services like dialysis, tracheotomy, or ventilator care as well as Alzheimer's or hospice care.

Every nursing home in Florida must comply with all administrative and care standards set out in AHCA rules and must:

- Be under the administrative direction and charge of a licensed administrator;[4]
- Appoint a physician medical director;[5]
- Have available regular, consultative, and emergency services of one or more physicians;
- Provide residents with the use of a community pharmacy of their choice;
- Provide access for residents to dental and other health-related services, recreational services, rehabilitative services, and social work services;

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[1] The Agency for Health Care Administration, *Division of Health Quality Assurance* http://ahca.myflorida.com/MCHQ/index.shtml (last visited Jan. 26, 2020).

[2] The Agency for Health Care Administration, Division of Health Quality Assurance, Long Term Care Service Units, *Nursing Homes, available at* https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Long_Term_Care/Index_LTCU.shtml (last visited Jan. 26, 2020).

[3] Agency for Health Care Administration, FloridaHealthFinder.gov; Consumer Guides, *Nursing Home Care In Florida, available at* https://www.floridahealthfinder.gov/reports-guides/NursingHomesFL.aspx# (Last visited Jan. 24, 2020).

[4] Fla. Adm. Code R. 59A-4.103(4)(b),(2019). The nursing home administrator of each facility must be licensed by the Florida Department of Health, Board of Nursing Home Administrators, under Chapter 468, Part II, F.S., as the Administrator who oversees the day to day administration and operation of the facility. The "Practice of nursing home administration" requiring nursing home administration education, training, or experience and the application of such to the planning, organizing, staffing, directing, and controlling of the total management of a nursing home. Section 468.1655(4), F.S.

[5] Fla. Adm. Code R. 59A-4.1075(2019).

- Be permitted to provide other needed services, including, but not limited to, respite, therapeutic spa, and adult day services to nonresidents of the facility;
- Maintain the facility premises and equipment and conduct its operations in a safe and sanitary manner;
- Provide a wholesome and nourishing diet sufficient to meet generally accepted standards of proper nutrition for its residents and provide such therapeutic diets as may be prescribed by physicians if the nursing home furnishes food services;
- Keep records of:
  - Resident admissions and discharges;
  - Medical and general health status, including:
    - Medical records;
    - Personal and social history;
    - Identity and address of next of kin or other persons who may have responsibility for the affairs of the resident;
    - Individual resident care plans, including, but not limited to:
      - Prescribed services;
      - Service frequency and duration; and
      - Service goals.
- Keep fiscal records of its operations and conditions;
- Furnish copies of personnel records for employees affiliated with such facility, to any other facility licensed by this state requesting this information;
- Display a poster provided by the AHCA containing information for the:
  - State's abuse hotline;
  - State Long-Term Care Ombudsman;
  - AHCA consumer hotline;
  - Florida Statewide Advocacy Council; and
  - Medicaid Fraud Control Unit.
- Comply with state minimum-staffing requirements, as set by AHCA rule, including the number and qualifications of all personnel having responsibility for resident care, such as:
  - Management;
  - Medical;
  - Nursing;
  - Other professional personnel;
  - Nursing assistants;
  - Orderlies; and
  - Other support personnel.
- Ensure that any program for dining and use of a hospitality attendant is developed and implemented under the supervision of the facility director of nursing;
- Maintain general and professional liability insurance coverage or proof of financial responsibility as required by statute;
- Require all CNAs to chart in a resident's medical records, by the end of his or her shift, all services provided, including;
  - Assistance with activities of daily living,
  - Eating,
  - Drinking, and
  - All offers to a resident for nutrition and/or hydration.

- Provide to all consenting residents immunizations against influenza before November 30 each year;
- Assess each resident within five business days after admission for eligibility for pneumococcal vaccination or revaccination; and
- Annually encourage all employees to receive immunizations against influenza viruses.[6]

Nursing Home Staffing Standards

Section 400.23(3), F.S., requires the AHCA to adopt rules providing minimum staffing requirements for nursing home facilities. The requirements must include:

- A minimum weekly average of 3.6 hours of direct care per resident per day provided by a combination of CNAs and licensed nursing staff. A week is defined as Sunday through Saturday.
- A minimum of 2.5 hours of direct care per resident per day provided by CNAs. A facility may not staff at a ratio of less than one CNA per 20 residents.
- A minimum of 1.0 hour of direct care per resident per day provided by licensed nursing staff. A facility may not staff at a ratio of less than one licensed nurse per 40 residents.
- Nursing assistants employed under s. 400.211(2), F.S., may be included in computing the staffing ratio for CNAs if their job responsibilities include only nursing-assistant-related duties.
- Each nursing home facility must document compliance with staffing standards and post daily the names of staff on duty for the benefit of facility residents and the public.
- Licensed nurses may be used to meet staffing requirements for CNAs if the licensed nurses are performing the duties of a CNA and the facility otherwise meets minimum staffing requirements for licensed nurses.
- Non-nursing staff providing eating assistance to residents do not count toward compliance with minimum staffing standards.

Section 400.23(3), F.S., also provides that LPNs who are providing nursing services in nursing home facilities may supervise the activities of other LPNs, CNAs, and other unlicensed personnel providing services in such facilities in accordance with rules adopted by the Board of Nursing (BON).

Nurse Practice Act

Florida's Nurse Practice Act is found in Part I of ch. 464, F.S. The purpose of the Nurse Practice Act is to ensure that every nurse practicing in this state meets minimum requirements for safe practice. It is legislative intent that nurses who fall below minimum competency or who otherwise present a danger to the public are prohibited from practicing in this state.

Registered Nurses

A registered nurse is any person licensed in this state or holding an active multistate license under the Nurse Practice Act to practice professional nursing. The practice of professional nursing means performing acts requiring substantial specialized knowledge, judgment, and

[6] Section 400.141, F.S.

nursing skill based on applied principles of psychological, biological, physical, and social sciences and includes, but is not limited to:

- The observation, assessment, nursing diagnosis, planning, intervention, and evaluation of care; health teaching and counseling of the ill, injured, or infirm; and the promotion of wellness, maintenance of health, and prevention of illness of others.
- The administration of medications and treatments as prescribed or authorized by a duly licensed practitioner authorized by the laws of this state to prescribe such medications and treatments.
- The supervision and teaching of other personnel in the theory and performance of any of the acts described in this subsection.

A professional nurse is responsible and accountable for making decisions that are based upon the individual's educational preparation and experience in nursing.

Licensed Practical Nurses

A licensed practical nurse is any person licensed in this state or holding an active multistate license under the Nurse Practice Act to practice practical nursing. The practice of practical nursing means performing selected acts, including the administration of treatments and medications, in the care of the ill, injured, or infirm; the promotion of wellness, maintenance of health, and prevention of illness of others under the direction of an RN, a licensed physician, a licensed osteopathic physician, a licensed podiatric physician, or a licensed dentist; and the teaching of general principles of health and wellness to the public and to students other than nursing students. A practical nurse is responsible and accountable for making decisions based on the individual's educational preparation and experience in nursing.

Certified Nursing Assistants

Florida's statutory governance for CNAs is found in Part II of ch. 464, F.S. Section 464.201(5), F.S., defines the practice of a CNA as providing care and assisting persons with tasks relating to the activities of daily living. Activities of daily living include tasks associated with: personal care, maintaining mobility, nutrition and hydration, toileting and elimination, assistive devices, safety and cleanliness, data gathering, reporting abnormal signs and symptoms, postmortem care, patient socialization and reality orientation, end-of-life care, cardiopulmonary resuscitation and emergency care, patients' rights, documentation of nursing-assistant services, and other tasks that a CNA may perform after training.[7]

Direct Care Staff

Federal law defines "direct care staff" as those individuals who, through interpersonal contact with nursing home residents or resident care management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Direct care staff does not include individuals whose primary duty is maintaining the physical environment of the long-term care facility (for example, housekeeping).[8]

[7] Section 464.201, F.S.
[8] 42 CFR s. 483.70(q)(1)

Direct care staff are the primary providers of paid, hands-on care for more than 13 million elderly and disabled Americans. They assist individuals with a broad range of support, including preparing meals, helping with medications, bathing, dressing, getting about (mobility), and getting to planned activities on a daily basis.[9]

Direct care staff fall into three main categories tracked by the U.S. Bureau of Labor Statistics: Nursing Assistants (usually known as CNAs), Home Health Aides, and Personal Care Aides:

- CNAs generally work in nursing homes, although some work in assisted living facilities, other community-based settings, or hospitals. They assist residents with activities of daily living (ADLs) such as eating, dressing, bathing, and toileting. They also perform clinical tasks such as range-of motion exercises and blood pressure readings.
- Home Health Aides provide essentially the same care and services as nursing assistants, but they assist people in their homes or in community settings under the supervision of a nurse or therapist. They may also perform light housekeeping tasks such as preparing food or changing linens.
- Personal Care Aides work in either private or group homes. They have many titles, including personal care attendant, home care worker, homemaker, and direct support professional. (The latter work with people with intellectual and developmental disabilities). In addition to providing assistance with ADLs, these aides often help with housekeeping chores, meal preparation, and medication management. They also help individuals go to work and remain engaged in their communities. A growing number of these workers are employed and supervised directly by consumers.[10]

The federal government requires training only for nursing assistants and home health aides who work in Medicare-certified and Medicaid-certified nursing homes and home health agencies. Such training includes training on residents' rights; abuse, neglect, and exploitation; quality assurance; infection control; and compliance and ethics; and specifies that direct care staff must be trained in effective communications.[11]

The Gold Seal Program

The Gold Seal Program is a legislatively created award and recognition program, developed and implemented by the Governor's Panel on Excellence in Long-Term Care (Panel) for nursing facilities that demonstrate excellence in long-term care over a sustained period.[12] Facilities must

[9] Understanding Direct Care Workers: a Snapshot of Two of America's Most Important Jobs, *Certified Nursing Assistants and Home Health Aides*, Khatutsky, et al., (March 2011), *available at* https://aspe.hhs.gov/basic-report/understanding-direct-care-workers-snapshot-two-americas-most-important-jobs-certified-nursing-assistants-and-home-health-aides#intro (last visited on Jan. 27, 2020).

[10] See *Who are Direct Care Workers?* available at https://phinational.org/wp-content/uploads/legacy/clearinghouse/NCDCW%20Fact%20Sheet-1.pdf (last visited Jan. 27, 2020)

[11] 42 CFR s. 483.95

[12] Section 400.235, F.S. The panel is composed of three persons appointed by the Governor, to include a consumer advocate for senior citizens and two persons with expertise in the fields of quality management, service delivery excellence, or public sector accountability; three persons appointed by the Secretary of Elderly Affairs, to include an active member of a nursing facility family and resident care council and a member of the University Consortium on Aging; a representative of the State Long-Term Care Ombudsman Program; one person appointed by the Florida Life Care Residents Association; one person appointed by the State Surgeon General; two persons appointed by the Secretary of Health Care Administration; one person

meet the Panel's criteria for measuring quality of care and the following additional criteria to receive a Gold Seal Program designation:

- No class I or class II deficiencies within the 30 preceding months;
- Evidence of financial soundness and stability including, among other things, the use of financial statements;
- Participation in a consumer satisfaction process and evidence of the facility's efforts to act on the information gathered;
- Evidence of the involvement of families and members of the community in the facility on a regular basis;
- A stable workforce as evidenced by a relatively low turnover rate among CNAs and RNs within the 30 preceding months;
- Evidence that any complaints submitted to the State Long-Term Care Ombudsman Program within the preceding 30 months did not result in a licensure citation; and
- Evidence of targeted in-service training programs to meet staff training needs identified by internal or external quality assurance efforts.

Home Health Agencies and Home Health Aides

Home health agencies deliver health and medical services and medical supplies through visits to private homes, assisted living facilities (ALFs), and adult family care homes. Some of the services include nursing care, physical therapy, occupational therapy, respiratory therapy, speech therapy, home health aide services, and nutritional guidance. Medical supplies are restricted to drugs and biologicals prescribed by a physician. Along with services in the home, an agency can also provide staffing services in nursing homes and hospitals. Home health agencies differ in the quality of care and services they provide to patients. Home health agencies are required to be licensed and inspected by the state of Florida.[13]

The Home Health Consumer Assessment of Healthcare Providers & Systems (HHCAHPS) star ratings provide a snapshot of the four measures of patient experience of care. In addition, the HHCAHPS summary star rating combines all four HHCAHPS star ratings into a single, comprehensive metric. If a home health agency doesn't have an HHCAHPS summary star rating, it means that the home health agency did not have enough surveys to have star ratings calculated in a meaningful way. In addition to the patient survey results, the HHCAHPS star ratings summarize patient experience, which is one aspect of home health agency quality.[14]

Section 400.462(15), F.S., defines a "home health aide" as a person who is trained or qualified, as provided by AHCA rule, to:

- Provide hands-on personal care,
- Perform simple procedures as an extension of therapy or nursing services,
- Assist in ambulation or exercises, and

appointed by the Florida Association of Homes for the Aging; and one person appointed by the Florida Health Care Association. Vacancies on the panel shall be filled in the same manner as the original appointments.

[13] Agency for Health Care Administration, FloridaHealthFinder.gov, Alternative to Nursing Homes, *Home Health Agencies*, *available at* https://www.floridahealthfinder.gov/reports-guides/NursingHomesFL.aspx#NHStay (last visited Jan. 26, 2020).

[14] U.S. Centers for Medicare & Medicaid Services, Medicare.gov, Home Health Compare, *Patient Survey Star Ratings available at https://www*.medicare.gov/homehealthcompare/About/Patient-Survey-Star-Ratings.html (last visited Jan. 26, 2020).

- Assist in administering medications for which the person has received training established by the AHCA.

Assistance with Administering Medications

According to Rule 59A-18.0081, F.A.C., a CNA or home health aide referred by a nurse registry may assist with self-administration of medication if they have received a minimum of two hours of training covering the following content:

- State law and rule requirements with respect to the assistance with self-administration of medications in the home;
- Procedures for assisting the resident with self-administration of medication;
- Common types of medication;
- Recognition of side effects and adverse reactions; and
- Procedures to follow when patients appear to be experiencing side effects and adverse reactions.

The training must include verification that, for prescription medications, each CNA and home health aide can read the prescription label and any instructions for the prescription. The rule provides that individuals who cannot read are not allowed to assist with prescription medications.

III. Effect of Proposed Changes:

Section 1 amends s. 400.141, F.S., to require that if a licensed a nursing home authorizes an RN to delegate tasks, including medication administration, to a CNA, the nursing home must ensure that the CNA meets the requirements of ch. 464, F.S., and applicable rules.

Section 2 creates s. 400.212, F.S., to provide that a CNA may perform any task delegated to him or her by an RN as authorized in ch. 464, F.S., including, but not limited to, medication administration.

Section 3 amends s. 400.23, F.S., to provide that nonnursing staff providing eating assistance to nursing home residents may count toward compliance with the nursing home's minimum staffing standards, as opposed to current law which provides that such assistance cannot be counted toward compliance.

Section 4 amends s. 400.462, F.S., to redefine "home health aide" to provide that a person who performs tasks delegated to him or her pursuant to ch. 464, F.S., may qualify as a home health aide.

Section 5 amends s. 400.464, F.S., to provide that if a home health agency authorizes an RN to delegate tasks, including medication administration, to a CNA pursuant to ch. 464, F.S., or to a home health aide pursuant to s. 400.490, F.S., the home health agency must ensure that such delegation meets the requirements of chs. 400 and 464, F.S., and applicable rules adopted under those chapters.

Section 6 amends s. 400.488, F.S., relating to provisions under which an unlicensed person may assist a patient with the self-administration of medication under certain circumstances, to provide

that such medications include intermittent positive pressure breathing treatments and nebulizer treatments. The bill also provides that assistance with self-administered medication includes:

- In the presence of the patient, confirming that the medication is intended for that patient and orally advising the patient of the medication's name and purpose;
- When applying topical medications, the provision of routine preventative skin care and basic wound care; and
- For intermittent positive pressure breathing treatments or for nebulizer treatments, assisting with setting up and cleaning the device in the presence of the patient, confirming that the medication is intended for that patient, orally advising the patient of the medication's name and purpose, opening the container, removing the prescribed amount for a single treatment dose from a properly labeled container, and assisting the patient with placing the dose into the medicine receptacle or mouthpiece.

Section 7 creates s. 400.489, F.S., relating to administration of medication by a home health aide. The bill provides that a home health aide may administer oral, transdermal, ophthalmic, otic, rectal, inhaled, enteral, or topical prescription medications if the home health aide:

- Has been delegated such task by an RN licensed under ch. 464, F.S.;
- Has satisfactorily completed an initial six-hour training course approved by the AHCA; and
- Has been found competent to administer medication to a patient in a safe and sanitary manner.

The bill requires a home health aide to annually and satisfactorily complete a two-hour inservice training course in medication administration and medication error prevention approved by the AHCA. This inservice training course must be in addition to the annual inservice training hours required by AHCA rules under current law.

The bill requires the AHCA, in consultation with the BON, to establish by rule standards and procedures that a home health aide must follow when administering medication to a patient. Such rules must, at a minimum, address qualification requirements for trainers, requirements for labeling medication, documentation and recordkeeping, the storage and disposal of medication, instructions concerning the safe administration of medication, informed-consent requirements and records, and training curriculum and validation procedures.

The training, determination of competency, and initial and annual validations required under this new section of statute must be conducted by an RN or a physician licensed under chs. 458 or 459, F.S.

Section 8 creates s. 400.490, F.S., to authorize a CNA or home health aide to perform any task delegated by an RN as authorized under ch. 464, F.S., including, but not limited to, medication authorization.

Section 9 creates s. 400.52, F.S., to establish the Excellence in Home Health Program (Program) for the purpose of awarding designations to home health agencies that meet specified criteria.

The AHCA is directed to adopt rules establishing criteria for the Program which must include, at a minimum, meeting standards relating to:

- Patient satisfaction.
- Patients requiring emergency care for wound infections.
- Patients admitted or readmitted to an acute care hospital.
- Patient improvement in the activities of daily living.
- Employee satisfaction.
- Quality of employee training.
- Employee retention rates.

The AHCA is directed to annually evaluate home health agencies seeking Program designation. To receive Program designation, a home health agency must:

- Apply on a form and in the manner designated by AHCA rule.
- Be actively licensed and have been operating for at least 24 months before applying for Program designation.
- Have not had any licensure denials, revocations, or Class I, Class II, or uncorrected Class III deficiencies within the 24 months before the application for Program designation.

A designation awarded under the Program is not transferrable to another licensee, unless the existing home health agency is being relicensed in the name of an entity related to the current license-holder by common control or ownership, and there will be no change in the management, operation, or programs of the home health agency as a result of the relicensure.

Program designation expires on the same date as the home health agency's license. A home health agency must reapply and be approved for Program designation to continue using Program designation in advertising and marketing. A home health agency may not use Program designation in any advertising or marketing if the home health agency:

- Has not been awarded the designation;
- Fails to renew the designation upon expiration of the awarded designation;
- Has undergone a change in ownership that does not qualify for a transfer of the designation as described above; or
- Has been notified that it no longer meets the criteria for the award upon reapplication after expiration of the awarded designation.

Section 10 creates s. 408.064, F.S., to establish a Home Care Services Registry (Registry). For purposes of the Registry, the bill defines a "home care services provider" as a home health agency licensed under part III, of ch. 400, F.S., or a nurse registry licensed under part III, of ch. 400, F.S.; and a "home care worker" as a home health aide[15] or a CNA[16] certified under part II of ch. 464, F.S.

The bill requires the AHCA to develop and maintain a voluntary Registry of home care workers, display a link to the Registry on its website homepage, and develop rules to implement the Registry. Home care workers must submit an AHCA application to be included in the Registry and the AHCA must develop a process by which home care service providers may include the required information for their employees. The Registry must include, at a minimum:

[15] Section 400.462, F.S.
[16] Section 464,203, F.S.

- The home care worker's full name, date of birth, social security number, and a full-face, passport-type, color photograph of the home care worker;
- The home care worker's contact information, including, but not limited to, his or her address and contact phone number;
- Other information of the home care worker, as determined by the AHCA;
- The name of the state-approved training program completed by the home care worker and the date on which such training was completed;
- The number of years the home care worker has provided home health care services for compensation, and the AHCA may automatically populate employment history as provided by current and previous employers with a method for a home care worker to correct inaccuracies and supplement the information;
- For CNAs, any disciplinary action taken or pending against the CNA's certification, and the AHCA may enter into an agreement with the DOH to obtain disciplinary history;
- Whether the home care worker provides services to special populations and, if so, the special populations served; and
- For home health workers not employed by home care service providers, the results of a background screening satisfying the requirements of s. 408.809, F.S., and ch. 435. F.S., and the completion of the training requirements of part III of ch. 400, F.S., or part II of ch. 464, F.S., as applicable.

Each page of the Registry website must contain the following notice in at least 14-point boldfaced type:

NOTICE

The Home Care Services Registry provides limited information about home care workers. Information contained in the registry is provided by third parties. The Agency for Health Care Administration does not guarantee the accuracy of such third-party information and does not endorse any individual listed in the registry. In particular, the information in the registry may be outdated or the individuals listed in the registry may have lapsed certifications or may have been denied employment approval due to the results of a background screening. It is the responsibility of those accessing this registry to verify the credentials, suitability, and competency of any individual listed in the registry.

Section 11 creates s. 408.822, F.S., to establish an AHCA direct care workforce survey (Survey). The bill defines the term "direct care worker" for purposes of the Survey to means a:

- CNA;
- Home health aide;
- Personal care assistant;
- Companion services;
- Homemaker services provider; or
- Provider of personal care as defined in s. 400.462(24), F.S., to individuals who are elderly, developmentally disabled, or chronically ill.

Beginning January 1, 2021, nursing home facilities, assisted living facilities, home health agencies, a nurse registry, companion services providers, and homemaker services providers applying for licensure renewal, must furnish the following information to the AHCA before the license will be renewed:

- The number of direct care workers employed;
- The turnover and vacancy rates of direct care workers and contributing factors to these rates;
- The average employee wage for each category of direct care worker;
- The employment benefits provided for direct care workers and the average cost of such benefits to the employer and the employee; and
- The type and availability of training for direct care workers.

An administrator or designee must attest that the information provided in the Survey is true and accurate to the best of his or her knowledge; and the AHCA must continually analyze the results of the Surveys and publish the results on its website. The AHCA must update the information published on its website monthly.

Section 12 creates s. 464.0156, F.S., to expand the scope of practice of CNAs and home health aides to include authorized tasks delegated by an RN. The bill authorizes the BON, in consultation with the AHCA, to adopt rules to implement this change.

Section 464.0156, F.S., provides parameters for when a registered nurse (RN) may delegate tasks to a CNA or a home health aide.[17] If an RN determines that a CNA or home health aide is competent to perform a task, and the task is delegable under federal law, he or she may delegate a task that:

- Is within the nurse's scope of practice.
- Frequently recurs in the routine care of a patient or group of patients.
- Is performed according to an established sequence of steps.
- Involves little or no modification from one patient to another.
- May be performed with a predictable outcome.
- Does not inherently involve ongoing assessment, interpretation, or clinical judgment.
- Does not endanger a patient's life or well-being.

If a CNA or home health aide satisfies the requirements of the bill's newly created ss. 464.2035 or 400.489, F.S., an RN may also delegate to a CNA or home health aide the administration prescription medications, except controlled substances,[18] to residents of nursing homes or home health agency patients by the following routes:

- Oral;
- Transdermal;[19]
- Ophthalmic;
- Otic;
- Rectal;
- Inhaled;

[17] Section 400,462, F.S.
[18] Controlled substance listed in Schedule II, Schedule III, or Schedule IV of s. 893.03 or 21 U.S.C. s. 812.
[19] *See* The Farlex Medical Dictionary, Transdermal, available at https://medical-dictionary.thefreedictionary.com/Transdermal (last visited Jan. 27, 2020). Transdermal means entering through the dermis, or skin, as in administration of a drug applied to the skin in ointment or patch form.

- Enteral,[20] or
- Topical.

Section 13 amends s. 464.018, F.S., relating to grounds for denial or disciplinary action under the Nurse Practice Act, to add an additional ground for nursing disciplinary action. The additional ground would be to delegate professional responsibilities to a person when the nurse delegating such responsibilities knows or has reason to know that such person is not qualified by training, experience, certification, or licensure to perform them.

Section 14 creates s. 464.2035, F.S., to expand the scope of practice of CNAs to include the administration of medications to residents of nursing homes or home health agency patients. A CNA may administration medications via specified routes to residents of nursing homes or home health agency patients if the CNA has initially completed:

- A BON-approved six-hour training course;
- Has been found competent to administer medication to a resident or patient in a safe and sanitary manner; and
- If the medication administration has been delegated to the CNA by an RN.

The CNA must annually complete a BON- and AHCA-approved two-hour inservice training in medication administration and medication error prevention. The inservice training is in addition to the other annual inservice training hours required for renewal of the CNA's certificate. The training, determination of competency, and initial and annual validations required by the bill must be conducted by an RN or physician.

The routes of medication administration that an RN may delegate to a CNA to nursing home residents or home health patients specified in the bill include:

- Oral;
- Transdermal;[21]
- Ophthalmic;
- Otic;
- Rectal;
- Inhaled;
- Enteral,[22] or
- Topical.

[20] *See* The Farlex Medical Dictionary, *Enteral, available at* https://medical-dictionary.thefreedictionary.com/enteral (last visited Jan. 27, 2020). Enteral means within, or by way of, the intestine or gastrointestinal tract, especially as distinguished from parenteral.
[21] *See* The Farlex Medical Dictionary, Transdermal, *available at* https://medical-dictionary.thefreedictionary.com/Transdermal (last visited Jan. 27, 2020). Transdermal means entering through the dermis, or skin, as in administration of a drug applied to the skin in ointment or patch form.
[22] *See* The Farlex Medical Dictionary, *Enteral, available at* https://medical-dictionary.thefreedictionary.com/enteral (last visited Jan. 27, 2020). Enteral means within, or by way of, the intestine or gastrointestinal tract, especially as distinguished from parenteral.

The bill requires the BON, in consultation with the AHCA, to establish rules covering, at a minimum:

- The standards and procedures a CNA must follow when administering medication to a nursing home resident or home health agency patient;
- The qualifications required for trainers;
- Medication labeling requirements;
- Medication documentation and recordkeeping;
- Medication storage and disposal;
- Safe medication administration instruction requirements;
- Medication informed-consent requirements and records;
- The medication administration training curriculum for CNAs specific to residents of nursing homes or home health agency patients; and
- CNA medication administration validation procedures.

Section 15 provides that the bill takes effect 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:

None.

C. Government Sector Impact:

The AHCA has not provided an estimate of the fiscal impact of the bill's requirement for the AHCA to establish the Excellence in Home Health Program and the Home Care Services Registry. Each program is likely to have a recurring negative fiscal impact on the AHCA.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill does not provide any mechanism for the AHCA or the DOH to track, regulate, or license or certify CNAs or home health aides who have, or do not have, the additional training and competency to administer medications to nursing home residents or home health agency patients.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 400.141, 400.23, 400.462, 4000464, 400.488, and 464.018.

This bill creates the following sections of the Florida Statutes: 400.212, 400.489, 400.490, 400.52, 408.064, 408.822, 464.0156, and 464.2035.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Albritton

26-01666-20 20201676__

A bill to be entitled

An act relating to direct care workers; amending s. 400.141, F.S.; requiring a nursing home facility that authorizes a registered nurse to delegate tasks to a certified nursing assistant to ensure that certain requirements are met; creating s. 400.212, F.S.; authorizing a certified nursing assistant to perform tasks delegated by a registered nurse; amending s. 400.23, F.S.; authorizing certain nonnursing staff to count toward compliance with staffing standards; amending s. 400.462, F.S.; revising the definition of the term "home health aide"; amending s. 400.464, F.S.; requiring a licensed home health agency that authorizes a registered nurse to delegate tasks to a certified nursing assistant to ensure that certain requirements are met; amending s. 400.488, F.S.; authorizing an unlicensed person to assist with self-administration of certain treatments; revising the requirements for such assistance; creating s. 400.489, F.S.; authorizing a home health aide to administer certain prescription medications under certain conditions; requiring the home health aide to meet certain training and competency requirements; requiring the training, determination of competency, and annual validations of home health aides to be conducted by a registered nurse or a physician; requiring a home health aide to complete annual inservice training in medication administration and medication error prevention, in addition to existing

annual inservice training requirements; requiring the Agency for Health Care Administration, in consultation with the Board of Nursing, to adopt rules for medication administration by home health aides; creating s. 400.490, F.S.; authorizing a certified nursing assistant or home health aide to perform tasks delegated by a registered nurse; creating s. 400.52, F.S.; creating the Excellence in Home Health Program within the agency; requiring the agency to adopt rules establishing program criteria; requiring the agency to annually evaluate certain home health agencies that apply for a program designation; providing program designation eligibility requirements; providing that a program designation is not transferrable, with an exception; providing for the expiration of awarded designations; requiring home health agencies to reapply biennially to renew the awarded program designation; authorizing a program designation award recipient to use the designation in advertising and marketing; prohibiting a home health agency from using a program designation in any advertising or marketing, under certain circumstances; creating s. 408.064, F.S.; defining the terms "home care services provider" and " home care worker"; requiring the agency to develop and maintain a voluntary registry of home care workers; requiring the agency to display a link to the registry on its website homepage; providing requirements for the registry; requiring a home care worker to apply to the agency to be included in the

registry; requiring the agency to develop a process by which a home care services provider may include its employees on the registry; requiring certain home care workers to undergo background screening and training; requiring each page of the registry website to contain a specified notice; requiring the agency to adopt rules; creating s. 408.822, F.S.; defining the term "direct care worker"; requiring certain licensees to provide specified information about their employees in a survey beginning on a specified date; requiring that the survey be completed on a form with a specified attestation adopted by the agency by rule; requiring licensees to submit such survey before the agency renews their licenses; requiring the agency to continually analyze the results of such surveys and publish their results on the agency's website; requiring the agency to update such information monthly; creating s. 464.0156, F.S.; authorizing a registered nurse to delegate certain tasks to a certified nursing assistant or home health aide under certain conditions; providing the criteria that a registered nurse must consider in determining if a task may be delegated; authorizing a registered nurse to delegate medication administration to a certified nursing assistant or home health aide, subject to certain requirements; providing an exception for certain controlled substances; requiring the Board of Nursing, in consultation with the agency, to adopt rules; amending s. 464.018, F.S.; subjecting a

registered nurse to disciplinary action for delegating certain tasks to a person who the registered nurse knows or has reason to know is unqualified to perform such tasks; creating s. 464.2035, F.S.; authorizing certified nursing assistants to administer certain prescription medications under certain conditions; requiring the certified nursing assistants to meet certain training and competency requirements; requiring the training, determination of competency, and annual validations of certified nursing assistants to be conducted by a registered nurse or a physician; requiring a certified nursing assistant to complete annual inservice training in medication administration and medication error prevention in addition to existing annual inservice training requirements; requiring the board, in consultation with the agency, to adopt rules for medication administration by certified nursing assistants; providing an effective date.

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

Section 1. Paragraph (v) is added to subsection (1) of section 400.141, Florida Statutes, to read:

400.141 Administration and management of nursing home facilities.—

(1) Every licensed facility shall comply with all applicable standards and rules of the agency and shall:

(v) Ensure that a certified nursing assistant meets the

requirements of chapter 464 and the rules adopted thereunder, if the facility authorizes a registered nurse to delegate tasks, including medication administration, to the certified nursing assistant.

Section 2. Section 400.212, Florida Statutes, is created to read:

400.212 Nurse-delegated tasks.—A certified nursing assistant may perform any task delegated to him or her by a registered nurse as authorized in chapter 464, including, but not limited to, medication administration.

Section 3. Paragraph (b) of subsection (3) of section 400.23, Florida Statutes, is amended to read:

400.23 Rules; evaluation and deficiencies; licensure status.—

(3)

(b) Nonnursing staff providing eating assistance to residents may ~~shall not~~ count toward compliance with minimum staffing standards.

Section 4. Subsection (15) of section 400.462, Florida Statutes, is amended to read:

400.462 Definitions.—As used in this part, the term:

(15) "Home health aide" means a person who is trained or qualified, as provided by rule, and who provides hands-on personal care, performs simple procedures as an extension of therapy or nursing services, assists in ambulation or exercises, or assists in administering medications as permitted in rule and for which the person has received training established by the agency under this part or a person who performs tasks delegated to him or her pursuant to chapter 464 ~~s. 400.497(1)~~.

Section 5. Present subsections (5) and (6) of section 400.464, Florida Statutes, are redesignated as subsections (6) and (7), respectively, a new subsection (5) is added to that section, and present subsection (6) of that section is amended, to read:

400.464 Home health agencies to be licensed; expiration of license; exemptions; unlawful acts; penalties.—

(5) If a licensed home health agency authorizes a registered nurse to delegate tasks, including medication administration, to a certified nursing assistant pursuant to chapter 464 or to a home health aide pursuant to s. 400.490, the licensed home health agency must ensure that such delegation meets the requirements of this chapter and chapter 464, and the rules adopted thereunder.

(7) ~~(6)~~ Any person, entity, or organization providing home health services which is exempt from licensure under subsection (6) ~~subsection (5)~~ may voluntarily apply for a certificate of exemption from licensure under its exempt status with the agency on a form that specifies its name or names and addresses, a statement of the reasons why it is exempt from licensure as a home health agency, and other information deemed necessary by the agency. A certificate of exemption is valid for a period of not more than 2 years and is not transferable. The agency may charge an applicant $100 for a certificate of exemption or charge the actual cost of processing the certificate.

Section 6. Subsections (2) and (3) of section 400.488, Florida Statutes, are amended to read:

400.488 Assistance with self-administration of medication.—

(2) Patients who are capable of self-administering their

own medications without assistance shall be encouraged and allowed to do so. However, an unlicensed person may, consistent with a dispensed prescription's label or the package directions of an over-the-counter medication, assist a patient whose condition is medically stable with the self-administration of routine, regularly scheduled medications that are intended to be self-administered. Assistance with self-medication by an unlicensed person may occur only upon a documented request by, and the written informed consent of, a patient or the patient's surrogate, guardian, or attorney in fact. For purposes of this section, self-administered medications include both legend and over-the-counter oral dosage forms, topical dosage forms, and topical ophthalmic, otic, and nasal dosage forms, including solutions, suspensions, sprays, ~~and~~ inhalers, intermittent positive pressure breathing treatments, and nebulizer treatments.

(3) Assistance with self-administration of medication includes:

(a) Taking the medication, in its previously dispensed, properly labeled container, from where it is stored and bringing it to the patient.

(b) In the presence of the patient, confirming that the medication is intended for that patient, orally advising the patient of the medication name and purpose ~~reading the label~~, opening the container, removing a prescribed amount of medication from the container, and closing the container.

(c) Placing an oral dosage in the patient's hand or placing the dosage in another container and helping the patient by lifting the container to his or her mouth.

(d) Applying topical medications, including providing routine preventative skin care and basic wound care.

(e) Returning the medication container to proper storage.

(f) For intermittent positive pressure breathing treatments or for nebulizer treatments, assisting with setting up and cleaning the device in the presence of the patient, confirming that the medication is intended for that patient, orally advising the patient of the medication name and purpose, opening the container, removing the prescribed amount for a single treatment dose from a properly labeled container, and assisting the patient with placing the dose into the medicine receptacle or mouthpiece.

(g) ~~(f)~~ Keeping a record of when a patient receives assistance with self-administration under this section.

Section 7. Section 400.489, Florida Statutes, is created to read:

400.489 Administration of medication by a home health aide; staff training requirements.—

(1) A home health aide may administer oral, transdermal, ophthalmic, otic, rectal, inhaled, enteral, or topical prescription medications if the home health aide has been delegated such task by a registered nurse licensed under chapter 464; has satisfactorily completed an initial 6-hour training course approved by the agency; and has been found competent to administer medication to a patient in a safe and sanitary manner. The training, determination of competency, and initial and annual validations required in this section shall be conducted by a registered nurse licensed under chapter 464 or a physician licensed under chapter 458 or chapter 459.

(2) A home health aide must annually and satisfactorily complete a 2-hour inservice training course in medication administration and medication error prevention approved by the agency. The inservice training course shall be in addition to the annual inservice training hours required by agency rules.

(3) The agency, in consultation with the Board of Nursing, shall establish by rule standards and procedures that a home health aide must follow when administering medication to a patient. Such rules must, at a minimum, address qualification requirements for trainers, requirements for labeling medication, documentation and recordkeeping, the storage and disposal of medication, instructions concerning the safe administration of medication, informed-consent requirements and records, and the training curriculum and validation procedures.

Section 8. Section 400.490, Florida Statutes, is created to read:

400.490 Nurse-delegated tasks.—A certified nursing assistant or home health aide may perform any task delegated by a registered nurse as authorized in chapter 464, including, but not limited to, medication administration.

Section 9. Section 400.52, Florida Statutes, is created to read:

400.52 Excellence in Home Health Program.—

(1) There is created within the agency the Excellence in Home Health Program for the purpose of awarding program designations to home health agencies that meet the criteria specified in this section.

(2)(a) The agency shall adopt rules establishing criteria for the program which must include, at a minimum, meeting

standards relating to:

1. Patient satisfaction.

2. Patients requiring emergency care for wound infections.

3. Patients admitted or readmitted to an acute care hospital.

4. Patient improvement in the activities of daily living.

5. Employee satisfaction.

6. Quality of employee training.

7. Employee retention rates.

(b) The agency shall annually evaluate home health agencies seeking the program designation which apply on a form and in the manner designated by rule.

(3) To receive a program designation, the home health agency must:

(a) Be actively licensed and have been operating for at least 24 months before applying for the program designation. A designation awarded under the program is not transferrable to another licensee, unless the existing home health agency is being relicensed in the name of an entity related to the current licenseholder by common control or ownership, and there will be no change in the management, operation, or programs of the home health agency as a result of the relicensure.

(b) Have not had any licensure denials, revocations, or Class I, Class II, or uncorrected Class III deficiencies within the 24 months before the application for the program designation.

(4) The program designation expires on the same date as the home health agency's license. A home health agency must reapply and be approved for the program designation to continue using

the program designation in the manner authorized under subsection (5).

(5) A home health agency that is awarded a designation under the program may use the designation in advertising and marketing. A home health agency may not use the program designation in any advertising or marketing if the home health agency:

(a) Has not been awarded the designation;

(b) Fails to renew the designation upon expiration of the awarded designation;

(c) Has undergone a change in ownership that does not qualify for an exception under paragraph (3)(a); or

(d) Has been notified that it no longer meets the criteria for the award upon reapplication after expiration of the awarded designation.

Section 10. Section 408.064, Florida Statutes, is created to read:

408.064 Home Care Services Registry.—

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

(a) "Home care services provider" means a home health agency licensed under part III of chapter 400 or a nurse registry licensed under part III of chapter 400.

(b) "Home care worker" means a home health aide as defined in s. 400.462 or a certified nursing assistant certified under part II of chapter 464.

(2) The agency shall develop and maintain a voluntary registry of home care workers. The agency shall display a link to the registry on its website homepage.

(3) The registry must include, at a minimum:

(a) Each home care worker's full name, date of birth, social security number, and a fullface, passport-type, color photograph of the home care worker. The home care worker's date of birth and social security number may not be publicly displayed on the website.

(b) Each home care worker's contact information, including, but not limited to, his or her address and phone number. If employed by a home care services provider, the home care worker may use the provider's contact information.

(c) Any other identifying information of the home care worker, as determined by the agency.

(d) The name of the state-approved training program successfully completed by the home care worker and the date on which such training was completed.

(e) The number of years the home care worker has provided home health care services for compensation. The agency may automatically populate employment history as provided by current and previous employers of the home care worker. The agency shall provide a method for a home care worker to correct inaccuracies and supplement the automatically populated employment history.

(f) For a certified nursing assistant, any disciplinary action taken or pending against the nursing assistant's certification by the Department of Health. The agency may enter into an agreement with the Department of Health to obtain disciplinary history.

(g) Whether the home care worker provides services to special populations and, if so, the special populations served.

(4) A home care worker must submit an application on a form adopted by the agency to be included in the registry. The agency

shall develop a process by which a home care services provider may include its employees in the registry by providing the information specified in subsection (3).

(5) A home care worker who is not employed by a home care services provider must meet the background screening requirements under s. 408.809 and chapter 435 and the training requirements of part III of chapter 400 or part II of chapter 464, as applicable, the results of which must be included in the registry.

(6) Each page of the registry website must contain the following notice in at least 14-point boldfaced type:

NOTICE

The Home Care Services Registry provides limited information about home care workers. Information contained in the registry is provided by third parties. The Agency for Health Care Administration does not guarantee the accuracy of such third-party information and does not endorse any individual listed in the registry. In particular, the information in the registry may be outdated or the individuals listed in the registry may have lapsed certifications or may have been denied employment approval due to the results of a background screening. It is the responsibility of those accessing this registry to verify the credentials, suitability, and competency of any individual listed in the registry.

(7) The agency shall adopt rules necessary to implement the requirements of this section.

Section 11. Section 408.822, Florida Statutes, is created to read:

408.822 Direct care workforce survey.—

(1) For purposes of this section, the term "direct care worker" means a certified nursing assistant, a home health aide, a personal care assistant, a companion services or homemaker services provider, or another individual who provides personal care as defined in s. 400.462 to individuals who are elderly, developmentally disabled, or chronically ill.

(2) Beginning January 1, 2021, each licensee that applies for licensure renewal as a nursing home facility licensed under part II of chapter 400; an assisted living facility licensed under part I of chapter 429; or a home health agency, nurse registry, or companion services or homemaker services provider licensed under part III of chapter 400 shall furnish the following information to the agency in a survey on the direct care workforce:

(a) The number of direct care workers employed by the licensee.

(b) The turnover and vacancy rates of direct care workers and contributing factors to these rates.

(c) The average employee wage for each category of direct care worker.

(d) Employment benefits for direct care workers and the average cost of such benefits to the employer and the employee.

(e) Type and availability of training for direct care workers.

(3) An administrator or designee shall include the information required in subsection (2) on a survey form developed by the agency by rule which must contain an attestation that the information provided is true and accurate to the best of his or her knowledge.

(4) The licensee must submit the completed survey prior to the agency issuing the license renewal.

(5) The agency shall continually analyze the results of the surveys and publish the results on its website. The agency shall update the information published on its website monthly.

Section 12. Section 464.0156, Florida Statutes, is created to read:

464.0156 Delegation of duties.—

(1) A registered nurse may delegate a task to a certified nursing assistant certified under part II of this chapter or a home health aide as defined in s. 400.462, if the registered nurse determines that the certified nursing assistant or the home health aide is competent to perform the task, the task is delegable under federal law, and the task:

(a) Is within the nurse’s scope of practice.

(b) Frequently recurs in the routine care of a patient or group of patients.

(c) Is performed according to an established sequence of steps.

(d) Involves little or no modification from one patient to another.

(e) May be performed with a predictable outcome.

(f) Does not inherently involve ongoing assessment, interpretation, or clinical judgment.

(g) Does not endanger a patient's life or well-being.

(2) A registered nurse may delegate to a certified nursing assistant or a home health aide the administration of oral, transdermal, ophthalmic, otic, rectal, inhaled, enteral, or topical prescription medications, if the certified nursing assistant or home health aide meets the requirements of s. 464.2035 or s. 400.489, respectively. A registered nurse may not delegate the administration of any controlled substance listed in Schedule II, Schedule III, or Schedule IV of s. 893.03 or 21 U.S.C. s. 812.

(3) The board, in consultation with the Agency for Health Care Administration, may adopt rules to implement this section.

Section 13. Paragraph (r) is added to subsection (1) of section 464.018, Florida Statutes, to read:

464.018 Disciplinary actions.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in ss. 456.072(2) and 464.0095:

(r) Delegating professional responsibilities to a person when the nurse delegating such responsibilities knows or has reason to know that such person is not qualified by training, experience, certification, or licensure to perform them.

Section 14. Section 464.2035, Florida Statutes, is created to read:

464.2035 Administration of medication.—

(1) A certified nursing assistant may administer oral, transdermal, ophthalmic, otic, rectal, inhaled, enteral, or topical prescription medication to a resident of a nursing home or a patient of a home health agency if the certified nursing

assistant has been delegated such task by a registered nurse licensed under part I of this chapter, has satisfactorily completed an initial 6-hour training course approved by the board, and has been found competent to administer medication to a resident or patient in a safe and sanitary manner. The training, determination of competency, and initial and annual validations required under this section must be conducted by a registered nurse licensed under this chapter or a physician licensed under chapter 458 or chapter 459.

(2) A certified nursing assistant shall annually and satisfactorily complete 2 hours of inservice training in medication administration and medication error prevention approved by the board, in consultation with the Agency for Health Care Administration. The inservice training is in addition to the other annual inservice training hours required under this part.

(3) The board, in consultation with the Agency for Health Care Administration, shall establish by rule standards and procedures that a certified nursing assistant must follow when administering medication to a resident or patient. Such rules must, at a minimum, address qualification requirements for trainers, requirements for labeling medication, documentation and recordkeeping, the storage and disposal of medication, instructions concerning the safe administration of medication, informed-consent requirements and records, and the training curriculum and validation procedures.

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

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 1344
INTRODUCER:	Senator Harrell
SUBJECT:	Intermediate Care Facilities
DATE:	January 27, 2020
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Favorable**
2.			AHS	
3.			AP	

I. Summary:

SB 1344 establishes a new certificate of need (CON) exemption for an intermediate care facility for the developmentally disabled (ICFDD) for use by individuals exhibiting severe maladaptive behaviors and co-occurring psychiatric diagnoses requiring increased levels of behavioral, medical, and therapeutic oversight. The bill specifies requirements that the ICFDD must meet in order to obtain the CON exemption and establishes additional licensure criteria for an ICFDD that has been granted the CON exemption.

The bill has an effective date of July 1, 2020.

II. Present Situation:

Intermediate Care Facilities for the Developmentally Disabled

An intermediate care facility for the developmentally disabled (ICFDD) provides care and residence for individuals with developmental disabilities. A developmental disability is a disorder or syndrome that is attributable to intellectual disability, cerebral palsy, autism, spina bifida, Down syndrome, Phelan-McDermid syndrome, or Prader-Willi syndrome; that manifests before the age of 18; and that constitutes a substantial handicap that can reasonably be expected to continue indefinitely.[1]

The licensure of ICFDDs is controlled by Part VIII of ch. 400, F.S., and Chapter 59A-26, F.A.C. Additionally, as a health care facility, as defined in s. 408.032, F.S., prior to obtaining licensure, the applicant must obtain a CON from the Agency for Health Care Administration (AHCA).

[1] *See* s. 393.063(12), F.S.

CON 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, expedited, and exempt.[2] 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.[3] 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.

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,"[4] 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,[5] adult and child psychiatric services,[6] adult substance abuse services,[7] and comprehensive rehabilitation services.[8]

Upon determining that a need exists, the AHCA accepts applications for CON based on batching cycles. CON application fees are a base fee of $10,000 and an additional fee of 1.5 cents for each dollar of the proposed project expenditures up to a maximum combined total of $50,000.[9] 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.[10]

Severe Maladaptive Behaviors

Maladaptive behaviors are those behaviors that are disruptive, destructive, aggressive, or significantly repetitive.[11] The Florida Agency for Persons with Disabilities (APD) has developed a Global Behavioral Service Need Matrix (Matrix) in order to classify the severity of person's maladaptive behavior.[12] The Matrix categorizes symptoms of maladaptive behaviors such as behavior frequency, behavioral impact, physical aggression to others, police involvement, property destruction, and elopement/wandering, among others. Each symptom is ranked on a

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[2] Section 408.036, F.S.
[3] Pub. Law No. 93-641, 42 U.S.C. s. 300k et seq.
[4] 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.
[5] Rule 59C-1.042(3), F.A.C.
[6] Rule 59C-1.040(4), F.A.C.
[7] Rule 59C-1.041(4), F.A.C.
[8] Rule 59C-1.039(5), F.A.C.
[9] Section 408.038, F.S.
[10] Rule 59C-1.002(5), F.A.C. Note: s. 408.032(5), F.S., establishes the 11 district service areas in Florida.
[11] Fulton, Elizabeth et al. "Reducing maladaptive behaviors in preschool-aged children with autism spectrum disorder using the early start denver model." Frontiers in pediatrics vol. 2 40. available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4023017/ (last visited on Jan. 24, 2020).
[12] Available at http://apdcares.org/news/news/2011/ib-matrix-instructions.pdf (last visited on Jan. 24, 2020).

scale of one to six, with one being the least severe and six being the most severe. If a symptom is not present, it is ranked as a zero. Based on their behavior score, the person will be evaluated for services. The initial evaluation period is 12 months and then the frequency of evaluations afterwards depends on the severity of the person's score, with a need level of six being evaluated more frequently than a need level of one.[13]

III. Effect of Proposed Changes:

SB 1344 amends s. 408.036, F.S., to create a CON exemption for a new ICFDD which has a total of 24 beds, comprising three eight-bed homes, for use by individuals exhibiting severe maladaptive behaviors and co-occurring psychiatric diagnoses requiring increased levels of behavioral, medical, and therapeutic oversight. In order to obtain the exemption, The ICFDD must not have had a license denied, revoked, or suspended within the 36 months preceding the request for exemption and must have at least 10 years of experience serving individuals with severe maladaptive behaviors in this state. The AHCA is prohibited from granting an additional exemption to an ICFDD that has been granted an exemption under these provisions unless the facility has been licensed and operational for a period of at least two years. Additionally, the bill specifies that the exemption does not require a specific appropriation.

The bill also amends s. 400.962, F.S., to establish additional licensure and application requirements for an ICFDD that has been granted the CON exemption, including:

- The total number of beds per home within the facility may not exceed eight, with each resident having his or her own bedroom and bathroom. Each eight-bed home must be co-located on the same property with two other eight-bed homes and must serve individuals with severe maladaptive behaviors and co-occurring psychiatric diagnoses.
- A minimum of 16 beds within the facility must be designated for individuals with severe maladaptive behaviors who have been assessed using the Matrix with a score of at least Level 3 and up to Level 6, or assessed using criteria deemed appropriate by the AHCA regarding the need for a specialized placement in an ICFDD.
- The applicant has not had a facility license denied, revoked, or suspended within the 36 months preceding the request for exemption.
- The applicant must have at least 10 years of experience serving individuals with severe maladaptive behaviors in the state.
- The applicant must implement a state-approved staff training curriculum and monitoring requirements specific to the individuals whose behaviors require higher intensity, frequency, and duration of services.
- The applicant must make available medical and nursing services 24 hours per day, 7 days per week.
- The applicant must demonstrate a history of using interventions that are least restrictive and that follow a behavioral hierarchy.
- The applicant must maintain a policy prohibiting the use of mechanical restraints.

The bill is effective July 1, 2020.

[13] *Id.*

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:

SB 1344 may have an indeterminate positive fiscal impact on applicants for a new ICFDD which obtain the newly created CON exemption.

C. Government Sector Impact:

The bill may have an indeterminate negative fiscal impact on the AHCA due to potential loss of CON application fees for ICFDD applicants that obtain the newly created CON exemption.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends sections 400.962 and 408.036 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Harrell

25-01156A-20 20201344__

A bill to be entitled

An act relating to intermediate care facilities; amending s. 400.962, F.S.; requiring certain facilities that have been granted a certificate-of-need exemption to demonstrate and maintain compliance with specified criteria; amending s. 408.036, F.S.; providing an exemption from a certificate-of-need requirement for certain intermediate care facilities; prohibiting the Agency for Health Care Administration from granting an additional exemption to a facility unless a certain condition is met; providing that a specific legislative appropriation is not required for such exemption; providing an effective date.

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

Section 1. Subsection (6) is added to section 400.962, Florida Statutes, to read:

400.962 License required; license application.—

(6) An applicant that has been granted a certificate-of-need exemption under s. 408.036(3)(o) must also demonstrate and maintain compliance with the following criteria:

(a) The total number of beds per home within the facility may not exceed eight, with each resident having his or her own bedroom and bathroom. Each eight-bed home must be colocated on the same property with two other eight-bed homes and must serve individuals with severe maladaptive behaviors and co-occurring psychiatric diagnoses.

(b) A minimum of 16 beds within the facility must be

designated for individuals with severe maladaptive behaviors who have been assessed using the Agency for Persons with Disabilities' Global Behavioral Service Need Matrix with a score of at least Level 3 and up to Level 6, or assessed using the criteria deemed appropriate by the Agency for Health Care Administration regarding the need for a specialized placement in an intermediate care facility for the developmentally disabled.

(c) The applicant has not had a facility license denied, revoked, or suspended within the 36 months preceding the request for exemption.

(d) The applicant must have at least 10 years of experience serving individuals with severe maladaptive behaviors in the state.

(e) The applicant must implement a state-approved staff training curriculum and monitoring requirements specific to the individuals whose behaviors require higher intensity, frequency, and duration of services.

(f) The applicant must make available medical and nursing services 24 hours per day, 7 days per week.

(g) The applicant must demonstrate a history of using interventions that are least restrictive and that follow a behavioral hierarchy.

(h) The applicant must maintain a policy prohibiting the use of mechanical restraints.

Section 2. Paragraph (o) is added to subsection (3) of section 408.036, Florida Statutes, to read:

408.036 Projects subject to review; exemptions.—

(3) EXEMPTIONS.—Upon request, the following projects are subject to exemption from subsection (1):

(o) For a new intermediate care facility for the developmentally disabled as defined in s. 408.032 which has a total of 24 beds, comprising three eight-bed homes, for use by individuals exhibiting severe maladaptive behaviors and co-occurring psychiatric diagnoses requiring increased levels of behavioral, medical, and therapeutic oversight. The facility must not have had a license denied, revoked, or suspended within the 36 months preceding the request for exemption and must have at least 10 years of experience serving individuals with severe maladaptive behaviors in this state. The agency may not grant an additional exemption to a facility that has been granted an exemption under this paragraph unless the facility has been licensed and operational for a period of at least 2 years. The exemption under this paragraph does not require a specific legislative appropriation.

Section 3. This act shall take effect July 1, 2020.

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/28/2020
Meeting Date

SB 1374
Bill Number (if applicable)

Topic Intermediate Care Facilities

Amendment Barcode (if applicable)

Name Olivia Babis

Job Title Public Policy Analyst

Address 2473 Care Dr. Ste 200
Street

Phone 850-617-9718

Tallahassee FL 32308
City *State* *Zip*

Email oliviab@disabilityrights floridaorg

Speaking: ☐ For ☑ Against ☐ Information

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

Representing Disability Rights 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)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/28/20
Meeting Date

1344
Bill Number (if applicable)

Topic ICF/IID CON Exemption

Amendment Barcode (if applicable)

Name Suzanne Sewell

Job Title President & CEO

Address 2475 Apalachee Pkway
Street

Phone 850-878-3502

Tallahassee FL 32308
City *State* *Zip*

Email

Speaking: ☑ For ☐ Against ☐ Information

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

Representing FL Association of Rehabilitation Facilities

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)

Meeting Date	Bill Number (if applicable)
	1344

Topic ICF/IID CON EXEMPTION

Amendment Barcode (if applicable)

Name ZACH WRAY

Job Title CEO

Address 9040 Sunset Dr. (Street)

Phone 305-710-2282

Miami (City) FL (State) 33173 (Zip)

Email ZWray@sunrisegroup.org

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.

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

S-001 (10/14/14)

CourtSmart Tag Report

Room: KN 412 **Case:** **Type:**
Caption: Senate Health Policy Committee **Judge:**

Started: 1/28/2020 1:32:55 PM
Ends: 1/28/2020 3:13:07 PM **Length: 01:40:13**

1:32:54 PM Meeting called to order
1:33:02 PM Chair
1:33:16 PM Roll call - Quorum is present
1:33:53 PM Chair
1:33:59 PM SB 1676 by Senator Albritton, has been TP'd
1:34:25 PM Tab 1 - SB 120 by /Senator Pizzo - Naloxone in Schools
1:35:02 PM Questions? None
1:35:07 PM Appearance Cards?
1:35:12 PM Jerad Willis, FL Osteopathic Medical Association, waives in support
1:35:17 PM Eric Stern, FL PTA, waives in support
1:35:22 PM Steve Winn, ED, FOMA, waives in support
1:35:35 PM Debate?
1:35:37 PM Senator Cruz
1:36:19 PM Senator Pizzo
1:36:44 PM Senator Hooper
1:37:33 PM Senator Pizzo to close
1:37:46 PM Roll Call SB 120 - Favorable
1:38:17 PM Tab 3 - SB 1374 by Senator Harrell - Regional Perinatal Intensive Care Center
1:38:59 PM Gavel to Vice Chair Berman
1:41:10 PM Questions?
1:42:11 PM Senator Berman
1:42:20 PM Senator Harrell
1:43:01 PM Senator Berman
1:43:42 PM Senator Harrell
1:44:18 PM Senator Cruz
1:44:23 PM Senator Harrell
1:45:30 PM Senator Cruz
1:45:35 PM Senator Harrell
1:46:52 PM Senator Cruz
1:47:24 PM Senator Harrell
1:47:56 PM Senator Cruz
1:48:01 PM Senator Harrell
1:48:38 PM Chair
1:48:45 PM Appearance Card?
1:48:49 PM De Paul Robinson, President, FL Chapter AAP, waives in support
1:48:59 PM Debate? None
1:49:03 PM Senator Harrell to close
1:49:11 PM Roll Call SB 1374 - Favorable
1:50:08 PM Gavel back to Chair Harrell
1:50:23 PM Tab 2 - SB 916 by Senator Baxley - Program of All-Inclusive Care for the Elderly
1:51:18 PM Questions?
1:51:47 PM Senator Berman
1:52:04 PM Senator Baxley
1:52:24 PM Appearance Cards?
1:52:41 PM Matt Hudson, ED, FL PACE Providers Association, waives in support
1:52:49 PM Cliff Bauer, FL PACE, waives in support
1:52:58 PM Doreen Backer, Associate State Director, AARP, FL, waives in support
1:53:06 PM Debate? None
1:53:09 PM Senator Baxley waives close
1:53:16 PM Roll Call SB 916 - Favorable
1:53:40 PM Chair - Presentation on Organ Donation & Transplantation System
1:54:42 PM Becky Vickers, Chief Legislative Lobbyist, OPPAGA, speaking on Organ Donation and Transplantation

System
1:56:14 PM Questions?
1:57:13 PM Senator Rouson
1:57:16 PM Becky Vickers
1:57:35 PM Senator Baxley
1:57:42 PM Becky Vickers
1:58:04 PM Senator Berman
1:58:30 PM Becky Vickers
1:58:36 PM Senator Berman
1:58:59 PM Becky Vickers
1:59:21 PM Senator Cruz
1:59:41 PM Becky Vickers
2:01:25 PM Chair
2:01:51 PM Gavel to Senator Baxley
2:02:52 PM Tab 5 - SB 1516 by Senator Harrell - Organ Transplant Technical Advisory Council
2:03:10 PM Strike-all amendment 705054 by Senator Harrell
2:07:33 PM Questions on strike-all amendment?
2:08:51 PM Barcode 410934 Amendment to Amendment by Senator Berman
2:09:08 PM Questions on A to A? None
2:09:11 PM Senator Bean
2:09:40 PM Appearance Cards? None
2:09:41 PM Chair
2:09:42 PM Senator Harrell
2:09:45 PM Debate? None
2:09:49 PM Senator Berman waives close
2:09:56 PM Amendment to Amendment 410934 is adopted
2:10:08 PM Barcode 578120 - Amendment to Amendment by Senator Harrell
2:10:56 PM Questions? None
2:10:59 PM Appearance Cards? None
2:11:05 PM Debate? None
2:11:07 PM Senator Harrell waives close
2:11:14 PM Amendment to Amendment 578120 is adopted
2:11:24 PM Amendment to Amendment 624380 by Senator Harrell
2:11:35 PM Senator Harrell
2:11:38 PM Questions? None
2:11:41 PM Appearance Cards?
2:11:46 PM Debate? None
2:11:50 PM Senator Harrell waives close
2:11:52 PM Amendment to Amendment 624380 is adopted
2:12:03 PM Back on Strike-all as amended
2:12:14 PM Appearance Cards?
2:12:19 PM Ron Watson, Lobbyist, FL Renal Association, waives in support
2:12:27 PM Lane Smith, Government Relations Director, Mayo Clinic, speaking for information
2:13:23 PM Lauren, Levis Betz and Associates, waives in support
2:13:58 PM Missy Timmons, Transplants for Life, speaking for herself. Waiting list for organ donors, speaking in support
2:15:03 PM Chair
2:16:03 PM Question?
2:16:07 PM Senator Book
2:16:13 PM Missy Timmons
2:16:42 PM Chair
2:17:41 PM Senator Mayfield
2:17:48 PM Missy Timmons
2:18:23 PM Chair
2:18:51 PM Dr. Kiran Dhanireddy, MD, Tampa General speaking for information
2:22:33 PM Lawrence Cochran, Assistant ED, Life Quest Organ Recovery, speaking for information
2:25:33 PM Louis Betz, More Transplants More Life PC, waives in support
2:26:37 PM Amy Kozsubh, Board President, National Kidney Foundation of Florida & FL Renal Assoc., waives in support
2:26:55 PM Debate on amendment?
2:27:14 PM Senator Harrell to close
2:29:12 PM Barcode 705054 strike-all is adopted

2:29:25 PM Back on the Bill as amended
2:29:35 PM Questions?
2:29:37 PM Debate?
2:29:42 PM Senator Harrell waives close
2:29:47 PM Roll Call - SB 1516 - Favorable
2:31:17 PM Tab 6 - SB 798 - by Senator Rouson - Procurement of Human Organs and Tissue
2:33:04 PM Questions?
2:33:06 PM Senator Bean
2:33:53 PM Senator Rouson
2:34:15 PM Senator Harrell
2:34:30 PM Appearance Cards?
2:34:58 PM Todd Josko, Partner, Ballard Partners, Lion's Eye Institute for Transplantation & Research, waives in support
2:35:08 PM Debate?
2:35:12 PM Senator Baxley
2:36:38 PM Senator Rouson waives close
2:36:55 PM Roll Call SB 798 - Favorable
2:37:23 PM Tab 7 - SB 1556 by Senator Bean -Nondiscrimination in Organ Transplants
2:38:23 PM Questions? None
2:38:31 PM Appearance Cards?
2:38:35 PM Missy Timmons waives in support
2:38:43 PM Ron Watson waives in support
2:39:33 PM Oliva Babis, Disability Rights, Public Policy Analyst, speaking for
2:40:33 PM Debate? None
2:40:39 PM Senator Bean to close
2:41:00 PM Roll Call SB 1556 - Favorable
2:41:30 PM Tab 8 - SB 1726 by Senator Bean- Agency for Health Care Administration
2:43:30 PM Amendment 941416 by Senator Bean
2:43:56 PM Questions on amendment? None
2:44:01 PM Debate on amendment? None
2:44:03 PM Objections on amendment? None
2:44:11 PM Amendment is adopted
2:44:29 PM Questions?
2:44:31 PM Appearance?
2:44:36 PM Amendment 941416 is adopted
2:44:43 PM Substitute Amendment 367544 by Senator Bean
2:45:53 PM Questions on amendment?
2:46:52 PM Senator Berman
2:47:10 PM Senator Bean
2:48:06 PM Senator Berman
2:48:16 PM Senator Bean
2:49:00 PM Senator Berman
2:49:10 PM Senator Bean
2:49:29 PM Molly McKenzie, Agency for Health Care, to answer Senator Berman
2:49:59 PM Senator Berman
2:50:02 PM Molly McKenzie
2:50:29 PM Appearance Cards?
2:50:35 PM Robert Beck, FL Community Care, waives in support
2:50:44 PM Debate? None
2:50:52 PM Amendment 367544 is adopted
2:51:05 PM Amendment 117312 by Senator Bean
2:51:23 PM Questions on amendment? None
2:51:27 PM Appearance Cards on amendment? None
2:51:34 PM Objections to amendment? None
2:51:39 PM Amendment 117312 is adopted
2:51:44 PM Back on the bill as amended
2:51:49 PM Questions? None
2:51:56 PM Appearance Cards?
2:52:01 PM Doug Russell, Quest Diagnostic Labs, waives in support
2:52:11 PM Debate? None
2:52:15 PM Senator Bean waives close
2:52:19 PM Roll Call SB 1726 - Favorable

2:52:47 PM Tab 9 SB 1742 by Senator Mayfield - Home Medical Equipment Providers
2:53:23 PM Questions? None
2:53:30 PM Appearance Card. Jack Hebert, Gov. Affairs Dir., FL Chiropractic Assn., waives in support
2:53:34 PM Debate? None
2:53:38 PM Senator Mayfield waives close
2:53:46 PM Roll call SB 1742 - Favorable
2:54:15 PM Gavel to Vice Chair Berman
2:54:27 PM Tab 13 - SB 1344 by Senator Harrell - Intermediate Care Facilities
2:56:01 PM Questions?
2:57:02 PM Appearance Cards?
2:57:06 PM Suzanne Sewell, President & CEO, FL Association of Rehabilitation Facilities, speaking for
2:59:49 PM Zach Wray waives in support
3:00:50 PM Olivia Babis, speaking for information
3:03:02 PM Debate?
3:04:03 PM Senator Berman
3:04:31 PM Senator Harrell to close
3:05:18 PM Roll Call SB 1344 - Favorable
3:06:24 PM Tab 10 - SB 926 by Senator Harrell - Health Care Practitioner Licensure
3:08:07 PM Questions? None
3:09:06 PM Appearance Cards?
3:09:13 PM Jared Willis, Dir. Gov. Relations, FL Osteopathic Medical Association, waives in support
3:09:19 PM Ronald Giffler, MD, President, Fla. Medical Association, waives in support
3:09:26 PM Layne Smith, Gov. Rel. Director, Mayo Clinic, waives in support
3:09:33 PM Debate? None
3:09:40 PM Senator Harrell waives close
3:09:46 PM Roll Call SB 926 Favorable
3:10:04 PM Tab 11 - SB 928 by Senator Harrell, Public Records and Meeting/Interstate Medical Licensure Compact
3:10:21 PM Questions? None
3:10:28 PM Amendment 68173 by Senator Harrell
3:10:42 PM Questions on Amendment? None
3:10:44 PM Appearance Cards on Amendment? None
3:10:49 PM Debate on Amendment? None
3:10:54 PM Amendment 68173 is adopted
3:11:02 PM Amendment 943952 by Senator Harrell
3:11:11 PM Questions?
3:11:14 PM Appearance?
3:11:17 PM Debate?
3:11:18 PM Amendment is adopted
3:11:23 PM Back on bill as adopted
3:11:26 PM Questions?
3:11:29 PM Appearance Cards?
3:11:35 PM Debate?
3:11:36 PM Senator Harrell waives close
3:11:42 PM Roll call SB 928 - Favorable
3:12:01 PM Gavel back to Senator Harrell
3:12:11 PM Senator Book - Affirmative on Tabs 1-2-3. Senator Baxley affirmative on SB 120
3:12:36 PM Senator Diaz Motion to adjourn, Motion is adopted
3:12:46 PM Seeing no other business. We are adjourned