The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Harrell, Chair
Senator Berman, Vice Chair

MEETING DATE: Tuesday, February 4, 2020
TIME: 9:00—11:00 a.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	OFFICE and APPOINTMENT (HOME CITY)	FOR TERM ENDING	COMMITTEE ACTION
	Senate Confirmation Hearing: A public hearing will be held for consideration of the below-named executive appointment to the office indicated.		
	State Surgeon General		
1	Rivkees, Scott A. (Tallahassee)	Pleasure of Governor	Recommend Confirm Yeas 10 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
2	**SB 1764** Flores	Childbirth; Requiring a certificate for fetal death to include certain information if the death occurred in association with a planned out-of-hospital birth; requiring a certificate of live birth to list the intended place of birth; requiring certain health care practitioners to submit adverse incident reports to the Department of Health within a specified timeframe under certain circumstances; requiring the department to investigate adverse incident reports involving unlicensed individuals and take appropriate action; providing continuing education requirements for and duties of licensed health care practitioners providing out-of-hospital births, etc. HP 02/04/2020 Fav/CS AHS AP	Fav/CS Yeas 10 Nays 0
3	**SB 1676** Albritton (Similar H 7053, Compare CS/H 607)	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 HP 02/04/2020 Fav/CS AHS AP	Fav/CS Yeas 10 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	**SB 1544** Albritton (Compare CS/H 1373)	Elderly Care; Prohibiting the Department of Children and Families, in determining Medicaid eligibility, from considering the cash surrender value of certain life insurance policies as assets if certain conditions are met; specifying requirements for a collateral assignment by a Medicaid applicant; requiring the Agency for Health Care Administration to file a claim for the death benefit upon the recipient's death; revising the individuals who must be rescreened annually by aging resource centers under the Medicaid long-term care managed care program; requiring the Department of Elderly Affairs to develop, and adopt by rule, a tool for comprehensive assessment of long-term-care supports and services needed by family and friend caregivers for elderly and disabled adults, etc. HP 02/04/2020 Fav/CS AHS AP	Fav/CS Yeas 10 Nays 0
5	**SB 1650** Simmons (Compare CS/H 81)	Medicaid Provider Agreements for Charter and Private Schools; Revising qualification requirements for health care practitioners engaged by charter and private schools to provide Medicaid school-based services, etc. HP 02/04/2020 Favorable ED AP	Favorable Yeas 10 Nays 0
6	**SB 512** Hutson (Identical H 313)	Nonembryonic Stem Cells; Authorizing the administration of nonembryonic stem cells and the use of such cells in health care products; authorizing the importation of any sterile compound, drug, or other treatment containing nonembryonic stem cells under certain circumstances; requiring a stem cell bank to obtain or otherwise carry professional liability insurance, etc. HP 02/04/2020 Fav/CS AP RC	Fav/CS Yeas 10 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
7	**SB 1014** Rouson (Similar H 995)	Public Safety Telecommunicator Training; Defining the term "telecommunicator cardiopulmonary resuscitation training"; requiring certain 911 public safety telecommunicators to receive telecommunicator cardiopulmonary resuscitation training every 2 years; requiring the Department of Health to establish a procedure to monitor adherence to the training requirements; authorizing the department to adjust state grants or shared revenue funds to certain entities based on their employees' adherence or failure to adhere to the training requirements, etc. HP 02/04/2020 Favorable AHS AP	Favorable Yeas 10 Nays 0
8	**SB 744** Hooper (Compare CS/CS/H 351)	Podiatric Medicine; Revising the membership, terms, and duties of the Council on Physician Assistants; defining the term "physician" to include podiatric physicians; authorizing the Board of Podiatric Medicine to require as a condition for renewal of license a specified number of continuing education hours related to the safe and effective prescribing of controlled substances; authorizing a podiatric physician or group of podiatric physicians to supervise a specified number of physician assistants, etc. HP 02/04/2020 Fav/CS AHS AP	Fav/CS Yeas 10 Nays 0
9	**SB 1206** Harrell (Identical H 575)	Applied Behavior Analysis Services; Providing an exemption from licensure requirements for certain individuals who are employed or under contract with certain entities providing applied behavior analysis services; redefining the term "private instructional personnel" to include certain behavior analysts and paraprofessionals providing applied behavior analysis services, etc. HP 02/04/2020 Fav/CS AHS AP	Fav/CS Yeas 10 Nays 0
	Other Related Meeting Documents		

RECEIVED.
2019 JUL 12 AM 9:24
DIVISION OF ELECTIONS
TALLAHASSEE, FL

RON DESANTIS
GOVERNOR

June 20, 2019

Secretary Laurel Lee
Department of State
R.A. Gray Building, Room 316
500 South Bronough Street
Tallahassee, FL 32399-0250

Dear Secretary Lee:

Please be advised I have made the following appointment under the provision of Section 20.43, Florida Statutes:

Mr. Scott Rivkees
406 Northeast 7th Avenue
Gainesville, Florida 32601

as State Surgeon General and State Health Official, subject to confirmation by the Senate. This appointment is effective June 20, 2019 for a term ending at the pleasure of the Governor.

Sincerely,

Ron DeSantis
Governor

RD/mm

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DIVISION OF ELECTIONS
TALLAHASSEE, FL

OATH OF OFFICE

(Art. II. § 5(b), Fla. Const.)

STATE OF FLORIDA

County of Leon

I do solemnly swear (or affirm) that I will support, protect, and defend the Constitution and Government of the United States and of the State of Florida; that I am duly qualified to hold office under the Constitution of the State, and that I will well and faithfully perform the duties of

State Surgeon General and Secretary, Department of Health

(Title of Office)

on which I am now about to enter, so help me God.

[NOTE: If you affirm, you may omit the words "so help me God." *See* § 92.52, Fla. Stat.]

Signature

Sworn to and subscribed before me this 22nd *day of* July, 2019.

Signature of Officer Administering Oath or of Notary Public

WANDA DENESE YOUNG
Commission # GG 164701
Expires January 13, 2022
Bonded Thru Troy Fain Insurance 800-385-7019

Print, Type, or Stamp Commissioned Name of Notary Public

Personally Known ☑ ***OR*** *Produced Identification* ☐

Type of Identification Produced _____

ACCEPTANCE

I accept the office listed in the above Oath of Office.

Mailing Address: ☐ Home ☑ Office

4052 Bald Cypress Way, Bin A-00
Street or Post Office Box

Tallahassee, FL 32399-1700
City, State, Zip Code

Scott A. Rivkees, M.D.
Print Name

Signature

DS-DE 56 (Rev. 11/16)

CERTIFICATION

STATE OF FLORIDA
COUNTY OF LEON

Before me, the undersigned Notary Public of Florida, personally appeared Scott A. Rivkees,
who, after being duty sworn, say: (1) that he/she has carefully and personally prepared or read the answers to the foregoing questions; (2) that the information contained in said answers is complete and true; and (3) that he/she will, as an appointee, fully support the Constitutions of the United States and of the State of Florida.

Scott A. Rivkees
Signature of Applicant-Affiant

Sworn to and subscribed before me this 22nd day of August, 2019.

Wanda Denese Young
Signature of Notary Public-State of Florida

WANDA DENESE YOUNG
Commission # GG 164701
Expires January 13, 2022
Bonded Thru Troy Fain Insurance 800-385-7019

(Print, Type, or Stamp Commissioned Name of Notary Public)

My commission expires: January 13, 2022

Personally Known ☒ **OR** Produced Identification ☐

Type of Identification Produced _____

(seal)

The Florida Senate

Committee Notice Of Hearing

IN THE FLORIDA SENATE
TALLAHASSEE, FLORIDA

IN RE: Executive Appointment of

Scott A. Rivkees

State Surgeon General

NOTICE OF HEARING

TO: Dr. Scott A. Rivkees

YOU ARE HEREBY NOTIFIED that the Committee on Health Policy of the Florida Senate will conduct a hearing on your executive appointment on Tuesday, February 4, 2020, in the Pat Thomas Committee Room, 412 Knott Building, commencing at 9:00 a.m., pursuant to Rule 12.7(1) of the Rules of the Florida Senate.

Please be present at the time of the hearing.
DATED this the 30th day of January, 2020

Committee on Health Policy

Gayle Harrell

Senator Gayle Harrell
As Chair and by authority of the committee

cc: Members, Committee on Health Policy
Office of the Sergeant at Arms

THE FLORIDA SENATE

COMMITTEE WITNESS OATH

CHAIR:

Please raise your right hand and be sworn in as a witness.

Do you swear or affirm that the evidence you are about to give will be the truth, the whole truth, and nothing but the truth?

WITNESS'S NAME: Scott A. Rivkees, M.D.

ANSWER: I do

Pursuant to §90.605(1), *Florida Statutes*: "The witness's answer shall be noted in the record."

COMMITTEE NAME: Health Policy

DATE: February 4, 2020

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 1764
INTRODUCER:	Health Policy Committee and Senator Flores
SUBJECT:	Midwifery
DATE:	February 5, 2020
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1764 amends s. 467.015, F.S., to establish additional requirements for midwives when participating in in-hospital or out-of-hospital births. The midwife must advise the patient of certain clinical outcomes and advise, but not require, the patient to consult an obstetrician for more information related to such clinical outcomes; measure and record vital signs upon initial contact with the patient; and transfer care to a hospital upon if specified complications occur.

The bill amends s. 467.016, F.S., to specify that the informed consent form developed by the Department of Health (DOH) is required to be used by a midwife only when providing an out-of-hospital birth. The bill also provides additional requirements on how the form must be signed and what information must be included on the form.

The bill takes effect July 1, 2020.

II. Present Situation:

Licensed Midwives

Midwifery is the practice of supervising a normal labor and childbirth, with the informed consent of the parent, advising the parents as to the progress of childbirth, and rendering prenatal and postpartal care.[1] The Department of Health (DOH) licenses and regulates the practice of

[1] Section 467.003(8), F.S.

midwifery in this state. The Council of Licensed Midwifery assists and advises DOH on midwifery, including the development of rules relating to regulatory requirements, including but not limited to, training requirements, licensure examination, responsibilities of midwives, emergency care plans, and reports and records to be filed by licensed midwives.[2]

An individual must graduate from an approved midwifery program and pass a licensure examination to be eligible for licensure as a midwife.[3] A licensed midwife must submit a general emergency care plan that addresses consultation with other health care providers, emergency transfer protocols, and access to neonatal intensive care units and obstetrical units or other patient care areas with his or her application for licensure and licensure renewal.[4] A licensed midwife must also submit proof of professional liability coverage of at least $100,000, with an annual aggregate of at least $300,000.[5]

A licensed midwife must:[6]

- Accept only those patients who are expected to have a normal pregnancy, labor, and delivery;
- If a patient is not at low risk in her pregnancy, provide collaborative prenatal and postnatal care, within a written protocol with a physician who maintains supervision for directing the specific course of treatment;
- Ensure that each patient has signed an informed consent form developed by the DOH;
- Administer medicinal drugs pursuant to a prescription issued by a practitioner licensed under ch. 458, F.S., or ch. 459, F.S.;
- Prepare a written plan of action with the family to ensure continuity of medical care and to provide for immediate medical care if an emergency arises;
- Maintain appropriate equipment and supplies and instructing the patient and family regarding the preparation of the environment, if a home birth is planned;
- Instruct the patient in the hygiene of pregnancy and nutrition as it relates to prenatal care;
- Determine the progress of labor, and when birth is imminent, be immediately available until delivery is accomplished;
- Remain with the postpartal mother until the mother and neonate are stabilized;
- Instill a prophylactic into each eye of the newborn infant within one hour after birth for the prevention of neonatal ophthalmia;[7] and
- Ensure that the care of mothers and infants throughout the prenatal, intrapartal, and postpartal periods conforms to DOH rules and the state's public health laws.

Risk Assessment

A licensed midwife must assess the risk status of each potential patient to determine whether the licensed midwife can accept the patient or continue caring for the patient.[8] The licensed midwife

[2] Section 467.004, F.S.
[3] Section 467.011, F.S. Section 467.0125, F.S., provides for licensure by endorsement for applicants who hold a valid license to practice midwifery in another state.
[4] Section 467.017, F.S.
[5] Rule 64B24-7.013, F.A.C. An applicant does not have to submit proof of professional liability insurance if the applicant practices exclusively as an officer, employee, or agent of the federal government, practices only in conjunction with teaching duties at an approved midwifery school that provides such coverage on the applicant's behalf, or who does not practice midwifery in this state and provides proof of such.
[6] Section 467.015, F.S.
[7] Section 383.04, F.S.
[8] Rule 64B24-7.004, F.A.C.

must obtain a detailed medical history, perform a physical examination, and assess family circumstances along with social and psychological factors. The DOH provides a scoring system for the factors by rule, which assigns each factor a value of one to three.[9] For example, heart disease assessed by a cardiologist which does not place the mother or fetus at any risk has a score of one and chronic hypertension has a score of three.

If the assessment results in a risk score of three or higher, the licensed midwife must consult with a physician who has obstetrical hospital privileges.[10] If there is a joint determination that the patient can be expected to have a normal pregnancy, labor, and delivery, the licensed midwife may provide services to the patient.[11]

Responsibilities during Pregnancy and Delivery

The Florida Administrative Code outlines a licensed midwife's responsibilities during the antepartum, intrapartum, and postpartum periods. During each of these periods, the licensed midwife must assess the patient for risk factors and either consult with or transfer the patient's care to a physician.

In the antepartum period, a licensed midwife must refer the patient for a consultation with a physician with hospital obstetrical privileges if one of the following occurs:
- Hematocrit of less than 33 percent at 37th week gestation or hemoglobin less than 11 gms/100 ml;
- Unexplained vaginal bleeding;
- Abnormal weight change defined as less than 12 or more than 50 pounds at term;
- Non-vertex presentation persisting past 37th week of gestation;
- Gestational age between 41 and 42 weeks;
- Genital herpes confirmed clinically or by culture at term;
- Documented asthma attack;
- Hyperemesis not responsive to supportive care; or
- Any other severe obstetrical, medical, or surgical problem.

A licensed midwife must transfer a patient if one of the following occurs:
- Genetic or congenital abnormalities or fetal chromosomal disorder;
- Multiple gestation;
- Pre-eclampsia;
- Intrauterine growth retardation;
- Thrombophlebitis;
- Pyelonephritis;
- Gestational diabetes confirmed by abnormal glucose tolerance test; or
- Laboratory evidence of Rh sensitization.

[9] Rule 64B24-7.004(3), F.A.C.
[10] Rule 64B24-7.004(1), F.A.C.
[11] Id.

The licensed midwife may continue caring for the patient if the condition is resolved satisfactorily and the physician and licensed midwife determine that the patient is expected to have a normal pregnancy, labor, and delivery.[12]

During the intrapartum period or labor, the licensed midwife must consult with or refer or transfer a patient to a physician with hospital obstetrical privileges if one of the following occurs:[13]

- Premature labor, meaning labor occurring at less than 37 weeks of gestation;
- Premature rupture of membranes, meaning rupture occurring more than 12 hours before onset of regular active labor;
- Non-vertex presentation;
- Evidence of fetal distress;
- Abnormal heart tones;
- Moderate or severe meconium staining;
- Estimated fetal weight less than 2,500 grams or greater than 4,000 grams;
- Pregnancy induced hypertension;
- Failure to progress in active labor;
- Severe vulvar varicosities;
- Marked edema of cervix;
- Active bleeding;
- Prolapse of the cord;
- Active infectious process; or
- Other medical or surgical problems.

A licensed midwife may not perform any operative procedures other than clamping and cutting the umbilical cord, episiotomies, suturing to repair first and second degree lacerations, and artificial rupture of the membranes under certain conditions.[14] A licensed midwife may also not attempt to correct a fetal presentation and may not use artificial, forcible, or mechanical means to assist a birth.[15]

A licensed midwife must consult with or refer or transfer an infant under certain conditions, such as if the child has jaundice, respiratory problems, or major congenital anomalies.[16] The licensed midwife must consult with a physician or transfer a mother for emergency care if any postpartum complications arise, such as retained placenta or postpartum hemorrhage.[17] The licensed midwife must stay with the mother and infant for at least two hours after the birth or until the mother's and infant's conditions are stable, whichever is longer.[18]

[12] Rule 64B24-7.007, F.A.C.
[13] Rule 64B24-7.008(4), F.A.C.
[14] Rule 64B24-7.008(5), F.A.C.
[15] Rules 64B24-7.008(6) and 64B24-7.008(8), F.A.C.
[16] Rule 64B24-7.009(2), F.A.C.
[17] Rule 64B24-7.009(5), F.A.C.
[18] Rule 64B24-7.009(4), F.A.C.

Adverse Incident Reporting

A licensed midwife must submit an adverse incident report to the DOH within 15 days of an adverse incident occurring, providing a summary of the events that occurred. An adverse incident is an event over which the licensed midwife could exercise control and one of the following occurs:[19]

- A maternal death that occurs after delivery or within 42 days after delivery;
- A maternal patient is transferred to a hospital intensive care unit;
- A maternal patient experiences hemorrhagic shock or requires a transfusion of more than four units of blood or blood products;
- A fetal or newborn death, including a still birth, attributable to an obstetrical delivery;
- A newborn patient is transferred to a hospital neonatal intensive care unit (NICU) due to a traumatic birth injury; or
- A newborn patient is transferred to a hospital NICU within 72 hours after birth if the newborn remains in the NICU for more than 72 hours.

The DOH must review the report and determine whether the incident involves conduct requiring disciplinary action against the licensed midwife's license.[20]

Informed Consent

A licensed midwife must obtain informed consent from the patient on a form developed by the DOH.[21] The form explains that licensed midwives care for women who have normal, uncomplicated pregnancies and are expecting a normal delivery of a healthy newborn.[22] In signing the informed consent form, the patient acknowledges that:[23]

- The licensed midwife has explained her training and experience;
- The patient is aware of the benefits of natural childbirth relating to avoidance of potential injury resulting from either invasive procedures, anesthesia, or surgical intervention;
- In order to obtain care by the midwife, the patient must:
  - Provide a complete medical, health, and maternity history;
  - Review risk factors and other requirements with the midwife;
  - Maintain a regular schedule for prenatal visits; and
  - Make a plan for emergency care, with the assistance of the midwife, for unforeseen complications that may arise during pregnancy and delivery, as well as any pediatric care necessary for the baby;
- The licensed midwife provided the status of the midwife's malpractice insurance, including the amount of insurance; and
- The patient had an opportunity to review and discuss information contained in the informed consent form, including; but not limited to the conditions which require the midwife to refer or transfer care.

[19] Section 456.0495, F.S.
[20] Id.
[21] Section 467.016, F.S.
[22] Form DH-MQA 1047, Rev. 3/01, incorporated by reference in Rule 64B24-7.005, F.A.C., *available at* http://www.floridahealth.gov/licensing-and-regulation/midwifery/resources/_documents/midwife-consent.pdf (last visited Jan. 30, 2020).
[23] Id.

The form also requires the patient to expressly authorize the licensed midwife to perform maternity services that are within the scope of the midwifery license and provides that a copy of the statute and rules are available upon request.[24]

III. Effect of Proposed Changes:

Section 1 amends s. 467.015, F.S., to require a midwife, whether providing an in-hospital or out-of-hospital birth, to:

- Upon acceptance of a patient into care, advise the patient of the clinical outcomes of births in low-risk patients during an out-of-hospital birth and any increased risks associated with an individual having a vaginal birth after having a caesarean section, a breech birth, or a multiple gestation pregnancy. The licensed health care practitioner providing out-of-hospital births shall further advise, but may not require, the patient to consult an obstetrician for more information related to such clinical outcomes and increased risks.
- Prepare a written plan of action with the patient or the patient's family, if any, to ensure continuity of medical care throughout labor and delivery and to provide for immediate medical care if an emergency arises.
- Upon initial contact with the patient during the intrapartal period, measure and record the vital signs of the mother and fetus to serve as a baseline during labor and delivery.
- Transfer care of the patient to a hospital with obstetrical services in accordance with the written emergency plan if any of the following occurs or presents during labor or delivery or immediately thereafter:
  - An unexpected nonvertex presentation of the fetus;
  - Indication that the mother's uterus has ruptured;
  - Evidence of severe and persistent fetal or maternal distress;
  - Pregnancy-induced hypertension;
  - An umbilical cord prolapse;
  - Active infectious disease process; or
  - Any other severe emergent condition.

Section 2 amends s. 467.016, F.S., to require a midwife to obtain informed consent using a form developed by the DOH only when participating in out-of-hospital births. The form must be signed by the practitioner and the patient and a copy of the signed form must be provided to the patient. The form must include:

- A statement advising the patient of the clinical outcomes of births in low-risk patients during an out-of-hospital birth and any increased risks associated with having a vaginal birth after having a caesarean section, a breech birth, or a multiple gestation pregnancy.
- A detailed statement explaining to the patient hospital admitting privileges and the requirements to obtain and maintain such privileges.
- Disclosure of each hospital and specific department, if any, where the health care practitioner providing out-of-hospital births has been granted admitting privileges, including the scope and duration of the admitting privileges, the current contact information for the specific hospital or department that has granted the health care practitioner admitting privileges, and a copy of documentation from the hospital or department providing proof of such admitting

[24] *Id.*

privileges. A health care practitioner providing out-of-hospital births who does not have admitting privileges at any hospital must explicitly state that fact on the form.

Section 3 provides that 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.

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:

The bill amends s. 467.015, F.S., relating to a list of responsibilities for midwives. The bill provides that a midwife must do everything on the list, regardless of whether the midwife is participating in an in-hospital or out-of-hospital birth. However, one aspect of the list is somewhat unclear because it provides a responsibility that "the licensed health care practitioner" must fulfill but only for out-of-hospital births. The latter aspect seems out of place in a list of responsibilities that must be observed in all cases, regardless of whether the birth is in-hospital or

out-of-hospital. And, the term "licensed health care practitioner" could pertain to any of numerous types of practitioners, as opposed to midwives specifically.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends sections 467.015 and 467.016 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 February 4, 2020:
The CS eliminates all provisions of the underlying bill except that the CS requires a midwife, whether participating in an in-hospital or out-of-hospital birth, to:

- Upon acceptance of a patient into care, advise the patient of the clinical outcomes of births in low-risk patients during an out-of-hospital birth and any increased risks associated with an individual having a vaginal birth after having a caesarean section, a breech birth, or a multiple gestation pregnancy. The licensed health care practitioner providing out-of-hospital births shall further advise, but may not require, the patient to consult an obstetrician for more information related to such clinical outcomes and increased risks.
- For written plans of action required under current law, prepare such plans with the patient and the patient's family, if any.
- Upon initial contact with the patient during the intrapartal period, measure and record the vital signs of the mother and fetus to serve as a baseline during labor and delivery.
- Transfer care of the patient to a hospital with obstetrical services in accordance with the written emergency plan if any of the following occurs or presents during labor or delivery or immediately thereafter:
  - An unexpected nonvertex presentation of the fetus;
  - Indication that the mother's uterus has ruptured;
  - Evidence of severe and persistent fetal or maternal distress;
  - Pregnancy-induced hypertension;
  - An umbilical cord prolapse;
  - Active infectious disease process; or
  - Any other severe emergent condition.

The CS changes the current law requirement for midwives to use an informed consent form to provide certain information to a patient. Under the CS, the informed consent form must be used only for out-of-hospital births and must be signed by the patient and the midwife, and a copy must be provided to the patient. The form must include, at a minimum:

- A statement advising the patient of the clinical outcomes of births in low-risk patients during an out-of-hospital birth and any increased risks associated with having a

vaginal birth after having a caesarean section, a breech birth, or a multiple gestation pregnancy.

- A detailed statement explaining to the patient hospital admitting privileges and the requirements to obtain and maintain such privileges.
- Disclosure of each hospital and specific department, if any, where the health care practitioner providing out-of-hospital births has been granted admitting privileges, including the scope and duration of the admitting privileges, the current contact information for the specific hospital or department that has granted the health care practitioner admitting privileges, and a copy of documentation from the hospital or department providing proof of such admitting privileges. A health care practitioner providing out-of-hospital births who does not have admitting privileges at any hospital must explicitly state that fact on the form.

B. Amendments:

None.

By Senator Flores

39-00727A-20 20201764__

A bill to be entitled

An act relating to childbirth; amending s. 382.008, F.S.; requiring a certificate for fetal death to include certain information if the death occurred in association with a planned out-of-hospital birth; amending s. 382.013, F.S.; requiring a certificate of live birth to list the intended place of birth; requiring the certificate to list certain information if the mother or newborn was transferred to a hospital, an intensive care unit, or a similar facility during certain times; amending s. 456.0495, F.S.; revising the definition of the term "adverse incident"; requiring certain health care practitioners to submit adverse incident reports to the Department of Health within a specified timeframe under certain circumstances; requiring the department to investigate adverse incident reports involving unlicensed individuals and take appropriate action; creating a review panel within the department, in consultation with certain regulatory boards; providing for the membership, meetings, and duties of the panel; requiring the panel to submit annual reports to the department, the Board of Medicine, the Board of Osteopathic Medicine, the Board of Nursing, and the Council of Licensed Midwifery by a specified date; requiring the department to collect and analyze certain data relating to adverse incidents in planned out-of-hospital births; requiring the department to submit annual reports on its findings and

recommendations to the Governor and the Legislature by a specified date and publish the report on its website; requiring the department to deidentify information in such report; creating s. 456.0496, F.S.; providing continuing education requirements for and duties of licensed health care practitioners providing out-of-hospital births; requiring the department to adopt rules for such education requirements; requiring a patient informed consent form for out-of-hospital births to include specified information; providing for violations and penalties; providing grounds for disciplinary action; providing an effective date.

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

Section 1. Subsection (1) of section 382.008, Florida Statutes, is amended to read:

382.008 Death, fetal death, and nonviable birth registration.—

(1) A certificate for each death and fetal death which occurs in this state shall be filed electronically on the department electronic death registration system or on a form prescribed by the department with the department or local registrar of the district in which the death occurred within 5 days after such death and prior to final disposition, and shall be registered by the department if it has been completed and filed in accordance with this chapter or adopted rules. The certificate shall include the decedent’s social security number,

if available. In addition, each certificate of death or fetal death:

(a) If requested by the informant, shall include aliases or "also known as" (AKA) names of a decedent in addition to the decedent's name of record. Aliases shall be entered on the face of the death certificate in the space provided for name if there is sufficient space;

(b) If the place of death is unknown, shall be registered in the registration district in which the dead body or fetus is found within 5 days after such occurrence; ~~and~~

(c) If death occurs in a moving conveyance, shall be registered in the registration district in which the dead body was first removed from such conveyance; and

(d) If the fetal death occurred in association with a planned out-of-hospital birth, including a fetal death that occurs out-of-hospital or during a transfer or admission to a hospital, an intensive care unit, or a similar facility, shall include the name, title, and professional license number of each physician, certified nurse midwife, or midwife who treated the mother or fetus during the pregnancy, labor, or delivery, or immediately thereafter. If an individual who treated the mother or fetus is not appropriately licensed in this state but represented himself or herself as such, the certificate of fetal death must also include the name of the unlicensed individual and any title or professional license number the individual used to represent himself or herself as appropriately licensed in this state, with a clear notation that the individual is not appropriately licensed as such.

Section 2. Subsection (6) is added to section 382.013,

Florida Statutes, to read:

382.013 Birth registration.—A certificate for each live birth that occurs in this state shall be filed within 5 days after such birth with the local registrar of the district in which the birth occurred and shall be registered by the local registrar if the certificate has been completed and filed in accordance with this chapter and adopted rules. The information regarding registered births shall be used for comparison with information in the state case registry, as defined in chapter 61.

(6) INTENDED PLACE OF BIRTH.—A certificate of live birth must include the intended place of birth. If the mother or newborn was transferred to a hospital, an intensive care unit, or a similar facility at any point during labor or delivery, or within 72 hours of delivery, the certificate must also include the name and address of the transferring location and the name, title, and professional license number of each physician, certified nurse midwife, or midwife who treated the mother or newborn during the pregnancy, labor, or delivery, or immediately thereafter. If an individual who treated the mother or fetus prior to such transfer is not appropriately licensed in this state but represented himself or herself as such, the certificate of live birth must also include the name of the unlicensed individual and any title or professional license number the individual used to represent himself or herself as appropriately licensed in this state, with a clear notation that the individual is not appropriately licensed as such.

Section 3. Section 456.0495, Florida Statutes, is amended to read:

456.0495 Reporting adverse incidents occurring in planned out-of-hospital births.—

(1) For purposes of this section, the term "adverse incident" means an event over which a physician licensed under chapter 458 or chapter 459, a nurse midwife certified under part I of chapter 464, or a midwife licensed under chapter 467 could exercise control and which is associated with an attempted or completed planned out-of-hospital birth, and results in one or more of the following injuries or conditions:

(a) A maternal death that occurs during delivery or within 42 days after delivery;

(b) The transfer of a maternal patient to a hospital intensive care unit;

(c) A maternal patient experiencing hemorrhagic shock or requiring a transfusion of more than 4 units of blood or blood products;

(d) A fetal or newborn death, including a stillbirth, associated with an obstetrical delivery;

(e) A transfer of a newborn to a neonatal intensive care unit due to a traumatic physical or neurological birth injury, including any degree of a brachial plexus injury;

(f) A transfer of a newborn to a neonatal intensive care unit within the first 72 hours after birth if the newborn remains in such unit for more than 72 hours; ~~or~~

(g) Any transfer of a maternal patient or newborn from an out-of-hospital birth setting to a hospital during the prenatal, intrapartal, or postpartal period, as those periods are defined in s. 467.003, that results in fetal or maternal morbidity or mortality; or

(h) ~~(g)~~ Any other injury as determined by department rule.

(2) ~~Beginning July 1, 2018,~~ A physician licensed under chapter 458 or chapter 459, a nurse midwife certified under part I of chapter 464, or a midwife licensed under chapter 467 who performs an attempted or completed planned out-of-hospital birth must report an adverse incident, along with a medical summary of events, to the department within 15 days after the adverse incident occurs. A health care practitioner required to report adverse incidents under this section who is aware of an adverse incident related to an out-of-hospital birth attempted or completed by an individual who was not appropriately licensed in this state but who represented himself or herself as licensed must report such adverse incident, including all related information of which the health care practitioner has knowledge, to the department within 15 days after becoming aware of such adverse incident.

(3) The department shall review each incident report and determine whether the incident involves conduct by a health care practitioner which is subject to disciplinary action under s. 456.073. Disciplinary action, if any, must be taken by the appropriate regulatory board or by the department if no such board exists. If the department receives an adverse incident report involving conduct by an unlicensed individual, the department shall investigate the individual for unlicensed activity and take appropriate action under s. 456.065.

(4) A review panel is created within the department, in consultation with the Board of Medicine, the Board of Osteopathic Medicine, the Board of Nursing, and the Council of Licensed Midwifery, to review reported adverse incidents

involving a planned out-of-hospital birth.

(a) The panel shall be composed of one obstetrical medical physician, one obstetrical osteopathic physician, one certified nurse midwife, one paramedic, and one midwife, each of whom must have experience in out-of-hospital births and be appointed by the applicable board or council. The State Surgeon General or his or her designee shall serve as the chair and a nonvoting member of the panel. The panel shall meet quarterly and as often as necessary to perform its duties under this subsection and may conduct its meetings using any method of telecommunication. Panel members shall serve without compensation but may receive reimbursement for per diem and travel expenses as provided in s. 112.061.

(b) Based on its review of reported adverse incidents under this subsection, the panel shall collaborate with experts in data collection and public health to identify any patterns or trends linking certain adverse incidents to any licensed health care practitioner providing planned out-of-hospital births, identify causes for such patterns or trends, and make recommendations for changes to address causes for adverse incidents identified in the panel's review.

(c) By July 1 of each year, the panel shall report its collaborative findings and recommendations to the department, the Board of Medicine, the Board of Osteopathic Medicine, the Board of Nursing, and the Council of Licensed Midwifery.

(5)(a) Using data collected from adverse incident reports submitted under this section, from certificates of live birth and certificates of fetal death filed with its Office of Vital Statistics, and from information submitted by licensed midwives

to the Council of Licensed Midwifery, the department or its designee shall, at a minimum:

1. Analyze data relating to the frequency and nature of adverse incidents in planned out-of-hospital births;

2. Identify the rate of adverse incidents by the type of adverse incident and attending health care practitioners or unlicensed individuals;

3. Identify any patterns or trends linking types of adverse incidents to attending health care practitioners or unlicensed individuals, and study causes for such patterns or trends;

4. Compare the findings to any comparable research and data associated with out-of-hospital births available from other states; and

5. Make recommendations for policy changes that may reduce the rate of adverse incidents in planned out-of-hospital births in this state.

(b) By July 1 of each year, the department shall submit a report of its findings and any recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives. The report shall also be published on the department's website. All information in the report must be deidentified.

(6) ~~(4)~~ The department shall adopt rules to implement this section and shall develop a form to be used for the reporting of adverse incidents.

Section 4. Section 456.0496, Florida Statutes, is created to read:

456.0496 Out-of-hospital births; continuing education requirements; responsibilities; violations and penalties;

grounds for discipline; enforcement.—

(1) CONTINUING EDUCATION REQUIREMENTS.—

(a) A licensed health care practitioner who provides out-of-hospital births shall biennially satisfy the following continuing education hours as a condition for renewal of his or her license:

1. Three hours of instruction on the risk of complications during pregnancy, labor, and delivery.

2. Four hours of instruction on ethics and collaborative care, including informed consent, patient confidentiality, patient relationships, transportation from a home or birth center to a hospital, and malpractice and negligence.

(b) The department shall prescribe by rule continuing education requirements as a condition for renewal of a license. The criteria for continuing education programs must be approved by the department. Any individual, institution, organization, or agency that is approved by the department to provide continuing education programs for the purpose of license renewal to a licensed health care practitioner providing out-of-hospital births must demonstrate that such programs comply with all of the following requirements:

1. The programs have clinical relevance to practitioners providing out-of-hospital birth.

2. The programs are at least 1 clock hour in duration.

3. The programs have an organized structure with objectives and expected outcomes.

4. Each presenter, instructor, or facilitator of a program is a recognized professional, such as a physician, nurse, certified nurse midwife, psychologist, or licensed midwife.

(2) RESPONSIBILITIES OF A HEALTH CARE PRACTITIONER.—A licensed health care practitioner providing out-of-hospital births shall do all of the following:

(a) Upon acceptance of a patient into care, advise the patient of the clinical outcomes of births in low-risk patients during an out-of-hospital birth and any increased risks associated with an individual having a vaginal birth after having a caesarean section, a breech birth, or a multiple gestation pregnancy. The licensed health care practitioner providing out-of-hospital births shall further advise, but may not require, the patient to consult an obstetrician for more information related to such clinical outcomes and increased risks.

(b) Prepare a written plan of action with the family to ensure continuity of medical care throughout labor and delivery and to provide for immediate medical care if an emergency arises. The family should have specific plans for medical care throughout the prenatal, intrapartal, and postpartal periods.

(c) If a home birth is planned, instruct the patient and family regarding the preparation of the home and ensure availability of equipment and supplies needed for delivery and infant care.

(d) Instruct the patient in personal hygiene and sanitary measures as they relate to pregnancy and in nutrition as it relates to prenatal care.

(e) Maintain equipment and supplies required for providing care during the intrapartum and immediate postpartum periods in an out-of-hospital setting.

(f) Upon initial contact with the patient during the

intrapartal period, measure and record the vital signs of the mother and fetus to serve as a baseline during labor and delivery.

(g) Transfer care of the patient to a hospital with obstetrical services in accordance with the written emergency plan if any of the following occurs or presents during labor or delivery or immediately thereafter:

1. An unexpected nonvertex presentation of the fetus;

2. Indication that the mother's uterus has ruptured;

3. Evidence of severe and persistent fetal or maternal distress;

4. Pregnancy-induced hypertension;

5. An umbilical cord prolapse;

6. Active infectious disease process; or

7. Any other severe emergent condition.

(3) INFORMED CONSENT.—The department shall develop a uniform patient informed consent form to be used by the licensed health care practitioner providing out-of-hospital births to inform the patient of the health care practitioner's qualifications and the nature and risk of the procedures to be performed by the health care practitioner and to obtain the patient's consent for the provision of out-of-hospital birth services. The form must be signed by the patient and the health care practitioner providing out-of-hospital births, and a copy must be provided to the patient. The form shall include, at a minimum, all of the following:

(a) A statement advising the patient of the clinical outcomes of births in low-risk patients during an out-of-hospital birth and any increased risks associated with having a

vaginal birth after having a caesarean section, a breech birth, or a multiple gestation pregnancy.

(b) A detailed statement explaining to the patient hospital admitting privileges and the requirements to obtain and maintain such privileges.

(c) Disclosure of each hospital and specific department, if any, where the health care practitioner providing out-of-hospital births has been granted admitting privileges, including the scope and duration of the admitting privileges, the current contact information for the specific hospital or department that has granted the health care practitioner admitting privileges, and a copy of documentation from the hospital or department providing proof of such admitting privileges. A health care practitioner providing out-of-hospital births who does not have admitting privileges at any hospital must explicitly state that fact on the form.

(4) VIOLATIONS AND PENALTIES.—

(a) A person who knowingly conceals or fraudulently misrepresents information or a requirement relating to the practice of out-of-hospital birth commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) The fraudulent misrepresentation of a requirement relating to the practice of out-of-hospital birth is grounds for denial of a license or disciplinary action, as specified in s. 456.072(2).

(5) GROUNDS FOR DISCIPLINE; PENALTIES; ENFORCEMENT.—If the ground for disciplinary action is a first-time violation of a practice act for unprofessional conduct, as used in ss.

464.018(1)(h), 467.203(1)(f), 468.365(1)(f), and 478.52(1)(f), and no actual harm to the patient occurred, the board or department, as applicable, shall issue a citation in accordance with s. 456.077 and assess a penalty as determined by rule of the board or department.

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 29th, 2020

I respectfully request that **Senate Bill #1764**, relating to Child Birth, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Anitere Flores

Senator Anitere Flores
Florida Senate, District 39

2020 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Florida Department of Health

BILL INFORMATION	
BILL NUMBER:	HB 1255
BILL TITLE:	Childbirth
BILL SPONSOR:	Mercado
EFFECTIVE DATE:	7/1/2020

COMMITTEES OF REFERENCE
1) Health Quality Subcommittee
2) Health Care Appropriations Subcommittee
3) Health & Human Services Committee
4) Click or tap here to enter text.
5) Click or tap here to enter text.

CURRENT COMMITTEE
Health Quality Subcommittee

SIMILAR BILLS	
BILL NUMBER:	SB 1764
SPONSOR:	Flores

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:	1/22/2020
LEAD AGENCY ANALYST:	Claudia Kemp
ADDITIONAL ANALYST(S):	Click or tap here to enter text.
LEGAL ANALYST:	Louise St. Laurent
FISCAL ANALYST:	Jonathan Sackett

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

The bill requires a certificate for fetal death or live birth to include certain information. Health care practitioners are required to submit adverse incident reports to the Department of Health and the department must investigate certain reports based on whether the person involved was engaging in unlicensed activity. The panel created by the bill will review reported adverse incidents that involve a planned out-of-hospital birth and report its findings and recommendations to the department, Board of Medicine, Board of Osteopathic Medicine, Board of Nursing, and the Council on Licensed Midwifery by July 1 of each year. The department will submit a report of its findings and recommendations to the Governor, President of the Senate, and the Speaker of the House by July 1 of each year. The bill provides continuing education and patient consultation requirements for certain health care practitioners, provides requirements for patient informed consent for and provides penalties.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

Section 382.008, Florida Statutes (F.S.), Death, fetal death, and nonviable birth, requires that a certificate of each fetal death that occurs in the state must be filed with the department either electronically or on a form prescribed by the department within 5 days of the death. This section provides the requirements for the information that must be provided in the certificate and requirements for those persons involved in completing and filing the certificate.

Section 382.013, F.S., Birth registration, has 4 subsections: Filing, Paternity, Name of child, and Disclosure. A certificate for each live birth in the state must be filed within 5 days after the birth with the local registrar of the district where the birth occurred.

Section 456.0495, F.S., Reporting adverse incidents occurring in planned out-of-hospital births, requires health care practitioners specified in s. 456.001(4), F.S., to report any adverse incident, as defined by department rule, relating to an attempted or completed non-hospital birth or a birth occurring at a planned birthing center. The adverse incident, along with a medical summary of events must be reported to the department within fifteen days of the incident.

The department developed a form for reporting adverse incidents including, but not limited to: Maternal deaths that occur during delivery or within 42 days after delivery; Transfers of maternal patients to a hospital intensive care unit; Maternal patients who experience hemorrhagic shock or who require a transfusion of more than four units of blood or blood products; Fetal or infant deaths, including stillbirths, associated with obstetrical deliveries; Transfers of infants to a neonatal intensive care unit due to a traumatic physical or neurological birth injury; and Transfers of infants to a neonatal intensive care unit within the first 72 hours after birth if the infant remains in such unit for more than 72 hours.

According to the Bureau of Enforcement's Consumer Services Unit, there were 21 out-of-hospital birth adverse incidents reported from 01/01/2019 – 01/17/2020. 9 of those cases involved a death of either the child or the mother.

In addition, Rule 64B24-7.014(6), F.A.C., requires each licensed midwife to file an Annual Report of Midwifery practice (DH-MQA 5011). These reports include information about the number of patients accepted for care, the number and reasons for each transfer of care during the pre-partum, antepartum and post-partum periods.

The midwifery report includes only births attended by a licensed midwife. It does not include out-of-hospital births attended by a nurse midwife or obstetrician. The adverse incident report includes all out-of-hospital births in any out-of-hospital settings.

The Unlicensed Activity (ULA) section of Medical Quality Assurance’s Bureau of Enforcement reviews and investigates incidents/complaints of alleged unlicensed activity.

ULA cases (Medical Quality Assurance's 2018-2019 Annual Report) related to midwifery:

- 2017-2018 3
- 2018-2019 2
- 2019-2020 0

For sections 1 and 2 of HB 1255, the birth and fetal death certificate captures the name, location and specific type of facility where the delivery occurred. Facility type options are hospital, birthing center, clinic/doctor's office, home or another designated place. On current birth and fetal certificates, home births are the only type that requires completion of an additional question of whether the home delivery was planned.

The attendant on the birth certificate is the person who was present at the time of delivery. The attendant is usually a health care clinician (i.e. physician, nurse, midwife), but can also include non-clinicians, such as a family member or any other person that was present at the time of the delivery. The certifier on the birth certificate is the person who attests to the facts presented on the birth certificate but may not have been present at the time of delivery. The attendant and the certifier may be the same person.

There is a minor difference on the certifier designation for the current fetal death certificate. The certifier on the fetal death certificate must be a physician who attests to the cause of death and the facts of delivery. The attendant on the fetal death certificate is the person who was present at the time of delivery. The attendant and the certifier may be the same person. However, if the attendant is not a physician, then the certifier must be a physician or a medical examiner.

The birth certificate also captures information if the mother was transferred from another facility to the place where she delivers, or if the infant was transferred to another facility within 24 hours after delivery. The transfer information is currently recorded if a birthing facility/hospital is involved.

- The current fetal death certificate does not capture any transfer information on the mother or infant.

2. EFFECT OF THE BILL:

Sections 1 and 2—No impact on DoH

Section 3

The bill amends s. 456.0495 (1), F.S., and adds the transfer of a maternal patient or newborn from an out-of-hospital birth setting to a hospital during the prenatal, intrapartal, or postpartal periods that results in fetal or maternal morbidity or mortality as a trigger for complying with the requirements for reporting adverse incidents under this section.

The bill amends subsection (2) and provides that a health care practitioner who is required under this section to report adverse incidents must report an adverse incident involving unlicensed individuals who were not appropriately licensed in the state but represented themselves as licensed. The report must be submitted to the department within 15 days of the adverse incident.

The bill amends subsection (3) to provide that if the department receives an adverse incident report involving conduct by an unlicensed individual, the department will investigate the individual for unlicensed activity.

The bill creates subsection (4) and provides that a review panel is created within the department in consultation with the Boards of Medicine, Osteopathic Medicine, Nursing, and the Council of Licensed Midwifery. The panel will review reported adverse incidents that involve a planned out-of-hospital birth.

The panel will be comprised of: one obstetrical medical physician, one obstetrical osteopathic physician, one certified nurse midwife, one paramedic and one midwife. These members must have experience in out-of-hospital births and be appointed by their respective board or council. The State Surgeon General, or their designee, will serve as chair of the panel and a nonvoting member. The panel will meet quarterly or more often if necessary. The panel may conduct its meetings by telecommunication. The panel will review the adverse incident reports required under this subsection and collaborate with experts in data collection and public health to identify patterns or trends that may link certain adverse incidents to licensed practitioners performing planned out-of-hospital births, identify causes for the patterns or trends, and make recommendations for changes.

The panel will report its findings and recommendations to the department, Board of Medicine, Board of Osteopathic Medicine, Board of Nursing, and the Council on Licensed Midwifery by July 1 of each year.

The department, or its designee, will use the data collected from the adverse incident reports required under this subsection, certificates of live births and fetal deaths, and information submitted by The Council of Licensed Midwifery, and will, at a minimum:

- Analyze data related to the frequency and nature of adverse incidents in planned out-of-hospital births;

- Identify the rate by type of adverse incidents and the attending health care practitioners or unlicensed individuals;
- Identify patterns or trends that link types of adverse incidents to attending health care practitioners or unlicensed individuals, and study causes for those patterns or trends;
- Compare the findings to comparable research and data available from other states; and
- Make recommendations for policy changes that may reduce the number of adverse incident reports.

The department will submit a report of its findings and recommendations to the Governor, President of the Senate, and the Speaker of the House by July 1 of each year. The department will deidentify all information in the report and post the report to its website.

The bill requires the report from the panel to be provided by July 1 each year and the department's report, which is based on the panel report, to also be provided by July 1 each year. The reports for the same period from the panel and the department cannot be submitted contemporaneously by July 1 of each year.

The bill creates s. 456.0496, F.S., titled “Out-of-hospital births; continuing education requirements; responsibilities; violations and penalties; grounds of discipline; penalties; enforcement.”

Subsection (1) provides continuing education requirements for a licensed health care practitioner who provides planned out-of-hospital births. As a condition of renewal these practitioners must biennially complete:

- 3 hours on the risk of complications during pregnancy, labor and delivery; and
- 4 hours on ethics and collaborative care including informed consent, patient confidentiality, patient relationships, transportation from a home or birth center to a hospital, and malpractice and negligence.

The department will prescribe by rule continuing education program requirements as a condition for renewal. The department will also approve the criteria for these programs. If an individual or entity is approved by the department to provide these continuing education programs, these criteria must be met:

- Have clinical relevance to practitioners providing out-of-hospital births;
- Be at least one clock hour in duration; Have an organized structure with objectives and expected outcomes; and
- Presenters, instructors, or facilitators must be a recognized professional such as a physician, nurse, certified nurse midwife, psychologist, or licensed midwife.

Subsection (2) provides the responsibilities for health care practitioners. A licensed health care practitioner providing out-of-hospital births must:

- After accepting a patient into care, advise the patient about clinical outcomes of births in low-risk patients, increased risks associated with a patient who is having a vaginal birth after cesarean section, breech birth, or multiple gestation pregnancy, and advise but not require a patient to consult an obstetrician for more information about outcomes and risks;
- Prepare a written plan of action with the family to ensure continuity of medical care throughout labor and delivery and provide for immediate medical care in case of emergency. The family should have specific plans for medical care during prenatal, intrapartal, and postpartal periods;
- Provide instructions to family on how to the prepare the home and ensure availability of equipment and supplies when planning a home birth;
- Provide instructions to the patient about personal hygiene and sanitary measures related to pregnancy and nutrition;
- Maintain equipment and supplies required for providing care;

- After initial contact with patient during the intrapartal period, measure and record the mother's and fetus' vitals to serve as a baseline during labor and delivery;

- Transfer the patient for care to a hospital with obstetrical services according to the written emergency plan if any of these conditions occur during labor, delivery, or immediately after:

1. Unexpected nonvertex presentation of the fetus;

2. Indication that the mother's uterus has ruptured;

3. Evidence of severe and persistent fetal or maternal distress;

4. Pregnancy-induced hypertension;

5. Umbilical cord prolapses;

6. Active infectious disease process; or

7. Any other severe emergent condition.

Subsection (3) provides requirements for informed consent. The department will develop a uniform patient informed consent form. The form will be used by all licensed health care practitioners providing out-of-hospital births to inform the patient about the practitioner's qualifications, the nature and risk of the procedures the practitioner will use, and to obtain the patient's consent for providing out-of-hospital birth services. The patient and practitioner must sign the consent form and the patient must be provided with a copy. At a minimum, the form must include:

- A statement advising the patient about the clinical outcomes of births in low-risk patients and any increased risks associated with having a vaginal birth after a cesarean section, breech birth, or multiple gestation pregnancy;

- A detailed statement about hospital admitting privileges and the requirements to obtain and maintain these privileges; and

- Disclosure of all information and documentation, including locations, related to the health care practitioners admitting privileges or an explicit statement if the practitioner does not have admitting privileges at any hospital.

Subsection (4) addresses violations and penalties. Under the bill, any person who practices out-of-hospital births and knowingly conceals or fraudulently misrepresents information or requirements related to the practice commits a third-degree felony punishable under the applicable provisions in chapter 775, F.S. Fraudulent misrepresentation of the requirements related to this practice is grounds for denying a license or disciplinary action under s. 456.072(2), F.S.

Subsection (5) provides grounds of discipline, penalties and enforcement.

HB 1255 would require the Bureau of Vital Statistics to modify the current birth and fetal death certificates and its electronic registration system to collect some of the new information proposed, such as the planned deliveries and transfer information.

The Bureau would be able to modify the current Florida birth and fetal death certificates to include the intended/planned question on all birth locations instead of just the home birth. In addition, the mother transferred from and infant transferred to items on the birth certificate can be modified to capture any type of place, and not just facilities, if the information is available before the certificate is completed. (99% of all birth certificates are completed electronically within 48 hours). The transfer information would need to be added to the fetal death certificate to match the birth certificate. The Bureau of Vital Statistics currently collects information on the physician, certified nurse midwife or midwife involved in the delivery of a live birth and fetal death at the time of the delivery.

However, the Bureau of Vital Statistics does not have access to information of other health care professionals involved in the mother's prenatal care before she delivers nor of the health care professionals she visits after she delivers, or if the mother and/or baby are transferred. The Bureau also does not have licensure data on all professional medical certifiers, which could be addressed by developing a process with the Department's Division of Medical Quality Assurance to determine licensure status. Despite establishing an internal Department process, challenges would remain with recording information about all health care practitioners that treated the mother or fetus.

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:	The department will develop rules to implement the bill.
Is the change consistent with the agency's core mission?	Y☒ N☐
Rule(s) impacted (provide references to F.A.C., etc.):	N/A

***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:	The bill creates a panel that will be comprised of one obstetrical medical physician, one obstetrical osteopathic physician, one certified nurse midwife, one paramedic, and one midwife. These members must have experience in out-of-hospital births and be appointed by their respective board or council. The State Surgeon General, or their designee, will serve as chair of the panel and a nonvoting member. The panel will report its findings and recommendations to the department, Board of Medicine, Board of Osteopathic Medicine, Board of Nursing, and the Council on Licensed Midwifery by July 1 of each year. The department will submit a report of its findings and recommendations to the Governor, President of the Senate, and the Speaker of the House by July 1 of each year. The department will deidentify all information in the report and post the report to its website.
Date Due:	7/1/2021
Bill Section Number(s):	Section 3

6. ARE THERE ANY NEW GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSIONS, ETC. REQUIRED BY THIS BILL? Y☐ N☒

Board:	N/A
Board Purpose:	N/A
Who Appoints:	N/A
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:	N/A
Expenditures:	N/A
Does the legislation increase local taxes or fees? If yes, explain.	N/A
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?	N/A

2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT? Y☒ N☐

Revenues:	None
Expenditures:	DOH/MQA may experience a recurring increase in workload and costs associated with investigations for unlicensed activity related to out-of-hospital births. The impact is unknown, yet it is anticipated that current resources and budget authority are adequate to absorb. DOH/MQA will experience a recurring increase in workload and costs associated with the creation of a review panel within the department. The panel will meet at least quarterly and can be conducted either in person or by telecommunication. The department, or its designee, will analyze the data collected and make recommendations. The impact is unknown, yet it is anticipated that current resources and budget authority are adequate to absorb. DOH/MQA will experience a non-recurring increase in workload associated with the development of a uniform patient informed consent form, which current resources are adequate to absorb. DOH/MQA will incur non-recurring costs for 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:	N/A

Expenditures:	N/A
Other:	N/A

4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y☐ N☒

If yes, explain impact.	N/A
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☐

If yes, describe the anticipated impact to the agency including any fiscal impact.	DOH/MQA will experience a non-recurring increase in workload associated with updating its continuing education tracking system and the system interfaces with its vendor, CE Broker

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.	N/A

ADDITIONAL COMMENTS

Requiring licensees to report every transfer of care, especially for transfers occurring prepartum, may result in a significant amount of reporting to the Department that does not provide meaningful outcome data to the review panel or for subsequent reporting and publication. This bill would require every patient who contacts an out-of-hospital healthcare provider and is accepted for care, who is told after risk assessment that they do not qualify for care in an out-of-hospital setting to report to the Department.

LEGAL - GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	Line 82 requires a certificate of live birth to include the intended place of birth. Birth certificates are vital records which are collected using uniform forms approved by the national association of registrars. The current approved uniform birth record form will now accommodate this information. Further, the requirement is subject to challenge as vague.

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/4/2020
Meeting Date

SB 1764
Bill Number (if applicable)

Topic Childbirth

Amendment Barcode (if applicable)

Name Riva Majewski

Job Title

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Speaking: ☑ For ☐ Against ☐ Information

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

Representing self + husband

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)

2/4/2020
Meeting Date

SB 1764
Bill Number (if applicable)

Topic Childbirth

Amendment Barcode (if applicable)

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Speaking: ☑ For ☐ Against ☐ Information

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

Representing self + husband

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

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2/4/2020
Meeting Date

1764
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic child birth

Name Ron Watson

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

Representing Midwives Association of Florida

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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2/4/2020
Meeting Date

SB 1764
Bill Number (if applicable)

Topic Childbirth

Amendment Barcode (if applicable)

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing American College of Obstetricians · Gynecologists

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

2-4-2020 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) 1764

Meeting Date *Bill Number (if applicable)*

Topic SB 1764 Flores Childbirth Bill *Amendment Barcode (if applicable)*

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

Representing

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/4/2020
Meeting Date

SB 1764
Bill Number (if applicable)

Topic Childbirth

Amendment Barcode (if applicable)

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Association for Women Lawyers

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)

2/4/2020
Meeting Date

1764
Bill Number (if applicable)

921390
Amendment Barcode (if applicable)

Topic Childbirth

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Speaking: ☐ For ☐ Against ☒ Information

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

Representing Midwives Association of Florida

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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2/4/20
Meeting Date

1764
Bill Number (if applicable)

921390
Amendment Barcode (if applicable)

Topic Childbirth

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

Representing Florida 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.

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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:	CS/SB 1676
INTRODUCER:	Health Policy Committee and Senator Albritton
SUBJECT:	Direct Care Workers
DATE:	February 5, 2020
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1676 expands the scope of practice and defines relevant terms for registered nurses (RNs), certified nursing assistants (CNAs), and home health aides. The bill authorizes:

- Nursing home facilities to use paid feeding assistants if the assistant has completed a 12 hour program developed by the Agency for Health Care Administration (AHCA);
- An RN to delegate specific tasks, including medication administration, to CNAs and home health aides under specified conditions and provides grounds for disciplinary action for RNs who delegate to unqualified persons;
- A CNA to perform tasks delegated to him or her by an RN including the administration of prescription medications, except controlled substances, under specific circumstances;
- A home health aide to perform tasks delegated to him or her by an RN including the administration of prescription medications, except controlled substances, under specific circumstances;
- An unlicensed person, under certain circumstances, to assist a patient with intermittent positive pressure breathing treatments and nebulizers; and
- The AHCA to create the Excellence in Home Health Program (Program) for the purpose of awarding designations to home health agencies that meet specified criteria.

The bill takes effect 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:

Sections 1 and 2 amend ss. 400.141 and 400.23, F.S., within part II of ch. 400, F.S., relating to nursing homes, to provide that a licensed nursing home facility may use paid feeding assistants as defined in 42 C.F.R. s. 488.301, in accordance with 42 C.F.R. s. 483.60, if the paid feeding assistant has successfully completed a feeding assistant training program developed by the AHCA. The feeding assistant training program must consist of a minimum of 12 hours of education and training and must include all of the topics and lessons specified in the program curriculum. The program curriculum must include training in all of the following content areas:

- Feeding techniques;
- Assistance with feeding and hydration;
- Communication and interpersonal skills;
- Appropriate responses to resident behavior;
- Safety and emergency procedures, including the first aid procedure used to treat upper airway obstructions;
- Infection control;
- Residents' rights; and
- Recognizing changes in residents which are inconsistent with their normal behavior, and the importance of reporting those changes to the supervisory nurse.

The AHCA may adopt rules to implement these provisions.

Sections 3 through 8 of the bill amend or create statutes within part III of ch. 400, F.S., relating to home health agencies.

Section 3 amends s. 400.462, F.S., to redefine "home health aide" to provide that, in addition to the definition's other provisions, a home health aide may include a person who performs tasks delegated to him or her pursuant to ch. 464, F.S.

Section 4 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 5 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 6 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.

To remain qualified to administer medications as provided above, 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 7 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. As noted above, this provision is created within part III of ch. 400, F.S., relating to home health agencies.

Section 8 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; and
- 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; and
- 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 9 creates s. 408.822, F.S., within part II of ch. 408, F.S., relating to health care licensing, 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 or homemaker services provider;
- Paid feeding assistant trained under s. 400.141(1)(v), F.S.; or
- Provider of personal care as defined in s. 400.462(24), F.S., to individuals who are elderly, developmentally disabled, or chronically ill.

Under the bill, 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 registered nurses and the number of direct care workers by category employed;
- The turnover and vacancy rates of registered nurses and direct care workers and contributing factors to these rates;
- The average employee wage for registered nurses and each category of direct care worker;
- The employment benefits provided for registered nurses and direct care workers and the average cost of such benefits to the employer and the employee; and
- The type and availability of training for registered nurses and 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.

Sections 10 and 11 of the bill amend or create statutes within part I of ch. 464, F.S., relating to the Nurse Practice Act.

Section 10 creates s. 464.0156, F.S., to authorize RNs to delegate a task to a CNA or a home health aide if the registered nurse determines that the CNA or home health aide is competent to perform the task, the task is delegable under federal law, and the task:

- 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; and

- Does not endanger a patient's life or well-being.

If a CNA or home health aide satisfies the qualifications and training 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,[15] by the following routes: oral, transdermal,[16] ophthalmic, otic, rectal, inhaled, enteral,[17] or topical.

The BON, in consultation with the AHCA, is required to adopt rules to implement this section of the bill.

Section 11 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 a nurse's delegation of professional responsibilities to a person when the nurse knows or has reason to know that such person is not qualified by training, experience, certification, or licensure to perform them.

Section 12 creates s. 464.2035, F.S., within part II of ch. 464, F.S., relating to certified nursing assistants, to expand the scope of practice of CNAs by providing that a CNA may administer oral, transdermal, ophthalmic, otic, rectal, inhaled, enteral, or topical prescription medication to a patient of a home health agency if the CNA has:
- Been delegated such task by an RN;
- Satisfactorily completed an initial six-hour training course approved by the BON; and
- Been found competent to administer medication to such a patient in a safe and sanitary manner.

The training, determination of competency, and initial and annual validations must be conducted by a licensed RN or a physician licensed under chapter 458 or 459, F.S.

To remain qualified to administer medications as provided above, a CNA must annually and satisfactorily complete two hours of inservice training in medication administration and medication error prevention approved by the BON, in consultation with the AHCA. The inservice training required under the bill is in addition to other annual inservice training hours required under current law.

The bill requires the BON, in consultation with the AHCA, to establish by rule standards and procedures that a CNA 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;

[15] Controlled substance listed in Schedule II, Schedule III, or Schedule IV of s. 893.03 or 21 U.S.C. s. 812.
[16] *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.
[17] *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 storage and disposal of medication;
- Instructions concerning the safe administration of medication;
- Informed-consent requirements and records, and;
- Training curriculum and validation procedures.

Section 13 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. The program is likely to have a recurring negative fiscal impact on the AHCA.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 400.141, 400.23, 400.462, 400.464, 400.488, and 464.018.

This bill creates the following sections of the Florida Statutes: 400.489, 400.490, 400.52, 408.822, 464.0156, and 464.2035.

IX. Additional Information:

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

CS by Health Policy on February 4, 2020:
The CS:

- Removes from the underlying bill a provision for non-nursing staff providing eating assistance to residents of a nursing home to count toward the nursing home's compliance with minimum staffing standards;
- Authorizes nursing home facilities to use paid feeding assistants as defined under federal law if the assistant has completed a 12-hour program developed by the AHCA;
- Removes from the underlying bill the specific authorization within nursing home statutes for a CNA to perform any task delegated to him or her by an RN, including, medication administration, in a nursing home setting;
- Removes from the underlying bill provisions to establish a Home Care Services Registry; and
- Removes from the underlying bill the specific authorization within CNA statutes for a CNA to administer medications to nursing home residents if delegated such a task by an RN.

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

Committee Agenda Request

To: Senator Gayle Harrell, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 22, 2020

I respectfully request that **Senate Bill #1676**, relating to Direct Care Workers, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Ben Albritton
Florida Senate, District 26

File signed original with committee office

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/4/2020
Meeting Date

SB 1676
Bill Number (if applicable)

414062 DE
Amendment Barcode (if applicable)

Topic Direct Care Workers

Name Marcus Dixon

Job Title

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Email Marcus.Dixon@SEIUFL.ORG

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

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

Representing SEIU 1199 Healthcare Workers

Appearing at request of Chair: [ ] Yes [X] No

Lobbyist registered with Legislature: [X] 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)

2/4/20
Meeting Date

SB 1676
Bill Number (if applicable)

414062
Amendment Barcode (if applicable)

Topic Direct Care Staffing

Name Susan Langstm

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing Leading Age Florida

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)

2/4/20
Meeting Date

1676
Bill Number (if applicable)

414062
Amendment Barcode (if applicable)

Topic DIRECT CARE

Name JACK McRAY

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing AARP

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)

2/04/2020
Meeting Date

1676
Bill Number (if applicable)

Topic Pressing Need for Personal Care Workers
Amendment Barcode (if applicable)

Name Bobby Lolley

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Speaking: ☑ For ☐ Against ☐ Information

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

Representing Home Care Industry

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)

2/4/20
Meeting Date

1676
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Bob Asztalos

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Health Care 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)

2/4/20
Meeting Date

1167c
Bill Number (if applicable)

Topic Direct Care Workers

Amendment Barcode (if applicable)

Name Jennifer Ungru

Job Title

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Street

Phone 850 999 - 9900

City *State* *Zip*

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing Home Care Association of America

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

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:	CS/SB 1544
INTRODUCER:	Health Policy Committee and Senator Albritton
SUBJECT:	Long-term Care
DATE:	February 6, 2020
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1544 amends s. 409.979, F.S., to provide additional clarity for individuals on the Medicaid long term care managed care waitlist regarding the likelihood that he or she will be eligible for services through the program and amends s. 430.205, F.S., to allow a community-care-for-the-elderly service provider to dispute a referral from protective investigations of an elderly adult determined to be in need of services or to be the victim of abuse.

The bill is effective July 1, 2020.

II. Present Situation:

Statewide Medicaid Managed Care

The Statewide Medicaid Managed Care (SMMC) program is an integrated managed care program for Medicaid enrollees to provide all mandatory and optional Medicaid benefits. In the SMMC program, each Medicaid recipient has one managed care organization to coordinate all health care services, rather than various entities.[1] The SMMC program is administered by the Agency for Health Care Administration (AHCA) and is financed with federal and state funds.[2]

[1] This comprehensive coordinated system of care was first successfully implemented in the 5-county Medicaid reform pilot program from 2006-2014.
[2] Section 409.963, F.S.

Eligibility for the SMMC program is determined by the Department of Children and Families (DCF).[3]

Within the SMMC program, the Managed Medical Assistance (MMA) program provides primary and acute medical assistance and related services to enrollees. The Long-Term Care Managed Care (LTC) Program provides services to frail elderly or disabled Medicaid recipients in nursing facilities and in community settings, including an individual's home, an assisted living facility, or an adult family care home.

Implementation of the LTC Program required approval by the federal Centers for Medicare & Medicaid Services (CMS) by virtue of 1915(b) and (c) waivers submitted by the AHCA. The waivers were approved on February 1, 2013, and authorized the LTC Program to operate effective July 1, 2013, through June 30, 2016.[4] Initial enrollment into the LTC Program began August 1, 2013.

Long-Term Care Program

The LTC Program provides long term care services, including nursing facility and home and community based services, to eligible Medicaid recipients.

Federal law requires state Medicaid programs to provide nursing facility services to individuals, age 21 or older, who are in need of nursing facility care.[5] States are prohibited from limiting access to nursing facility services, but the provision of home and community based services is optional.[6] Home and community based services in Florida are delivered through a federal 1915(c), home and community based services waiver.[7] The waiver establishes that home and community based LTC services are available to qualified recipients, subject to an enrollment cap. As such, the LTC program is managed based on a priority enrollment system and a waitlist for individuals who are not high-priority clients. Delivery of home and community based services to eligible recipients is dependent on the availability of annual funding.

As of December 31, 2019, there were 116,507 individuals enrolled in the LTC Program, including 65,822 individuals enrolled in the home and community based services portion of the LTC Program, and 50,685 individuals receiving nursing facility services.[8]

Long-term care managed care plans are required to, at a minimum, cover the following:

- Nursing facility care;

---

[3] *Id.*

[4] Letter from U.S. Department of Health and Human Services, Disabled and Elderly Health Programs Group to Justin Senior, Deputy Secretary for Medicaid, Agency for Health Care Administration (February 1, 2013), *available at* http://ahca.myflorida.com/medicaid/Policy_and_Quality/Policy/federal_authorities/federal_waivers/docs/mma/Signed_approval_FL0962_new_1915c_02-01-2013.pdf (last visited Jan. 31, 2020).

[5] Medicaid.gov, *Nursing Facilities*, available at https://www.medicaid.gov/medicaid/long-term-services-supports/institutional-long-term-care/nursing-facilities/index.html (last visited Jan. 31, 2020).

[6] *Id.*

[7] Section 409.906(13), F.S.

[8] Agency for Health Care Administration, *SMMC LTC Enrollment by County/Plan Report* (as of December 31, 2019), *available at* http://ahca.myflorida.com/Medicaid/Finance/data_analytics/enrollment_report/index.shtml (last visited Jan. 31, 2020).

- 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;
- Occupation therapy;
- Speech therapy;
- Respiratory therapy;
- Physical therapy;
    - Intermittent and skilled nursing;
    - Medication administration;
    - Medication Management;
    - Nutritional assessment and risk reduction;
    - Caregiver training;
    - Respite care;
    - Transportation; and
    - Personal emergency response systems.[9]

LTC Program Eligibility

To be eligible for the LTC Program, an individual must:

- Be age 65 or older and eligible for Medicaid, or age 18 or older and eligible for Medicaid by reason of a disability;
- Have annual income at or below 222 percent of the federal poverty level (FPL);[10] and,
- Be in need of nursing home care, as determined by the Comprehensive Assessment Review and Evaluation for Long-Term Care Services (CARES) Program.[11]

In addition, an individual seeking Medicaid eligibility must demonstrate that he or she meets limits on personal assets. Both federal and state law set parameters for Medicaid LTC eligibility based on personal property, such as a home or vehicle, and on financial assets, such as bank accounts, stocks and bonds, and life insurance policies.[12] Life insurance policies with a cash value greater than $1,500 may not be retained by individuals seeking Medicaid eligibility.

[9] Section 409.98, F.S.
[10] This equates to $28,327 for an individual and $38,273 for a family of two. For 2020 FPL standards, see U.S. Department of Health and Human Services, *HHS Poverty Guidelines for 2020* (January 8, 2020), *available at* https://aspe.hhs.gov/poverty-guidelines (last visited Jan. 31, 2020).
[11] Section 409.979(1), F.S.
[12] U.S. Department of Health and Human Services, *Financial Requirements – Assets* (last modified October 10, 2017), *available at* https://longtermcare.acl.gov/medicare-medicaid-more/medicaid/medicaid-eligibility/financial-requirements-assets.html (last visited Jan. 31, 2020).

Generally, assets above certain cash thresholds must be divested at least 60 months prior to a period of Medicaid eligibility.[13]

When determining the need for nursing facility care, the DOEA considers the nature of the services prescribed, the level of nursing or other health care personnel necessary to provide such services, and the availability of and access to community or alternative resources.[14] Imminent risk of nursing home placement can be evidenced by the need for medical observation throughout a 24-hour period and the need for care performed on a daily basis by, or under the direct supervision of, a registered nurse or other health care professional. An individual at risk of nursing home care requires services that are sufficiently medically complex to require supervision, assessment, planning, or intervention by a registered nurse because of a mental or physical incapacitation.[15]

LTC Program Enrollment

The DOEA administers programs and services for elders through 11 Area Agencies on Aging (AAAs), which also operate Aging and Disability Resource Centers (ADRCs). The ADRCs provide information and referral services to individuals seeking long-term care services and also screen individuals for eligibility for long-term care services.

The LTC Program enrollment process is administered by the DOEA, the DCF, and the AHCA. An individual in need of services or seeking services must contact the appropriate ADRC to request a screening. The screening is intended to provide the ADRC with information describing the individual's level of frailty. During the screening, the ADRC gathers basic information about the individual, including general health information and any assistance the individual needs with activities of daily living. Based on the screening, the individual receives a priority score, which indicates the level of need for services and reflects the level of the individual's frailty. Using the priority score, the individual is then placed on the waitlist. An individual seeking LTC services may request a rescreening any time his or her circumstances change. In addition, ADRC staff are required to rescreen waitlisted individuals on an annual basis.[16]

The prioritization of the waitlist is not described in statute but rather in administrative rule promulgated by the AHCA.[17] The rule sets five frailty-based levels based on the priority score calculation by the DOEA. The levels rank the individual's level of need in ascending order, meaning that an individual with a priority score of "1" has very low needs and an individual with a priority score of "5" has very high needs.

When funding becomes available, the frailest individuals are taken off the waitlist first, based upon priority score. The individual must then go through a comprehensive face-to-face

[13] 42 U.S.C. §1396p. See also Agency for Health Care Administration, *Medicaid State Plan Attachments – Eligibility Conditions and Requirements*, available at https://ahca.myflorida.com/medicaid/stateplan_attach.shtml (last visited Jan. 31, 2020).
[14] Section 409.985(3), F.S.
[15] Section 409.985(3), F.S.
[16] Section 409.979(3), F.S.
[17] Rule 59G-4.193, F.A.C.

assessment conducted by the local CARES staff.[18] After CARES confirms the medical eligibility of the individual, the DCF determines the financial eligibility of the individual. If the individual is approved for both medical and financial eligibility, the AHCA must notify him or her and provide information on selecting a long-term care managed care plan.

Because the waitlist is prioritized, it is highly unlikely that individuals with low priority scores will actually receive services. It is the DOEA's current practice to add any individual who completes the initial needs screening to the wait list, even if he or she has very limited need for services and is unlikely to qualify for services in the near future. This approach may be confusing to individuals with low priority scores, giving the impression that services will become available at some point in time. In practice, only individuals with high priority scores will receive services. Current law stipulates an individual may request a rescreening if his or her circumstances change, which allows individuals with low priority scores the ability to move up the waitlist if need can be demonstrated.

Community Care for the Elderly

The Community Care for the Elderly (CCE) program provides community-based services in a continuum of care to help elders with functional impairments to live in the least restrictive and most cost-effective environment suitable to their needs.[19]

The CCE program provides a wide range of services to clients, depending on their needs. These services include, but are not limited to, adult day care, chore assistance, counseling, home-delivered meals, home nursing, legal assistance, material aid, medical therapeutic services, personal care, respite, transportation, and other community-based services. [20]

The DOEA administers the program through contracts with AAAs, which subcontract with CCE Lead Agencies. Service delivery is provided by 52 Lead Agencies around the state. The CCE program is not a component of Medicaid but rather is funded by a combination of state general revenue and client contributions. Clients are assessed a co-payment based on a sliding scale developed by the DOEA.[21]

To be eligible for the CCE program, an individual must be age 60 or older and functionally impaired,[22] as determined by an initial comprehensive assessment and annual reassessments.

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[18] Florida Department of Elder Affairs, *Comprehensive Assessment and Review for Long-Term Care Services (CARES)*, available at http://elderaffairs.state.fl.us/doea/cares.php (last visited Jan. 24, 2020). Comprehensive Assessment and Review for Long-Term Care Services (CARES) is Florida's federally mandated pre-admission screening program for nursing home applicants. A registered nurse or assessor performs client assessments. A physician or registered nurse reviews each application to determine the level of care that is most appropriate for the applicant. The assessment identifies long-term care needs, and establishes the appropriate level of care (medical eligibility for nursing facility care), and recommends the least restrictive, most appropriate placement. Federal law also mandates that the CARES Program perform an assessment or review of each individual who requests Medicaid reimbursement for nursing facility placement, or who seeks to receive home and community-based services through Medicaid waivers.

[19] Section 430.202, F.S.

[20] Florida Department of Elderly Affairs, *2019 Summary of Programs and Services – Section C: State General Revenue Programs* (January 2019), *available at* http://elderaffairs.state.fl.us/doea/sops.php (last visited Jan. 31, 2020).

[21] *Id.*

[22] Section 430.203(7), F.S.

Primary consideration for services is given to elders referred to the DCF's Adult Protective Services (APS) and determined by APS to be victims of abuse, neglect, or exploitation and in need of immediate services to prevent further harm.[23] Individuals not referred by APS may still receive services, but according to a prioritization which is based upon the potential recipient's frailty level and likelihood of institutional placement. The DOEA is also required to consider an applicant's income when prioritizing services. Those less able to pay for services must receive higher priority than those with a greater ability to pay for services.[24]

III. Effect of Proposed Changes:

Section 1 amends s. 409.979, F.S., to specify that Medicaid long term care managed care eligibility screenings, both annual and upon notification of a significant change in an individual's circumstances, are required for individuals with a high priority score and are not required, but are authorized, for individuals with a low priority score. After completing a screening or rescreening, the DOEA is required to place all individuals with a high priority score on the waitlist. The DOEA must maintain contact information for individuals with low priority scores and ADRC personnel must inform individuals with a low priority score of community resources available to assist them and inform them that they may contact the ADRC for a new assessment at any time if they experience a change in circumstances.

Section 2 amends s. 430.205, F.S., to allow a community-care-for-the-elderly service provider to dispute a referral from protective investigations of an elderly adult determined to be in need of services or to be the victims of abuse by requesting that the adult protective services program negotiate the referral placement of, and services provided to, the adult. If an agreement cannot be reached with the adult protective services program, the program's determination controls.

Section 3 establishes 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.

[23] Section 430.205(5)(a), F.S.
[24] Section 430.205(5)(b), F.S.

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:

Section 2 of the bill republishes current statutory language requiring vulnerable elderly persons to begin to receive services from the community-care-for-the-elderly services provider within 72 of being referred to the provider by protective investigations. The bill's new language added in that section allows the service provider to dispute such referral, however, it is unclear whether the bill would require this dispute to be resolved within the 72-hour time frame established in current law. The bill may need to be clarified on this point.

VIII. Statutes Affected:

This bill substantially amends sections 409.979 and 430.205 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 February 4, 2020:
The CS eliminates provisions of the underlying bill related to exempting the value of life insurance policies from an applicant's assets when applying for Medicaid. The bill also revises language related to placement of individuals on the LTC waitlist to make technical changes.

B. Amendments:

None.

By Senator Albritton

26-01529A-20 20201544__

A bill to be entitled

An act relating to elderly care; creating s. 409.9022, F.S.; providing applicability; prohibiting the Department of Children and Families, in determining Medicaid eligibility, from considering the cash surrender value of certain life insurance policies as assets if certain conditions are met; specifying requirements for a collateral assignment by a Medicaid applicant; requiring Medicaid recipients, or their guardians or legal representatives, to continue to pay premiums on such policies; requiring the deduction of the cost of premiums from a recipient's income for certain purposes; requiring the Agency for Health Care Administration to file a claim for the death benefit upon the recipient's death; specifying requirements for the payment of a certain funeral expense benefit by the state and the distribution of remaining balances by the issuer of the policy; providing that certain transfers constitute improper asset transfers unless certain conditions are met; requiring the Department of Children and Families and the agency, in collaboration with the Office of Insurance Regulation, to adopt rules; authorizing the agency to seek a federal waiver; amending s. 409.979, F.S.; revising the individuals who must be rescreened annually by aging resource centers under the Medicaid long-term care managed care program; revising the individuals who must be placed on the wait list for potential enrollment for certain services; requiring that

certain other individuals be placed on a registry of interest maintained by the Department of Elderly Affairs; requiring personnel of the aging resource center to provide certain information to individuals on the registry of interest; providing construction; requiring the Department of Elderly Affairs to notify individuals or their authorized representatives of placement on the registry of interest; amending s. 430.04, F.S.; requiring the Department of Elderly Affairs to develop, and adopt by rule, a tool for comprehensive assessment of long-term-care supports and services needed by family and friend caregivers for elderly and disabled adults; providing the purpose of the tool; amending s. 430.205, F.S.; authorizing a community-care-for-the-elderly services provider to dispute certain referrals and request certain negotiations by the adult protective services program; providing construction; providing an effective date.

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

Section 1. Section 409.9022, Florida Statutes, is created to read:

409.9022 Exemption for certain life insurance policies as assets; requirements.—

(1) This section applies to an applicant:

(a) Who is in need of the services of a licensed nursing facility;

(b) Who meets the nursing facility level of care;

(c) Whose income does not exceed 300 percent of the Supplemental Security Income standard;

(d) Who owns one or more whole or universal life insurance policies; and

(e) Who would meet the assets standards for Medicaid eligibility except for the cash surrender value of the whole or universal life insurance policy or policies he or she owns.

(2) Notwithstanding any law to the contrary, in determining an applicant's eligibility for Medicaid, the department may not consider the cash surrender value of a whole or universal life insurance policy owned by the applicant as an asset if the applicant collaterally assigns the face value of the life insurance policy to the state for an amount that is not greater than the amount of Medicaid benefits to be provided to the applicant.

(3) The collateral assignment:

(a) Must be a written agreement submitted to and recorded by the issuing company of the life insurance.

(b) Must provide for the issuer to notify the department before a potential lapse in the policy.

(c) Must be completed and accepted by the department as part of the application process before Medicaid benefits may be authorized or provided.

(d) Is void if the application for Medicaid benefits is not approved.

(4) The Medicaid recipient, or his or her guardian or legal representative, shall continue to pay premiums on a life insurance policy that is subject to the collateral assignment. The cost of premiums must be deducted from the recipient's

income for purposes of calculating his or her assets.

(5) Upon the recipient's death:

(a) The agency shall file a claim for the death benefit under the policy, up to the costs expended to provide Medicaid services to the recipient, to be remitted to the state.

(b) The state shall pay to the recipient's estate a funeral expense benefit of $7,500 or 5 percent of the policy's face value, whichever is less.

(c) Any remaining balance of the death benefit must be paid by the issuer of each policy to other beneficiaries under the policy.

(6) A transfer of ownership of a whole or universal life insurance policy within the 60-month period preceding the Medicaid application by the applicant to a person or entity related to the applicant for less than the net present value of the death benefit, as determined by a standard actuarial discount factor, constitutes an improper asset transfer by the applicant unless the transferee collaterally assigns the face value of the policy pursuant to this section.

(7) The department and the agency shall, in collaboration with the Office of Insurance Regulation, adopt rules to administer this section.

(8) The agency may seek any federal waiver to implement this section.

Section 2. Subsection (3) of section 409.979, Florida Statutes, is amended to read:

409.979 Eligibility.—

(3) REGISTRY OF INTEREST, WAIT LIST, RELEASE, AND OFFER PROCESS.—The Department of Elderly Affairs shall maintain a

statewide wait list for enrollment for home and community-based services through the long-term care managed care program.

(a) The Department of Elderly Affairs shall prioritize individuals for potential enrollment for home and community-based services through the long-term care managed care program using a frailty-based screening tool that results in a priority score. The priority score is used to set an order for releasing individuals from the wait list for potential enrollment in the long-term care managed care program. If capacity is limited for individuals with identical priority scores, the individual with the oldest date of placement on the wait list shall receive priority for release.

1. Pursuant to s. 430.2053, aging resource center personnel certified by the Department of Elderly Affairs shall perform the screening for each individual requesting enrollment for home and community-based services through the long-term care managed care program. The Department of Elderly Affairs shall request that the individual or the individual's authorized representative provide alternate contact names and contact information.

2. The individual requesting the long-term care services, or the individual's authorized representative, must participate in an initial screening or rescreening for placement on the wait list. The screening or rescreening must be completed in its entirety before placement on the wait list.

3. Pursuant to s. 430.2053, aging resource center personnel shall administer rescreening annually <u>for individuals with a priority score of 3, 4, or 5;</u> or upon notification of a significant change in an individual's circumstances.

4. The Department of Elderly Affairs shall adopt by rule a

screening tool that generates the priority score, and shall make publicly available on its website the specific methodology used to calculate an individual's priority score.

(b) Upon completion of the screening or rescreening process, the Department of Elderly Affairs shall place all individuals with a priority score of 3, 4, or 5 on the wait list. Individuals with a priority score of 1 or 2 must be placed on a registry of interest established and maintained by the Department of Elderly Affairs. Aging resource center personnel shall inform individuals who are placed on the registry of interest of other community resources that may be available to assist them and shall inform them that they may contact the agency resource center for a new assessment if they experience a significant change in circumstances. Placement on the registry of interest does not prohibit an individual from receiving services, if available. The Department of Elderly Affairs shall notify the individual or the individual's authorized representative that the individual has been placed on the wait list or on the registry of interest.

(c) If the Department of Elderly Affairs is unable to contact the individual or the individual's authorized representative to schedule an initial screening or rescreening, and documents the actions taken to make such contact, it shall send a letter to the last documented address of the individual or the individual's authorized representative. The letter must advise the individual or his or her authorized representative that he or she must contact the Department of Elderly Affairs within 30 calendar days after the date of the notice to schedule a screening or rescreening and must notify the individual that

failure to complete the screening or rescreening will result in his or her termination from the screening process and the wait list.

(d) After notification by the agency of available capacity, the CARES program shall conduct a prerelease assessment. The Department of Elderly Affairs shall release individuals from the wait list based on the priority scoring process and prerelease assessment results. Upon release, individuals who meet all eligibility criteria may enroll in the long-term care managed care program.

(e) The Department of Elderly Affairs may terminate an individual's inclusion on the wait list if the individual:

1. Does not have a current priority score due to the individual's action or inaction;

2. Requests to be removed from the wait list;

3. Does not keep an appointment to complete the rescreening without scheduling another appointment and has not responded to three documented attempts by the Department of Elderly Affairs to contact the individual;

4. Receives an offer to begin the eligibility determination process for the long-term care managed care program; or

5. Begins receiving services through the long-term care managed care program.

An individual whose inclusion on the wait list is terminated must initiate a new request for placement on the wait list, and any previous priority considerations must be disregarded.

(f) Notwithstanding this subsection, the following individuals are afforded priority enrollment for home and

community-based services through the long-term care managed care program and do not have to complete the screening or wait-list process if all other long-term care managed care program eligibility requirements are met:

1. An individual who is 18, 19, or 20 years of age who has a chronic debilitating disease or condition of one or more physiological or organ systems which generally make the individual dependent upon 24-hour-per-day medical, nursing, or health supervision or intervention.

2. A nursing facility resident who requests to transition into the community and who has resided in a Florida-licensed skilled nursing facility for at least 60 consecutive days.

3. An individual who is referred by the Department of Children and Families pursuant to the Adult Protective Services Act, ss. 415.101-415.113, as high risk and who is placed in an assisted living facility temporarily funded by the Department of Children and Families.

(g) The Department of Elderly Affairs and the agency may adopt rules to implement this subsection.

Section 3. Subsection (15) is added to section 430.04, Florida Statutes, to read:

430.04 Duties and responsibilities of the Department of Elderly Affairs.—The Department of Elderly Affairs shall:

(15) Develop, and adopt by rule, a tool for comprehensive assessment of long-term-care supports and services needed by family and friend caregivers for elderly and disabled adults. The tool is to be used by persons administering state funds for such supports and services in determining eligibility and which supports and services are appropriate for service recipients and

their caregivers.

Section 4. Paragraph (a) of subsection (5) of section 430.205, Florida Statutes, is amended to read:

430.205 Community care service system.—

(5) Any person who has been classified as a functionally impaired elderly person is eligible to receive community-care-for-the-elderly core services.

(a) Those elderly persons who are determined by protective investigations to be vulnerable adults in need of services, pursuant to s. 415.104(3)(b), or to be victims of abuse, neglect, or exploitation who are in need of immediate services to prevent further harm and are referred by the adult protective services program, shall be given primary consideration for receiving community-care-for-the-elderly services. As used in this paragraph, "primary consideration" means that an assessment and services must commence within 72 hours after referral to the department or as established in accordance with department contracts by local protocols developed between department service providers and the adult protective services program. However, a community-care-for-the-elderly services provider may dispute the referral by requesting that the adult protective services program negotiate the referral placement of, and the services to be provided to, a vulnerable adult or victim of abuse, neglect, or exploitation. If an agreement cannot be reached with the adult protective services program for modification of the referral decision, the adult protective services program's determination shall control.

Section 5. 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)

2/4/2020
Meeting Date

SB 1544
Bill Number (if applicable)

858654 DE
Amendment Barcode (if applicable)

Topic Elderly Care

Name Marcus Dixon

Job Title

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Street
Miramar FL 33025
City *State* *Zip*

Phone 305-720-1627

Email Marcus.Dixon@SEIUFL.ORG

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

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

Representing SEIU 1199 Healthcare Workers

Appearing at request of Chair: [ ] Yes [X] No

Lobbyist registered with Legislature: [X] 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)

2/4/20
Meeting Date

SB 1544
Bill Number (if applicable)

858654
Amendment Barcode (if applicable)

Topic Long Term Care - Elderly Care

Name Robert S. Beck

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Phone 766 1410

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing FLORIDA Association of Area Agencies on Aging

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)

2/4/20
Meeting Date

SB 1544
Bill Number (if applicable)

858654
Amendment Barcode (if applicable)

Topic Elderly Care

Name Susan Langston

Job Title VP of Advocacy

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing LeadingAge 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)

2/4/20
Meeting Date

1544
Bill Number (if applicable)

258654
Amendment Barcode (if applicable)

Topic ELDERLY CARE

Name JACK McRAY

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TLH FL 32308
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Speaking: ☐ For ☐ Against ☐ Information

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

Representing AARP

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)

2/4/20
Meeting Date

1544
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Bob Asztalos

Job Title Chief Lobbyist

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Street

Tallahassee FL 32301
City *State* *Zip*

Phone 850-284-1160

Email basztalos@thera

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Health Care 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 1650
INTRODUCER:	Senator Simmons
SUBJECT:	Medicaid Provider Agreements for Charter and Private Schools
DATE:	February 3, 2020
REVISED:	

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

I. Summary:

SB 1650 removes the requirement for health care practitioners who are employed by or contracted with a private or charter school to independently enroll in Florida Medicaid as credentialed providers to deliver Medicaid-covered, school-based services. The bill would instead require such practitioners to meet the qualifications specified in federal law in 42 C.F.R. s. 440.110 or the provider qualifications as set forth in the Florida Medicaid Certified School Match Coverage and Limitations Handbook.

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

II. Present Situation:

Florida Medicaid

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of federal and state governments established to provide coverage for health services for eligible persons. The program is administered by the Agency for Health Care Administration (AHCA) and financed through state and federal funds.[1]

A Medicaid state plan is an agreement between a state and the federal government describing how the state administers its Medicaid programs; it establishes groups of individuals covered under the Medicaid program, services that are provided, payment methodologies, and other administrative and organizational requirements.[2] In order to participate in Medicaid, federal law requires states to cover certain population groups (mandatory eligibility groups) and gives them

[1] Section 20.42, F.S.

[2] Agency for Health Care Administration, *Senate Bill 290 Analysis* (January 16, 2019) (on file with the Senate Committee on Health Policy).

the flexibility to cover other population groups (optional eligibility groups).[3] States set individual eligibility criteria within federal minimum standards. The AHCA may seek an amendment to the state plan as necessary to comply with federal or state laws or to implement program changes.

Florida Medicaid Certified School Match Program

Florida has 67 school districts that are each tasked with providing health services for students with disabilities while the student is at school.[4] Some of these students are enrolled in Medicaid. The Florida Medicaid Certified School Match Program (program) was established to provide school districts the opportunity to enroll in Medicaid to have Medicaid share in the cost of providing school health services to Medicaid recipients.[5]

Under the program, schools and school districts use state and local funds to pay for covered health services provided to students that are Medicaid recipients, for which AHCA then reimburses them with the federal Medicaid matching percentage (approximately 60 percent).[6] School districts participating in the program can either employ or contract with service providers.

The following services are covered by the program:
- Physical therapy services;
- Occupational therapy services;
- Speech-language pathology services;
- Transportation services (transportation to Medicaid-covered health care services delivered off campus);
- Behavioral services;
- Augmentive and alternative communication services; and
- Nursing services.[7]

Medicaid recipients who receive services through the program must be under the age of 21 and qualify for Part B or H of the Individuals with Disabilities Education Act (IDEA), qualify for exceptional student services, or have an Individualized Education Plan (IEP) or an Individualized Family Service Plan (IFSP).[8] Health services provided must be both educationally relevant and medically necessary and tailored to meet the recipient's individual needs.[9]

In December 2014, the federal Centers for Medicare & Medicaid Services updated its policies, allowing states to reimburse schools and school districts for health services that are included in the Medicaid program's state plan, regardless of whether the recipient has an IEP or IFSP.[10] This

[3] *Id.*
[4] Agency for Health Care Administration, *Medicaid Certified School Match Program Coverage and Limitations Handbook*, (rev. Jan. 2005), *available at* http://sss.usf.edu/Resources/format/pdf/MedicaidCertifiedSchoolMatchDec2005.pdf (last visited Jan. 31, 2020).
[5] Agency for Health Care Administration, *House Bill 81 Analysis* (October 21, 2019) (on file with the Senate Committee on Health Policy).
[6] *Supra* note 2.
[7] *Supra* note 4.
[8] *See* ss. 409.9071 and 409.9072, F.S.
[9] *Supra* note 2.
[10] *Id.*

policy update is not reflected in the current Florida Statutes and recipients under the program in this state must still qualify for Part B or H of the IDEA, qualify for exceptional student services, or have an IEP or an IFSP.

Florida Medicaid Certified School Match Coverage and Limitations Handbook (handbook)

Under the statutory authority of s. 409.919, F.S., the AHCA adopted Florida Administrative Code Rule 59G-4.035 which incorporates the handbook by reference. The rule requires that all school district providers enrolled in Medicaid under the certified school match program are in compliance with the handbook. The handbook was last published in January of 2005 for the purpose of furnishing a Medicaid provider with the policies and procedures needed to receive reimbursement for covered services provided under the program to eligible Florida Medicaid recipients.[11]

Private and Charter School Providers

In 2016, the Florida Legislature created s. 409.9072, F.S., to authorize the AHCA to reimburse private schools for providing Medicaid school-based services identical to those offered under the Medicaid certified school match program and under the same eligibility criteria as children eligible for services under that program.[12] Unlike school districts, however, private and charter schools do not use certified public expenditures or other local funds as a match to draw down federal Medicaid funding. Instead, the Legislature has appropriated state general revenue to serve as matching funds.[13] Currently, one charter school is enrolled and delivering services in the Florida Medicaid program.[14]

III. Effect of Proposed Changes:

Section 1 amends s. 409.9072, F.S., to remove a requirement that health care practitioners who are employed by or contracted with a private or charter school to independently enroll in Florida Medicaid to deliver Medicaid-covered school-based services. The bill would instead require such practitioners to meet the qualifications specified in federal law in 42 C.F.R. s. 440.110, or the provider qualifications as set forth in the Florida Medicaid Certified School Match Coverage and Limitations Handbook. Currently, s. 409.9072, F.S., already requires that providers meet the qualifications in 42 C.F.R. s. 440.110, as applicable for that provider type.

Under the bill, public school districts must attest that their health care practitioners meet the qualifications outlined in Medicaid policy, but those practitioners need not be enrolled as providers in the Medicaid program.[15] This bill aligns the requirements for private and charter schools with those that are in place for public school districts.

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

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[11] *Supra* note 4.
[12] House of Representatives, Health Care Appropriations Subcommittee, *Final Bill Analysis: HB 5101* (March 23, 2016), *available at* http://www.flsenate.gov/Session/Bill/2016/5101/Analyses/h5101z.HCAS.PDF (last visited Jan. 31, 2020).
[13] *See* Chapter 2016-65, s. 18, L.O.F., *available at* http://laws.flrules.org/2016/65 (last visited Jan. 31, 2020).
[14] *Supra* note 5.
[15] Agency for Health Care Administration, *Senate Bill 1650 Agency Summary Bill Analysis* & Economic Impact Statement (Jan. 30, 2020) (on file with the Senate Committee on Health Policy).

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:

Individuals who are providing or will seek to provide covered services in a private or charter school under the program will be relieved of the duty to enroll in Florida Medicaid as providers.

C. Government Sector Impact:

To implement the changes in SB 1650, the AHCA will need to modify the Florida Medicaid Management Information System to undo programming that has been put in place to implement the current law.[16] This change can be absorbed within existing resources.[17]

VI. Technical Deficiencies:

None.

[16] *Id.*
[17] *Id.*

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 409.9072 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 Simmons

9-01414-20 20201650__

A bill to be entitled

An act relating to Medicaid provider agreements for charter and private schools; amending s. 409.9072, F.S.; revising qualification requirements for health care practitioners engaged by charter and private schools to provide Medicaid school-based services; providing an effective date.

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

Section 1. Subsection (5) of section 409.9072, Florida Statutes, is amended to read:

409.9072 Medicaid provider agreements for charter schools and private schools.—

(5) For reimbursements to private schools and charter schools under this section, the agency shall apply the reimbursement schedule developed under s. 409.9071(5). Health care practitioners engaged by a school to provide services under this section must ~~be enrolled as Medicaid providers and~~ meet the qualifications specified under 42 C.F.R. s. 440.110, as applicable, or meet provider qualifications as set forth in the Florida Medicaid Certified School Match Program Coverage and Limitations Handbook. Each school's continued participation in providing Medicaid services under this section is contingent upon the school providing to the agency an annual accounting of how the Medicaid reimbursements are used.

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

2019 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

BILL INFORMATION	
BILL NUMBER:	SB 290
BILL TITLE:	Medicaid School-based Services
BILL SPONSOR:	Senator Montford
EFFECTIVE DATE:	July 1, 2019

COMMITTEES OF REFERENCE
1) N/A
2)
3)
4)
5)

CURRENT COMMITTEE
N/A

SIMILAR BILLS	
BILL NUMBER:	None filed as of January 16, 2019
SPONSOR:	

PREVIOUS LEGISLATION	
BILL NUMBER:	
SPONSOR:	
YEAR:	
LAST ACTION:	

IDENTICAL BILLS	
BILL NUMBER:	N/A
SPONSOR:	

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

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	January 16, 2019
LEAD AGENCY ANALYST:	Matt Brackett
ADDITIONAL ANALYST(S):	Brittney Austin
LEGAL ANALYST:	
FISCAL ANALYST:	

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

Senate Bill (SB) 290 amends sections 409.9071, 409.9072, and 409.908, Florida Statutes (F.S.). The bill aligns Florida Statutes to federal law by removing language requiring Medicaid recipients to be eligible for Part B or H of the Individuals with Disabilities Education Act (IDEA), the exceptional student education program, or have an individualized education plan (IEP) or individualized family support plan (IFSP) in order to receive Medicaid reimbursable services under the Florida Medicaid Certified School Match Program. In addition, SB 290 updates the statutes to reflect current terminology.

The changes in this bill will not have an operational impact to the Agency. The changes may increase federal Medicaid expenditures, and participating school districts will have to reallocate some of their existing local and state funding in order to match the federal funds. The level of federal expenditure increase is indeterminate.

The bill has an effective date of July 1, 2019.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

The Agency for Health Care Administration (Agency) is the single state agency responsible for the administration of the Florida Medicaid program, authorized under Title XIX of the Social Security Act. This authority includes establishing and maintaining a Medicaid state plan, approved by the 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; it establishes groups of individuals covered under the Medicaid program, services that are provided, payment methodologies, and other administrative and organizational requirements. In order to participate in Medicaid, federal law requires states to cover certain population groups (mandatory eligibility groups) and gives them the flexibility to cover other population groups (optional eligibility groups). States set individual eligibility criteria within federal minimum standards.

The Agency may seek an amendment to the state plan as necessary to comply with federal and/or state laws or to implement program changes.

Florida Medicaid Certified School Match Program

Florida has 67 school districts. Each district is tasked with providing health services for students with disabilities while the student is at school. Some of these students are enrolled in Medicaid.

The Florida Medicaid Certified School Match Program was established to provide school districts and private and charter schools the opportunity to enroll in Medicaid to have Medicaid share in the cost of providing school health services to Medicaid recipients. Services included in this benefit are therapies (physical, occupational, and speech-language pathology), nursing, behavioral health, and transportation. Schools and school districts participating in the program can either employ or contract directly with Medicaid enrolled health care providers.

The Certified School Match Program works by requiring participating schools and school districts to use state and local funds to pay for health services included in the benefit for which the Agency then reimburses them the federal Medicaid matching percentage. In addition to providing the federal match portion for health services, the Certified School Match Program also reimburses the federal share for administrative work associated with delivering care to recipients. Examples of this work includes making a referral to a medical service.

Medicaid recipients who receive services through the Certified School Match program must be under the age of 21 and qualify for Part B or H of IDEA or qualify for exceptional student services, or have an IEP or IFSP

(see sections 409.9071 and 409.9072, F.S.). Health services provided must be both educationally relevant and medically necessary and tailored to meet the recipient's individual needs.

To receive reimbursement, schools and school districts submit certified quarterly reports outlining their expenditures and the non-federal funds used to deliver health care services. The Agency then reimburses them the federal share (based on the Federal Medical Assistance Percentage-FMAP), which is approximately 60%. The percentage is set by the federal government and varies annually each federal fiscal year. The Certified School Match Program is reimbursed through the fee-for-service delivery system. Health plans participating in the Statewide Medicaid Managed Care program do not administer this benefit, although students enrolled in Medicaid health plans can receive services from schools through the school match program. To prevent duplication of services, the Agency requires health plans to enter into memoranda of agreement with enrolled schools and school districts to coordinate care.

The Centers for Medicare and Medicaid Services

The Agency's federal partner, the Centers for Medicare and Medicaid Services (CMS), historically had a policy in place that precluded state Medicaid programs from reimbursing for services delivered free of charge, otherwise known as "free care." In other words, Medicaid payments were prohibited for school-based services delivered when the service was free to all students. This policy also precluded school districts from seeking payment for services not detailed on an individualized education plan (IEP) or individualized family support plan (IFSP). The "free care" policies prevented Medicaid from reimbursing schools and school districts for services such as behavioral health and speech-language pathology available to students who are Medicaid recipients but do not have an IEP or IFSP.

In December 2014, CMS updated its "free care" policy allowing states to reimburse schools and school districts for health services that are included in the Medicaid program's state plan, regardless of whether the recipient has an IEP or IFSP. The requirement that the provider delivering the service must be enrolled in Medicaid still applies. In addition, CMS indicated that third party liability rules do not apply to schools because they are not considered as legal third parties at the federal level.

2. EFFECT OF THE BILL:

Senate Bill 290 amends sections 409.9071, 409.9072, and 409.908, F.S. removing the language requiring Florida Medicaid recipients who are receiving health services under the Certified School Match Program benefit to be eligible for Part B or H of IDEA, the exceptional student program, or have an IEP or IFSP. The revision of this policy also allows Medicaid to reimburse for the federal share of services such as vision and hearing screenings for Medicaid-eligible students. This will have the effect of allowing participating school districts to draw down federal matching funds for additional services provided to students. School districts must use state or local funds to draw down federal funding, which may cause districts to reallocate existing funds. In addition, SB 290 makes technical changes to update current terminology.

The bill's language poses a minimal operational impact to Florida Medicaid. SB 290's proposed changes align the Florida Statutes with federal requirements. Implementing these changes are part of the Agency's routine business practices and can be completed using existing resources. Although the Agency has taken some of the necessary steps, it has not yet implemented these changes and is continuing to work to obtain all necessary authorities.

The Agency has already received federal approval through a state plan amendment that grants authority to seek federal funds for school-based services without requiring an IEP or IFSP. The accompanying administrative rule, the Medicaid Certified School Match Coverage Policy, is being revised to align with the state plan.

The language of the bill further clarifies Florida Medicaid's ability to receive federal funds for medical services for any Medicaid eligible recipient ages 3 through 20 enrolled in a public, private, or charter school. These entities will have to certify the state funding used to receive federal match funds for these services.

SB 290 does not pose an operational impact to the Agency as the work can be completed using current resources. There is an indeterminate federal fiscal impact to Florida Medicaid due to the additional services that will be permitted to be billed for Medicaid-eligible students. The bill takes effect on July 1, 2019.

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

If yes, explain:	Existing rules will need to be amended to comply with the bill.
Is the change consistent with the agency's core mission?	Y _X__ N ___
Rule(s) impacted (provide references to F.A.C., etc.):	Rule 59G-4.035, F.A.C.

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:	N/A
Date Due:	N/A
Bill Section Number(s):	N/A

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

Board:	N/A
Board Purpose:	N/A
Who Appointments:	N/A
Appointee Term:	N/A
Changes:	N/A
Bill Section Number(s):	N/A

FISCAL ANALYSIS

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

Revenues:	The bill should increase the amount of federal funds received for services being provided to students.
Expenditures:	There will be an indeterminate increase in the amount of federal funds expended. The bill will not increase state funds expended, but school districts will have to reallocate existing local and state funds in order to receive federal matching funds.
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?	N/A

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

Revenues:	None
Expenditures:	N/A
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 ___ N _X__

Revenues:	Unknown
Expenditures:	Unknown
Other:	N/A

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

If yes, explain impact.	N/A
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.	N/A

FEDERAL IMPACT

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

If yes, describe the anticipated impact including any fiscal impact.	This bill will have a federal fiscal impact. As school districts use additional state and local funds to deliver health services to Medicaid-eligible students, the federal matching portion will increase, causing an increase in federal expenditures.

ADDITIONAL COMMENTS

N/A

LEGAL – GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	

2020 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

BILL INFORMATION	
BILL NUMBER:	HB 81
BILL TITLE:	Medicaid School-based Services
BILL SPONSOR:	Representative Andrade
EFFECTIVE DATE:	July 1, 2020

COMMITTEES OF REFERENCE
1) N/A
2)
3)
4)
5)

CURRENT COMMITTEE
N/A

SIMILAR BILLS	
BILL NUMBER:	SB 190
SPONSOR:	Senator Montford

PREVIOUS LEGISLATION	
BILL NUMBER:	
SPONSOR:	
YEAR:	
LAST ACTION:	

IDENTICAL BILLS	
BILL NUMBER:	N/A
SPONSOR:	

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

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	October 21, 2019
LEAD AGENCY ANALYST:	Matt Brackett
ADDITIONAL ANALYST(S):	
LEGAL ANALYST:	
FISCAL ANALYST:	

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

House Bill (HB) 81 amends sections 409.9071, 409.9072, and 409.908, Florida Statutes (F.S.). The bill aligns Florida Statutes to federal law by removing outdated eligibility and documentation language for children who receive Medicaid reimbursable services through the Florida Medicaid Certified School Match Program or through Medicaid-enrolled private and charter schools. This could expand the number of children whose health care services are currently provided and paid for by school districts or private/charter schools, but could be reimbursed by Medicaid.

The changes in this bill will have a minor operational impact to the Agency. However, the Agency can complete these tasks within existing resources (e.g., finalizing changes to the rule). The proposed changes would require school districts to reallocate some of the current local/state funding used to provide health care services for this population if they wish to receive additional federal Medicaid matching funds. This would result in an increase in federal Medicaid expenditures, but should result in savings for school districts. Currently, the Legislature appropriates the state share needed to draw down federal Medicaid matching funds for health care services provided to Medicaid-eligible students in private/charter schools. As such, the proposed change would not only result in an increase in federal expenditures, but also an increase in state general revenue needed for services provided by private/charter schools. The level of general revenue and federal expenditure increases are indeterminate as it is unknown how many additional private or charter schools may enroll, or additional children will be served based on these changes.

HB 81 also makes technical changes to update terminology in the law.

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

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

The Agency for Health Care Administration (Agency) is the single state agency responsible for the administration of the Florida Medicaid program, 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.

A Medicaid state plan is an agreement between a state and the federal government describing how that state administers its Medicaid programs; it establishes groups of individuals covered under the Medicaid program, services that are provided, payment methodologies, and other administrative and organizational requirements. In order to participate in Medicaid, federal law requires states to cover certain population groups (mandatory eligibility groups) and gives them the flexibility to cover other population groups (optional eligibility groups). States set individual eligibility criteria within federal minimum standards.

The Agency may seek an amendment to the state plan as necessary to comply with federal and/or state laws or to implement program changes.

Florida Medicaid Certified School Match Program

Florida has 67 school districts. Each district is tasked with providing health services for students with disabilities while the student is at school. Some of these students are enrolled in Medicaid.

The Florida Medicaid Certified School Match Program was established to provide school districts the opportunity to enroll in Medicaid to have Medicaid share in the cost of providing school health services to Medicaid recipients. Services included in this benefit are therapies (physical, occupational, and speech-language pathology), nursing, behavioral health, and transportation to Medicaid-covered health care services delivered off campus. School districts participating in the program can either employ or contract with Medicaid-enrolled health care providers.

The Certified School Match Program works by requiring participating school districts to use state and local funds to pay for health services included in the benefit. They then bill Medicaid, and Medicaid then reimburses them the federal Medicaid matching percentage (currently 61%). In addition to providing the federal match portion for health services, the Certified School Match Program also reimburses the federal share for administrative work associated with delivering care to recipients. Examples of this work includes making a referral to a medical service.

Medicaid recipients who receive services through the Certified School Match program must be under the age of 21. Health services provided must be both educationally relevant and medically necessary and tailored to meet the recipient's individual needs.

The Certified School Match Program is reimbursed through the fee-for-service delivery system. Statewide Medicaid Managed Care health plans do not administer this benefit, although students enrolled in Medicaid health plans can receive services from schools through the school match program. To prevent duplication of services and enhanced coordination of care, the Agency requires health plans to enter into memoranda of agreement with enrolled schools and school districts to coordinate care.

Private and Charter School Providers

In 2016, the Florida Legislature created section 409.9072, F.S., directing the Agency to update its policies and systems to enroll private and charter schools as Medicaid providers. Unlike school districts, private and charter schools do not use certified public expenditures or other local funds as a match to draw down federal Medicaid funding. Instead, the Legislature appropriated state general revenue funding to serve as matching funds. In every other respect, the program is the same for enrolled private and charter schools. Currently, one charter school is enrolled and delivering services in the Florida Medicaid program.

The Centers for Medicare and Medicaid Services

The Agency's federal partner, the Centers for Medicare and Medicaid Services (CMS), historically had a policy that precluded state Medicaid programs from reimbursing for services that are normally delivered free of charge, otherwise known as "free care." In other words, Medicaid payments were prohibited for school-based services delivered when the service was free to all students. This policy also precluded school districts from seeking payment for services not detailed on an individualized education plan (IEP)individualized family support plan (IFSP). These plans are required for children who, because of their diagnoses or disabilities, require medical services or accommodations to attend school. The "free care" policies prevented Medicaid from reimbursing schools and school districts for services such as behavioral health and speech-language pathology available to students who are Medicaid recipients but do not have an IEP or IFSP.

In December 2014, CMS clarified its "free care" policy through a State Medicaid Director letter. The updated guidance clarified that school health services delivered to the general student population, not just those included in student IEPs, are reimbursable by Medicaid. Additionally, the updated guidance clarified that state Medicaid programs may reimburse school districts for health services that are included in the Medicaid program's state plan, regardless of whether the recipient has an IEP or IFSP. The requirement that the provider delivering the service must be enrolled in Medicaid still applies.

In response to this updated CMS guidance, the Agency received federal approval for a state plan amendment in October 2016 that allows Florida Medicaid to reimburse for "free care" services delivered in schools to all Medicaid recipients, regardless if a recipient has an IEP or IFSP. Based on this authority, the Agency can reimburse schools for these additional services.

2. EFFECT OF THE BILL:

House Bill 81 amends sections 409.9071, 409.9072, and 409.908, F.S. removing the language requiring Florida Medicaid recipients receiving school-based services to be eligible for Part B or H of IDEA, exceptional student services, or to have an IEP or IFSP. The changes in the bill align state law with the 2014 federal "free-care" policy guidance. In addition, HB 81 aligns the Florida Statutes with the Agency's existing federal

authority that already allows schools to provide Medicaid services falling under the "free service" category to all Medicaid-eligible students, regardless of whether they have a diagnosis or condition that previously qualified them. Because the State has the federal authority, the current statutory language does not preclude delivery of these services. However, its removal will reduce confusion regarding what Florida Medicaid covers in schools. As previously noted, school districts, through the Medicaid Certified School Match Program, will still have to use state or local funds to draw down federal funding for any additional services.

The bill's language poses a minor operational impact to the Florida Medicaid program. The Agency has already received federal approval, through a state plan amendment, to seek federal funds for school-based services without requiring an IEP, IFSP, or other statutorily required qualification. The accompanying administrative rule, the Medicaid Certified School Match Coverage Policy, is being revised to align with the state plan. The Agency can complete this task using current resources.

HB 81 poses an indeterminate fiscal impact to Florida Medicaid. The level of general revenue and federal expenditure increases are indeterminate as it is unknown how many additional private or charter schools may enroll, or additional children will be served based on these changes. The proposed changes would require school districts to reallocate some of the current local/state funding used to provide health care services for this population if they wish to receive additional federal Medicaid matching funds. This would result in an increase in federal Medicaid expenditures, but should result in savings for school districts. Additionally, the Agency may see an increase in fee-for-service reimbursements, using a combination of general revenue and federal match, to private and charter schools for additional services and children once the language is clarified for providers.

HB 81 also makes technical changes to update current terminology, which have no impact on the Agency or Florida Medicaid program.

The bill takes 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 ___ 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:	We are aware of at least one advocacy group is in favor of this change.
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:	N/A
Date Due:	N/A
Bill Section Number(s):	N/A

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

Board:	N/A

Board Purpose:	N/A
Who Appointments:	N/A
Appointee Term:	N/A
Changes:	N/A
Bill Section Number(s):	N/A

FISCAL ANALYSIS

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

Revenues:	The bill may increase the amount of federal funds and general revenue received for services being provided to students.
Expenditures:	The proposed changes would require school districts to reallocate some of the current local/state funding used to provide health care services for this population if they wish to receive additional federal Medicaid matching funds. This would result in an increase in federal Medicaid expenditures, but should result in savings for school districts. Additionally, the Agency may see an increase in fee-for-service reimbursements, using a combination of general revenue and federal match, to private and charter schools for additional services and children once the language is clarified for providers.
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?	N/A

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

Revenues:	None
Expenditures:	N/A
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 ___ N _X__

Revenues:	Unknown
Expenditures:	Unknown
Other:	N/A

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

If yes, explain impact.	N/A
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.	N/A

FEDERAL IMPACT

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

If yes, describe the anticipated impact including any fiscal impact.	This bill may have a federal fiscal impact. As school districts and private/charter schools use additional state and local funds to deliver health services to Medicaid-eligible students, the federal matching portion may increase alongside additional clarification of existing policy.

ADDITIONAL COMMENTS

N/A

LEGAL – GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	

2020 AGENCY SUMMARY BILL ANALYSIS & ECONOMIC IMPACT STATEMENT

AGENCY: Agency for Health Care Administration

BILL#:	SB 1650
RELATING TO:	Medicaid Provider Agreements for Charter and Private Schools
SPONSOR(S):	Sen. Simmons
COMPANION BILLS:	N/A

ANALYST/REVIEWER NAME:	Matt Brackett
DIVISION/UNIT:	Medicaid Policy
CONTACT NUMBER:	4-4151

COORDINATED WITH:	N/A
DIVISION/UNIT:	N/A
CONTACT NUMBER:	N/A

I. SUMMARY:

Senate Bill (SB) 1650 (Medicaid Provider Agreements for Charter and Private Schools) amends section 409.9072 (5), Florida Statutes (F.S.), removing language requiring individual health care practitioners who are employed or contracted with a private or charter school to independently enroll in Florida Medicaid to deliver Medicaid-covered school-based services. Instead, individual practitioners must meet the requirements in federal law (42CFR 440.110) or the qualifications stated in the Florida Medicaid Certified School Match Program Coverage Policy.

SB 1650 aligns the Medicaid enrollment and approval process for private and charter schools with what is currently in place for public school districts. This bill is effective on July 1, 2020.

II. Does this bill impact the Agency? If yes, please provide a brief explanation of the impact:

SB 1650 poses a minor operational impact on Florida Medicaid. The bill deletes language in s. 409.9072, F.S. mandating Medicaid enrollment of health care practitioners employed or contracted with private and charter schools. This will align the requirements for private/charter schools with those that are in place for public school districts. The current requirement for private/charter schools in statute is administratively burdensome and does not align with the requirements for public school districts. Public school districts must only attest that their health care practitioners meet the qualifications outlined in Medicaid policy; those providers do not have to individually enroll in Medicaid.

In order to implement the changes in the bill, the Agency will have to modify the Florida Medicaid Management Information System (MMIS) to undo programming that has been put in place to implement the current requirements in law. This change can be absorbed within existing Agency resources.

III. FISCAL COMMENTS:

SB 1650 does not pose a fiscal impact.

IV. SUGGESTED AMENDMENTS:

N.A.

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 512
INTRODUCER:	Health Policy Committee and Senator Hutson
SUBJECT:	Nonembryonic Stem Cells
DATE:	February 5, 2020 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Fav/CS**
2.			AP	
3.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 512 defines multiple terms relating to the storing, making, and administering of nonembryonic stem cells. The bill treats nonembryonic stem cell banks (NSCBs) as health care clinics and requires them to:

- Register with the Agency for Health Care Administration (AHCA);
- Have a physician medical director who practices at the NSCB and is responsible for the NSCB complying with all requirements related to licensure, operation, and the good manufacturing practices requires under Florida and federal law;
- Maintain commercial and professional liability insurance in limits of minimum $250,000.

The bill authorizes an NSCB to:

- Make, collect, and store human nonembryonic stem cells and provide patient-specific health care services using human nonembryonic stem cells the NSCB manufactures;
- Sell and dispense nonembryonic stem cells manufactured by the NSCB, if the NSCB has a pharmacist, and is permitted as a pharmacy, to:
  - A health care practitioner to use in his or her office if the use is within the scope of the practitioner's license; and
  - Other stem cell banks, pharmacists, pharmacies, and establishments to sell or dispense to other health care practitioners if it is within the scope of practitioner's license to prescribe and administer human nonembryonic stem cells to patients.

The bill authorizes the Department of Health (DOH) to take disciplinary action against certain health care practitioners if found practicing in an unlicensed NSCB and requires the AHCA to make rules to administer NSCBs licensure and regulation, including specified topics to be included.

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

II. Present Situation:

Stem Cells

Stem cells are unspecialized cells that have the ability to divide for indefinite periods of time in culture medium and to give rise to specialized cells.[1] Stem cells have the potential to develop into many different types of cells during early life and growth. In addition, in many human tissues, stem cells serve as an internal repair system, dividing essentially without limit, to replenish other cells as long as a person is still alive. When a stem cell divides, each new cell has the potential to either remain an undifferentiated stem cell or become a cell with a specialized function such as a muscle, red blood, or brain cell.[2]

Stem cells are distinguished from other cells by two important characteristics:
- Unspecialized cells capable of renewing themselves through cell division; and
- The ability to be induced to become tissue-specific or organ-specific cells under certain physiologic or experimental conditions.[3]

In some organs – such as the alimentary canal (gut) – and bone marrow, stem cells regularly divide to repair and replace worn out or damaged tissues. In other organs, such as the pancreas and the heart, stem cells only divide under special conditions.[4]

Until recently, scientists primarily worked with two kinds of stem cells from animals and humans:
- Embryonic stem cells;[5] and
- Non-embryonic "somatic," or "adult," stem cells.[6]

Stem cells offer new potentials for treating diseases such as diabetes and heart disease, given their unique regenerative abilities. More research is needed to understand how to use these cells for cell-based therapies to treat disease. This practice is referred to as regenerative or reparative medicine.[7]

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[1] National Institutes of Health, Stem Cell Information, Glossary, *Stem Cells* https://stemcells.nih.gov/glossary.htm#stemcells (last visited Jan. 27, 2020).
[2] National Institutes of Health, Stem Cell Information, *Stem Cell Basics I.*, https://stemcells.nih.gov/info/basics/1.htm (last visited Jan. 27, 2020).
[3] *Id.*
[4] *Id.*
[5] Embryonic stem cells are primitive undifferentiated cells that are derived from preimplantation-stage embryos. They are capable of dividing without differentiating for a prolonged period in culture; and are known to develop into cells and tissues of the three primary germ layers. The three germ layers are the ectoderm, the mesoderm, and the endoderm. *See* National Institutes of Health, Stem Cell Information, Glossary, *Embryonic Stem Cells,* https://stemcells.nih.gov/glossary.htm#stemcells (last visited Jan. 27, 2020).
[6] Somatic (adult) stem cells are relatively rare undifferentiated cells found in many organs and differentiated tissues with a limited capacity for both self-renewal (in the laboratory) and differentiation. Such cells vary in their differentiation capacity, but it is usually limited to cell types in the organ of origin. *See* National Institutes of Health, Stem Cell Information, Glossary, *Somatic (adult) Stem Cells,* https://stemcells.nih.gov/glossary.htm#stemcells (last visited Jan. 27, 2020).
[7] National Institutes of Health, *Stem Cell Basics I.*, https://stemcells.nih.gov/info/basics/1.htm (last visited Jan. 27, 2020).

Federal Regulation of Stem Cells

Under 21 C.F.R. 1271, certain stem cells are labeled as a drug[8] and subject to FDA regulation if the stem cell has been derived from structural tissue or non-structural tissue in a manufacturing process involving more than minimal manipulation.[9]

The FDA regulates articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient as human cells, tissues, or cellular or tissue-based products (HCT/Ps) which are known as stem cells.[10]

The U.S. Center for Biologics Evaluation and Research (CBER) regulates HCT/Ps.[11] The CBER does not regulate the transplantation of vascularized human organ transplants such as the kidney, liver, heart, lung, or pancreas. The Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services oversees the transplantation of vascularized human organs.[12]

Minimally manipulated bone marrow is also used in stem cell treatments but is not considered by the FDA to be an HCT/Ps,[13] and thus is not regulated by the FDA.[14] The HRSA regulates minimally manipulated bone marrow stem cells used for transplant.[15]

Due to the unique nature of HCT/Ps, the FDA uses a tiered, risk-based approach to the regulation of HCT/Ps, rather than the Federal Food, Drug and Cosmetic Act (FDCA), for products that meet the definition of a drug, biologic, or device.[16] The tiered, risk-based approach includes

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[8] See 21 U.S.C. s. 321(g). The FDA defines a "drug" as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and "articles (other than food) intended to affect the structure or function of the body."

[9] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Evaluation and Research, Center for Devices and Radiological Health, Office of Combination Products, (Nov. 2017, corrected Dec. 2017), *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use, Guidance for Industry and Food and Drug Administration Staff,* (December 2017) *available at* https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/cellularandgenetherapy/ucm585403.pdf (last visited Jan. 27, 2020). Section 1271.10(a)(1) provides that one of the criteria for an HCT/P to be regulated solely under s. 361 of the PHSA and the regulations in Part 1271, is that the HCT/P is only "minimally manipulated." As defined in 21 CFR 1271.3(f), "minimal manipulation" means: 1) For *structural tissue*, processing that *does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement* (emphasis added); or 2) For *cells or nonstructural tissues*, processing *does not alter the relevant biological characteristics of cells or tissues*. Note: the FDA considers the processing of an HCT/P to be, "more than minimal manipulation," if information does not exist to show that the HCT/P qualifies for regulation solely under s. 361 of the PHSA. *See* 21 C.F.R. 1271.21 and 1271.10.

[10] 21 C.F.R. 1271.3(d).

[11] See 21 C.F.R., 1270 and 1271. The CBER is a part of the Food and Drug Administration.

[12] U.S. Food and Drug Administration, *Tissue and Tissue Products* (as of July 11, 2019), *available at* https://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm (last visited Jan. 27, 2020).

[13] *See* 21 C.F.R. 1271.3(d)(4).

[14] U.S. Food and Drug Administration, Food and Drug Administration, *FDA Warms About Stem Cell Therapies*, https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm286155.htm (last visited Jan. 27, 2020).

[15] U.S. Department of health and Human Services, Health Resources and Services Administration, *Healthcare Systems, available at* https://www.hrsa.gov/sites/default/files/ourstories/organdonation/factsheet.pdf (last visited Jan. 27, 2020).

[16] Although the FDA is authorized to apply the requirements in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to those products that meet the definition of drug, biologic, or device, under this tiered, risk-based approach, those HCT/Ps that meet specific criteria or fall within detailed exceptions do not require premarket review or approval. *See* U.S. Department of Health and Human Services, Food and Drug Administration, Center for Evaluation and

recommendations on how the transmission of communicable diseases can be prevented; the process controls necessary to prevent contamination and preserve the integrity and function of the products; and how clinical safety and effectiveness can be assured.[17]

The tiered, risk-based approach is contained in regulations referred to as the "tissue rules" issued by the FDA under the communicable disease authority of s. 361 of the Public Health Service Act (PHSA).[18]

For an HCT/P to be regulated solely under the requirements of s. 361 of the PHSA and 21 C.F.R. 1271, it must meet all of the following criteria:[19]

- The HCT/P is minimally manipulated;[20]
- The HCT/P is intended for homologous use only;[21]
- The HCT/P is not combined with any other article, except water, crystalloids, or a sterilizing, preserving, or storage agent; and
- The HCT/P either:
  - Does not have a systemic effect and is not dependent upon the metabolic activity of living cells, for its primary function; or
  - Has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and is for:
    - Autologous use;[22]
    - Allogeneic use;[23] or
    - Reproductive use.[24]

Research, Center for Devices and Radiological Health, Office of Combination Products, Nov. 2017, corrected Dec. 2017, *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use, Guidance for Industry and Food and Drug Administration Staff*, https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/cellularandgenetherapy/ucm585403.pdf (last visited Jan. 27, 2020).

[17] *Id.*

[18] 42 U.S.C. s. 264.

[19] 21 C.F.R. 1271.10.

[20] 21 C.F.R. 1271.10(a)(1) provides that one of the criteria for an HCT/P to be regulated solely under s. 361 of the PHSA and the regulations in 1271, is that the HCT/P is only "minimally manipulated". As defined in 21 C.F.R. 1271.3(f), "minimal manipulation" means: 1) For *structural tissue*, processing that *does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement* (emphasis added); or 2) For *cells or nonstructural tissues*, processing *does not alter the relevant biological characteristics of cells or tissues*. Note: the FDA considers the processing of an HCT/P to be, "more than minimal manipulation," if information does not exist to show that the HCT/P qualifies for regulation solely under s. 361 of the PHSA.

[21] 21 C.F.R. 1271.10(a)(2), provides that one of the criteria for an HCT/P to be regulated solely under s. 361 of the PHSA, and the regulations in 1271, is that the "HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent." As defined in 21 C.F.R. 1271.3(c), "homologous use" means the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor. This criterion reflects the FDA's conclusion that there would be increased safety and effectiveness concerns for HCT/Ps that are intended for a non-homologous use, because there is less basis on which to predict the product's behavior. *See supra* note 8, at 4.

[22] *"Autologous use"* means the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered. *See* 21 C.F.R. 1271.3(a).

[23] *"Allogeneic use"* means taken from different individuals of the same species. Two or more individuals are said to be allogeneic to one another when the genes at one or more loci are not identical. Medicinenet.com, *Medical Definition of Allogeneic*, https://www.medicinenet.com/script/main/art.asp?articlekey=25266 (last visited Jan. 27, 2020).

[24] 21 C.F.R. 1271.10(a).

To apply the minimally manipulated criteria, the FDA first determines if the HCT/P to be transplanted was derived from structural tissue or cellular/nonstructural tissue. This determination is made based on the characteristics of the HCT/P in the donor, prior to recovery, and before any processing takes place.[25]

In applying the minimally manipulated analysis, the FDA acknowledges that HCT/Ps perform multiple functions and that structural tissues contain cells. The FDA also acknowledges that some manufacturers assert that an HCT/P has both a structural and cellular/nonstructural function. However, under FDA regulations, HCT/Ps are considered either structural tissues or cells/nonstructural tissues. HCT/Ps that physically support or serve as a barrier or conduit, or connect, cover, or cushion, are generally considered structural tissues for the purpose of applying the HCT/P regulatory framework. The FDA gives the following examples of what it considers structural tissue: bone, skin, amniotic membrane and umbilical cord, blood vessel, adipose tissue, articular cartilage, non-articular cartilage, and tendon or ligament.[26]

HCT/Ps that serve metabolic or other biochemical roles in the body, such as hematopoietic, immune, and endocrine functions, are generally considered cells/nonstructural tissues for the purpose of applying the FDA HCT/P regulatory framework. The FDA examples of cells or nonstructural tissues include: reproductive cells or tissues (oocytes), hematopoietic stem/progenitor cells (cord blood), lymph nodes and thymus, parathyroid glands, peripheral nerve, and pancreatic tissue.[27]

The FDA defines "processing" as any activity performed on an HCT/P, other than: rinsing, cleaning, recovery, donor screening, donor testing, storage, sizing, labeling, packaging, distribution, testing for microorganisms, preparation, sterilizations, steps to inactivate or remove adventitious agents, preservation for storage, and removal from storage.[28] Under this definition, processing includes: cutting, grinding, shaping, culturing, enzymatic digestion, and decellurization.[29]

An HCT/P is exempt from registration and regulation under the PHSA and 21 C.F.R. 1271, if the establishment:[30]

- Uses the HTC/Ps solely for nonclinical scientific or educational purposes;
- Removes HCT/Ps from an individual and implants such HCT/Ps into the same individual, during the same surgical procedure;
- Is a carrier who accepts, receives, carries, or delivers HCT/P's in the usual course of business;

[25] *Supra* note 9.
[26] *Id.*
[27] *Supra* note 9.
[28] See 21 C.F.R. 1271.3(ff).
[29] *Supra* note 9.
[30] Establishment means a place of business under one management, at one general physical location, that engages in the manufacture of human cells, tissues, and cellular and tissue-based products. Establishment includes: (1) Any individual, partnership, corporation, association, or other legal entity engaged in the manufacture of human cells, tissues, and cellular and tissue-based products; and (2) Facilities that engage in contract manufacturing services for a manufacturer of human cells, tissues, and cellular and tissue-based products. 21 C.F.R. 1271.3(b).

- Does not recover, screen, test, process, label, package, or distribute, but only receives or stores HCT/P's, solely for implantation, transplantation, infusion, or transfer within its facility; or
- Only recovers reproductive cells or tissue and immediately transfers them into a sexually intimate partner of the cell or tissue donor.

If an individual is under contract with a registered establishment, and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment, he or she is not required to register or list the establishment's HCT/Ps independently, but he or she must comply with all other applicable requirements. [31]

If an HCT/P does not meet the above criteria, and the manufacturer of the HCT/P does not qualify for an exception,[32] the HCT/P will be regulated as a drug, device, and/or biological product under the FDCA, the PHSA,[33] and applicable regulations;[34] and premarket review will be required.[35]

According to the FDA, if a manufacturer or establishment isolates cells from structural tissue to produce a cellular therapy product, the definition of minimal manipulation applies regardless of the method used to isolate the cells. The definition applies because the assessment of whether the HCT/P is a structural tissue or cellular/nonstructural tissue is based on the characteristics of the HCT/P as it exists in the donor, prior to recovery, and prior to any processing that takes place.[36]

Federal law requires tissue establishments[37] that do not meet an exemption to:
- Screen and test donors;
- Prepare and follow written procedures for prevention of the spread of communicable disease; and
- Maintain records.[38]

The FDA has published rules to broaden the scope of products subject to regulation and to include more comprehensive requirements to prevent the introduction, transmission, and spread of communicable disease. Those rules include requiring tissue establishments to:
- Register and submit a list to the FDA of every HCT/P it manufactures within five days after operations begin, or within 30 days of the effective date of the registration;[39]
- Determine donor eligibility, including screening and testing;[40] and

[31] 21 C.F.R. 1271.15.
[32] 21 C.F.R., 1271.10, 1271.15 and 1271.155.
[33] 42 U.S.C. s. 262.
[34] 21 C.F.R. 1271.
[35] *Supra* note 9.
[36] *Id.*
[37] *Supra* note 31.
[38] *See* 21 C.F.R 1270 and 1271.2121.
[39] 21 C.F.R. 1271.21.
[40] 21 C.F.R. 1271.45.

- Recover, process, store, label, package, and distribute HCT/Ps, and screen and test cell and tissue donors, in such a way that prevents the introduction, transmission, or spread of communicable diseases.[41]

The requirements are intended to improve protection of the public health while minimizing regulatory burden.[42]

The only HCT/Ps that are FDA-approved for use in the United States consist of blood-forming stem cells, referred to as hematopoietic progenitor cells, derived from cord blood. These products are approved for limited use in patients with disorders that affect the hematopoietic system – the body system that is involved in the production of blood. The FDA-approved stem cell products are listed on the FDA website.[43]

Florida Regulation of Stem Cells

Stem Cell Preparation/Manufacturing

The registration of stem cell banks does not exist under current Florida law. The Department of Business and Professional Regulation (DBPR) administers and enforces the Florida Drug and Cosmetic Act (FDCA) to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.[44] In Florida, "a person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under the federal act or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce."[45]

The FDCA defines a "drug" as an article, or a component of an article,[46] that is:

- Recognized in the current edition of the United States Pharmacopoeia and National Formulary (USP-FM),[47] official Homeopathic Pharmacopoeia of the United States (HPUS),[48] or any supplement to any of those publications;

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[41] *Id.*

[42] U.S. Department of Health and Human Services, Food and Drug Administration, *Tissue and Tissue Products*, https://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm (last visited Jan. 31, 2020).

[43] U.S. Department of Health and Human Services, Food and Drug Administration, *FDA Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's) Product List* (page updated Feb. 2, 2018) *available at* https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/fda-regulation-human-cells-tissues-and-cellular-and-tissue-based-products-hctps-product-list (last visited Jan. 31, 2020).

[44] *See* part I of ch. 499, F.S.

[45] Section 499.023, F.S.

[46] Includes active pharmaceutical ingredients, but does not include devices or their non-drug components, parts, or accessories. *Also see* s. 499,003(1), F.S. The term "active pharmaceutical ingredient" includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or animals.

[47] USP-NF is a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). It contains standards for medicines, dosage forms, drug substances, excipients, biologics, compounded preparations, medical devices, dietary supplements, and other therapeutics. *See* 21 U.S.C. s. 301(g)(1).

[48] The HPUS is declared a legal source of information on drug products (along with the USP/NF) in the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 301. Section 201(g)(1) of the Act. 21 U.S.C. s. 321 defines the term "drug" as articles

- Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;
- Intended to affect the structure or any function of the body of humans or other animals; or
- Intended for use as a component of any article:
  - Listed in the USP-FM, or HPUS;
  - Used in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;
  - Used to affect the structure or any function of the body of humans or other animals; and
  - That includes active pharmaceutical ingredients.[49]

The FDCA defines the manufacturing of a drug to mean the preparation, deriving, compounding, propagation, processing, producing, or fabrication of a substance into a drug.[50]

Under the FDCA, a "manufacturer" is:
- A person who holds an application for a New Drug, Abbreviated New Drug, a Biologics License, or a New Animal Drug, approved under the federal act; or
- A person who holds a license issued under s. 351 of the Public Health Service Act, 42 U.S.C. s. 262, for such drug or biologics; or
- A person who manufactured the drug or biologics, not the subject of an approved application or license;
- A co-licensed partner of:
  - the holder of the drug application; or
  - the holder of the license, or
  - the manufacturer of the drug or biologics, not the subject of an approved application or license, who obtained the drug or biologics directly from the drug application holder license holder, or his or her affiliate;
- An affiliate of:
  - The holder of the drug application; or
  - The holder of the license, or
  - The co-licensed partner of the holder of the drug application; or
  - The co-licensed partner of the holder of the license; or
  - The co-licensed partner of the manufacturer of the drug or biologics, not the subject of an approved application or license, who receives the drug or biologics directly from the drug application or license holder, or the co-licensed partner; or
- A person who manufactures a device or cosmetic.[51]

Stem cells recovered, processed, and implanted in Florida that fit the above definitions are "unapproved new drugs" under both federal and state regulation and require a manufacturing

recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary or any supplement to any of them.

[49] Section 499.003(17), F.S.

[50] Section 499.003(28), F.S.

[51] Section 499.003(29), F.S.

permit issued by the DBPR to ensure the drugs are manufactured in accordance with good manufacturing practices.[52]

The FDCA defines the "distribution" of a drug to include the selling, purchasing, trading, delivering, handling, storing, or receiving of a drug; but does not include the administration or dispensing of a drug.[53]

Stem Cell Implantation or Transplantation

Stem cells may be collected, processed, and implanted or transplanted in a physician's office, health care clinic, ambulatory surgical center, or hospital.[54] In order to ship, mail, or deliver, in any manner, a medicinal drug into Florida, a nonresident pharmacy must be registered under s. 465.0156, F.S. In order to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into Florida, a nonresident pharmacy, or an outsourcing facility, must hold a nonresident sterile compounding permit issued by the Board of Pharmacy (BOP).[55]

Physician's Office

The DOH Office of Surgery Registration and Inspection Program was established to register and set standards for allopathic and osteopathic physicians performing surgery in an office setting. The DOH requires all physicians who perform the following to register their office with the DOH:

- Liposuction procedures where more than 1,000 cubic centimeters of supernatant fat is removed;
- Level II procedures; and
- All Level III surgical procedures.[56]

Each registered physician's office must establish financial responsibility[57] and designate a physician who is responsible for the office's compliance with the office health and safety requirements. The designated physician must have a full, active, and unencumbered license and must practice at the office for which he or she is responsible. Within ten days after the termination of the designated physician, the office must notify the DOH of the designation of another physician to serve as the designated physician. If the office fails to comply with these requirements the DOH may suspend the registration.[58]

The DOH will inspect registered physicians' offices that are not nationally accredited, to ensure the safety of the people of Florida.[59]

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[52] Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, *Does my company need a permit?* http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/do-i-need-a-license/#1508505246226-7153ba5b-b4c4 (last visited Jan. 31, 2020). See also s. 499.003(28), F.S.
[53] Section 499.003(16), F.S.
[54] See ss. 395.002, 458.328, 459.0138, and 400.9935, F.S.; Rules 64B8-9.009 and 64B15-14.007, F.A.C. (2019).
[55] Section 465.0158, F.S.
[56] Sections 458.328 and 459.0138, F.S.; Rules 64B8-9.009 and 64B15-14.007, F.A.C. (2019).
[57] Section 458.328(1)(c), F.S.
[58] Section 458.328 (1)(b), F.S.
[59] The Department of Health, Licensing and Regulation, *Office Surgery Registration* http://www.floridahealth.gov/licensing-and-regulation/office-surgery-registration/index.html (last visited Jan. 31, 2020).

Health Care Clinics

The Health Care Clinic Act[60] provides the Agency for Health Care Administration (AHCA) with licensing and regulatory authority to provide standards and oversite for health care clinics.[61] A clinic is defined as an entity where health care services are provided and which tenders charges for reimbursement for such services. Numerous exceptions to licensure exist.[62]The AHCA interprets the scope of its regulatory powers to solely include entities that bill third parties, such as Medicare, Medicaid, and insurance companies. Entities that provide health care services and accept "cash only" for services are excluded from the definition of "clinic" and are not subject to licensure or regulation by the AHCA.[63]

Hospitals and Ambulatory Surgical Centers

The AHCA is responsible for licensing, registering, and regulating hospitals and ambulatory surgical centers (ASC) pursuant to ch. 395, F.S. An ASC is a facility, the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility within 24 hours, and which is not part of a hospital.[64]

Regulation of Physicians in Florida

The BOM and the BOOM (the boards) within the DOH have the authority to adopt rules to regulate the practice of medicine and osteopathic medicine, respectively. The boards have authority to establish, by rule, standards of practice and standards of care for particular settings.[65] Such standards may include education and training, medications including anesthetics, assistance of and delegation to other personnel, sterilization, performance of complex or multiple procedures, records, informed consent, and policy and procedures manuals.[66]

Currently, the BOM is warning physicians and consumers that they should be aware of the risks involved in stem cell therapies and regenerative medicine that have not been FDA-approved.[67] Although certain stem-cell therapies offer hope and hold great potential in treating devastating conditions, the FDA has approved few treatments involving stem cells. The BOM warns physicians providing stem cell treatment that he or she should have an investigational new drug application (IND) or a single patient IND for Compassionate or Emergency Use.[68] Florida does not specifically regulate clinics that perform treatments using stem cells, but the Boards have authority to investigate and discipline physicians who fail to meet the standard of care for providing any medical services.

[60] Part X of ch. 400, F.S.
[61] Section 400.990, F.S.
[62] Section 400.9905(4). F.S.
[63] Id.
[64] Section 395.002(3), F.S.
[65] Sections 458.331(v) and 459.015(z), F.S.
[66] *Id*.
[67] The Department of Health, Board of Medicine, *Information on Stem Cell Clinics Offering Unapproved Therapies*, http://flboardofmedicine.gov/latest-news/october-2015-newsletter/(last visited Jan. 31 2020).
[68] *Id*.

In 2013, the BOM revoked the license of a physician who's administration of processed bone marrow cells, as "stem cell therapy," to a patient which caused the patient to die of a brain embolism.[69]

The U.S. Department of Justice, on behalf of the FDA, brought suit against a stem cell clinic located in Florida. In *United States of America vs. U.S. Stem Cell Clinic LLC*, 403 F.Supp.3d 1279 (2019), the U.S. District Court granted summary judgment and a permanent injunction requiring the defendant's stem cell business to stop advertising and marketing stem cell treatments which had been associated with severe complications in patients, including loss of sight.

The court, in its opinion rendered on June 3, 2019, held that individual stromal and vascular stem cells, known as the "stromal vascular fraction" (SVF), used in the defendant's stem cell therapy, involved the removal of the SVF from a patient's cells and implanting the SVF alone back in same patient, after subjecting the patient's adipose cells to a specific and complex multi-step procedure, thereby creating a "drug" under the FDCA. The defendant further advertised and intended the SVF for use in the treatment of, inter alia, Parkinson's disease, stroke, and lung disease in humans. Thus, the SVF was subject to the FDCA's adulteration and misbranding provisions as a drugs regulated by the FDA, and the defendant's practices had not been approved by the FDA.[70]

The administration of stem cells as an adulterated drug continues to cause injury to Florida residents. On December 18, 2019, the Board of Medicine issued a final disciplinary order restricting the license of a physician for administering adipose tissue cells, as "stem cell therapy," into the eyes of a patient to treat her macular degeneration, which caused the patient to be blinded in one eye, and severely worsened the vision in her other eye.[71]

III. Effect of Proposed Changes:

The bill defines a "nonembryonic stem cell," also referred to as a "somatic stem cell" or an "adult human stem cell," as an allogenic or autologous cell that is undifferentiated and unspecialized and that has the ability to divide for indefinite periods of time in a medium and to become a specialized cell. The term includes a human nonembryonic cell that is altered or processed to become undifferentiated, losing its original structural function, so that it can be differentiated into a specialized cell type. The term does not include cells that are minimally manipulated or are only rinsed, cleaned, or sized and remain differentiated.

The bill defines a NSCB as a publicly or privately owned establishment that does any of the following:

- Collects and stores human nonembryonic stem cells for use in a product or patient-specific medical administration;
- Provides patient-specific health care services using human nonembryonic stem cells;

[69] See *Department of Health vs. Zannos G. Grekos, M.D.*, Final Order, DOAH Case No. 11-4240PL, May 5, 2013; and
[70] *United States of America vs. U.S. Stem Cell Clinic LLC*, 403 F.Supp.3d 1279(2019).
[71] See *Department of Health vs. Shareen Mishal Greenbaum, M.D.*, Board of Medicine Final Order, DOH Case No.19-1922-S-MQA, December 18, 2019.

- Advertises human nonembryonic stem cell services, including, but not limited to, collection, manufacturing, storage, dispensing, use, or purported use of human nonembryonic stem cells or products containing human nonembryonic stem cells, which:
  - Have not been approved by the United States Food and Drug Administration; or
  - Are not the subject of clinical trials approved by the United States Food and Drug Administration; and
  - Which are intended to diagnose, cure, mitigate, treat, provide therapy for, or prevent an injury or a disease.
- Performs any procedure that is intended to:
  - Collect or store human nonembryonic stem cells for any purpose; or
  - Diagnose, cure, mitigate, treat, provide therapy for, or prevent an injury or a disease with the use or purported use of human nonembryonic stem cells or any product containing human nonembryonic stem cells which has not been approved by the United States Food and Drug Administration or is not the subject of a clinical trial approved by the United States Food and Drug Administration.
- Compounds human nonembryonic stem cells from human nonembryonic cells or tissue into products by combining, mixing, or altering the ingredients of one or more drugs or products to create another drug or product;
- Manufactures, through recovery, processing, manipulation, enzymatic digestion, mechanical disruption, or a similar process, human nonembryonic stem cells from human nonembryonic cells or tissue into undifferentiated human nonembryonic stem cells, causing the cells to lose their original structural function so that the nonembryonic stem cells may be differentiated into specialized cell types; or
- Dispenses human nonembryonic stem cells and products containing nonembryonic stem cells to any of the following, for a specific patient pursuant to a valid prescription from a licensed health care practitioner authorized within the scope of his or her license to prescribe and administer human nonembryonic stem cells:
  - A pharmacy permitted under ch. 465, F.S.;
  - A health care practitioner with privileges to practice at nonembryonic stem cell banks; or
  - A health care practitioner's office, a health care facility, or a treatment setting where the health care practitioner has privileges to practice, for office use.

The bill also defines the following specific terms relating to the making, storing and administration of nonembryonic stem cells:

- Compounding - means combining, mixing, or altering the ingredients of one or more drugs or products to create another drug or product.;
- Dispense - has the same meaning as in s. 465.003(6), F.S.;
- Establishment - means a place of business which is at one general physical location and may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. The term includes multiple buildings with an intervening thoroughfare if the buildings are under common exclusive ownership, operation, and control. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application;
- Federal Act - means the Food and Drug Administration Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.;
- Minimally manipulated means:

  - For structural tissue, processing that does not alter the original characteristics of the tissue which relate to the tissue's utility for reconstruction, repair, or replacement; or
  - For cells or nonstructural tissue, processing that does not alter the relevant biological characteristics of the cell or tissue; and
- Office use means the provision and administration of a drug, compounded drug, or compounded product to a patient by a health care practitioner in the practitioner's office or in a health care facility or treatment setting, including a hospital, ambulatory surgery center, or health care clinic licensed under chapter 395 or chapter 400. The term also includes the dispensing by a pharmacist at a nonembryonic stem cell bank that is also permitted as a pharmacy under chapter 465 to a nonembryonic stem cell bank within this state of any of the following:
  - Human nonembryonic stem cells;
  - A compounded drug containing human nonembryonic stem cells; or
  - A compounded product containing nonembryonic stem cells..

The bill requires the NSCB to:

- Adhere to the current good manufacturing practices for the collection, removal, manufacturing, processing, compounding, and implantation of nonembryonic stem cells, or products containing them, under Florida law, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.; and 21 C.F.R., parts 1270-1271;
- Obtain a health care clinic license and register each establishment separately, unless:
  - The clinic is a facility licensed under chapter 395; or
  - The clinic is affiliated with an accredited medical school that provides training to medical students, residents, or fellows.
- Have a physician medical director, a full, active, and unencumbered license, who actively practices at the NSCB, and who is responsible for the NSCB's compliance with all licensure, operations and good manufacturing practices requirements;
- Notify the AHCA, in writing, on a form approved by the AHCA within 10 days after termination of a physician medical director; and notify the AHCA within 10 days after such termination of the identity of the new physician medical director who has assumed the responsibilities for the NSCB. Failure to have a physician medical director practicing at the location of the NSCB is a basis for a summary suspension of the NSCB's license pursuant to s. 400.607 or s. 120.60(6), F.S.;
- Maintain commercial and professional liability insurance in an amount not less than $250,000 per claim;
- Operate each establishment using the same name as the one used to obtain the health care clinic license; and requiring all invoices, packing slips, and other business records to list the same name;
- Obtain a pharmacy permit for each person and establishment before dispensing, offering office use for the compounding of human nonembryonic stem cells, or dispensing a compounded product for office use; and
- Pay all costs associated with licensure, registration and inspection.

The bill authorizes a pharmacist at a NSCB, with a pharmacy permit, to dispense human nonembryonic stem cells, a compounded drug containing human nonembryonic stem cells; and

a compounded product containing human nonembryonic stem cells to another NSCB within the state, for office use.

The bill prohibits the sale or dispensing of human nonembryonic stem cells, a compounded drug containing human nonembryonic stem cells; or a compounded product containing human nonembryonic stem cells by any person or establishment, other than the NSCB or pharmacist at the NSCB that manufactured the human nonembryonic stem cells, the compounded drug, or product containing human nonembryonic stem cells, except that:

- A health care practitioner who requests the dispensing of the human nonembryonic stem cells, compounded drug, or compounded product from the manufacturing NSCB may sell or dispense such items to his or her patient if the health care practitioner is authorized within the scope of his or her license to prescribe and administer human nonembryonic stem cells; or
- A pharmacist, pharmacy, or establishment that requests the dispensing of the human nonembryonic stem cells, compounded drug, or compounded product from the manufacturing NSCB may sell or dispense such items to a health care practitioner who is authorized within the scope of his or her license to prescribe and administer human nonembryonic stem cells to patients.

The bill 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:

CS/SB 512 requires a NSCB to register with the AHCA as a health care clinic, to maintain commercial and professional liability insurance in an amount not less than $250,000 per claim, and to pay all costs associated with licensure, registration and inspection. These additional costs may result in an increase in the costs of NSCB's services to consumers.

C. Government Sector Impact:

The AHCA may experience a recurring increase in workload and costs associated with the registration of NSCBs as health care clinics.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 381.06017 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 February 4, 2020:
The CS:

- Creates s. 381.06017, F.S., rather than s. 381.4017, F.S., which authorizes NSCB's to operate in Florida;
- Requires NSCBs to register with the AHCA as a health care clinic, rather than the DOH;
- Defines an NSCB broadly, not just a facility that stores nonembryonic stem cells, but as any establishment that:
  - Manufactures, collects, or stores human embryonic stem cells;
  - Provides patient-specific health care services using human nonembryonic stem cells;
  - Advertises human nonembryonic stem cell services;
  - Preforms procedures that:
    1) Collects or stores human embryonic stem cells; or
    2) Use non-FDA approved human nonembryonic stem cells, alone, or as a compounded drug or product, to diagnose, cure, treat, provide therapy for, or to prevent injury or disease; or
  - Compounds human nonembryonic stem cells into a compounded drug or product.

- Authorizes the administration of nonembryonic stem cells only by health care practitioners that the scope of the practitioner's license permits the prescribing and administering of human nonembryonic stem cells; and does not authorize:
  - The self-administration of nonembryonic stem cells; or
  - The administration of nonembryonic stem cells by just any person licensed or authorized to administer, or assist in the administration of, medications or health care;
- Does not authorize every pharmacy, owned or operated in Florida, to compound health care products using nonembryonic stem cells either alone or with other sterile ingredients.
- Does not authorize a person to import any sterile compound, drug, or other treatment containing nonembryonic stem cells if such compound, drug, or other treatment:
  - Was obtained legally from the jurisdiction from which it came; and
  - Is for personal use.
- Requires the NSCB to carry both commercial and liability insurance in an amount not less than $250,000 per claim, where the original bill did not specify limits; and
- Authorizes the AHCA to adopt rules necessary to administer the licensure and regulation of NSCBs.

B. Amendments:

None.

By Senator Hutson

7-00555-20 2020512__

A bill to be entitled

An act relating to nonembryonic stem cells; creating s. 381.4017, F.S.; providing legislative findings and intent; providing definitions; authorizing the administration of nonembryonic stem cells and the use of such cells in health care products; authorizing the ownership and operation of a pharmacy in the state which compounds a drug, medicine, or health care product using nonembryonic stem cells; authorizing the importation of any sterile compound, drug, or other treatment containing nonembryonic stem cells under certain circumstances; authorizing certain licensed persons to administer or assist in the administration of such compounds, drugs, or other treatment; authorizing the operation of stem cell banks in the state; requiring a stem cell bank to register with the Department of Health; providing requirements for a department-approved registration form; requiring a stem cell bank to notify the department of any changes in information within a specified time period; requiring a stem cell bank to obtain or otherwise carry professional liability insurance; providing that a professional licensing board is not limited in its duties; providing liability for persons who fail to use reasonable care; requiring that the department adopt by rule standards developed by an independent third party; providing an effective date.

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

Section 1. Section 381.4017, Florida Statutes, is created to read:

381.4017 Nonembryonic stem cells; stem cell bank registration.—

(1) The Legislature finds that access to safe and high-quality health care services and products is of concern to all persons and regenerative medicine, including the use of nonembryonic stem cells, is a promising area of health care. It is the intent of the Legislature to encourage and facilitate the safety of all health care services and products.

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

(a) "Allogeneic" means originating from the body of another person.

(b) "Autologous" means originating from within a person's own body.

(c) "Department" means the Department of Health.

(d) "Independent third party" means an organization:

1. That provides industry safety standards, relevant research, and an industry-specific database in association with one or more stem cell banks; and

2. Whose members are registered with the department.

(e) "Nonembryonic stem cells" means autologous or allogeneic cellular material that:

1. Has not been isolated or obtained directly from human embryos; and

2. May have been or may be combined with one or more:

a. Naturally occurring biomaterials; or

b. Materials approved or cleared by the United States Food

and Drug Administration or other applicable agency or authority.

(f) "Stem cell bank" means a facility that stores nonembryonic stem cells.

(3) Nonembryonic stem cells may be administered to a person by:

(a) Himself or herself; or

(b) A person licensed or authorized in this state to administer or assist in the administration of medicine or health care if such person administers or assists in the administration of the nonembryonic stem cells using a mode of administration permitted under his or her license or authorization.

(4) A health care product may be compounded using nonembryonic stem cells as a sterile ingredient either by themselves or in combination with other sterile ingredients. A pharmacy that compounds a drug, medicine, or health care product using nonembryonic stem cells may be owned or operated, or both, in this state.

(5)(a) A person may import into this state any sterile compound, drug, or other treatment containing nonembryonic stem cells if such compound, drug, or other treatment:

1. Was obtained without violating the laws of the jurisdiction in which it was obtained; and

2. Is for personal use.

(b) A person licensed or authorized in this state to administer or assist in the administration of medicine or health care may administer or assist in the administration of the imported sterile compound, drug, or other treatment containing nonembryonic stem cells if such person administers or assists in the administration of such compound, drug, or other treatment

using a mode of administration permitted under his or her license or authorization.

(6)(a) Notwithstanding any other provision of law, a stem cell bank may operate in this state.

(b) Before organizing or arranging for the operation of a stem cell bank in this state, a stem cell bank must register with the department by submitting a department-approved registration form that contains:

1. The name, street address, and telephone number of the stem cell bank.

2. The name, street address, and telephone number of each officer, director, or organizational official of the stem cell bank who is responsible for the operation of the stem cell bank.

3. Identification of the types of human tissue used in business or research at the stem cell bank.

4. Identification of the product names produced at the stem cell bank for distribution.

5. Any other information required for registration by the department.

(c) Each stem cell bank shall notify the department in writing of any change in the information required for registration not later than 10 days after such change goes into effect.

(d) Each stem cell bank that operates in this state must obtain or otherwise carry, before engaging in such business, a policy of professional liability insurance that insures the stem cell bank against any liability arising from the operation of such business.

(7) This section does not absolve:

(a) A professional licensing board of the duty to regulate licenses or otherwise prohibit or limit the powers and duties of a licensing board to regulate the procedures used to administer nonembryonic stem cells.

(b) Any person of civil or criminal liability or penalty for failure to use the reasonable care, skill, or knowledge ordinarily used in rendering health care services or administering health care products under similar circumstances.

(8) The department shall adopt by rule standards developed by an independent third party to ensure public safety and to implement this section.

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 27, 2020

I respectfully request that **Senate Bill #512**, relating to Nonembryonic Stem Cells, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Senator Travis Hutson
Florida Senate, District 7

File signed original with committee office

S-020 (03/2004)

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 1014
INTRODUCER:	Senator Rouson
SUBJECT:	Public Safety Telecommunicator Training
DATE:	February 3, 2020 REVISED:

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

I. Summary:

SB 1014 modifies standards and requirements for public safety telecommunicator certification to add the requirement that 911 public safety telecommunicators who take telephone calls and provide dispatch functions for emergency medical conditions must receive "telecommunicator cardiopulmonary resuscitation (CPR) training," as that term is specifically defined, every two years. The bill directs the Department of Health (DOH) to establish a procedure to monitor adherence with the added training requirements and authorizes the DOH to adjust state grant and shared revenue funds to a public safety agency based on the agency's employees' adherence with the added requirements.

The fiscal impact of the bill is unknown.

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

II. Present Situation:

911 Public Safety Telecommunicator Certification

Chapter 401, F.S., relates to medical telecommunications and transportation. Part I of ch. 401, F.S., is specific to the state's emergency telecommunication systems, administered by the Department of Management Services. Part II of ch. 401, F.S., is specific to the emergency medical services (EMS) grants program administered by the DOH.

Part III of ch. 401, F.S., consisting of ss. 401.2101-401.465, F.S., is specific to medical transportation services and provides for the regulation of emergency medical services by the DOH, including the licensure of EMS service entities, the certification of staff employed by those services, and the permitting of vehicles used by such staff—whether for basic life support (BLS), advanced life support (ALS), or air ambulance services (AAS). At present, the DOH is

responsible for the licensure and oversight of more than 60,000 emergency medical technicians and paramedics, more than 270 advanced and basic life support agencies, and over 4,500 EMS vehicles.[1]

Section 401.465, F.S., is specific to 911 public safety telecommunicator certification, as administered as part of the DOH EMS program. For purposes of that section of statute, the following terms are defined:[2]

- "911 public safety telecommunicator" means a public safety dispatcher or 911 operator whose duties and responsibilities include the answering, receiving, transferring, and dispatching functions related to 911 calls; dispatching law enforcement officers, fire rescue services, emergency medical services, and other public safety services to the scene of an emergency; providing real-time information from federal, state, and local crime databases; or supervising or serving as the command officer to a person or persons having such duties and responsibilities. However, the term does not include administrative support personnel, such as, but not limited to, those whose primary duties and responsibilities are in accounting, purchasing, legal, and personnel.
- "Public safety telecommunication training program" means a 911 emergency public safety telecommunication training program that the DOH determines to be equivalent to the public safety telecommunication training program curriculum framework developed by the Department of Education (DOE) and consists of not less than 232 hours.

Any person employed as a 911 public safety telecommunicator (PST) at a public safety answering point, as defined in s. 365.172(3), F.S.,[3] must be certified by the DOH. A public safety agency, as defined in s. 365.171(3)(d), F.S.,[4] may employ a PST for a period not to exceed 12 months if the trainee works under the direct supervision of a certified 911 public safety telecommunicator, as determined by rule of the DOH, and is enrolled in a PST training program. An applicant for certification or recertification as a PST must apply to the DOH under oath on DOH-provided forms. The DOH establishes by rule educational and training criteria for the certification and recertification of PSTs. The DOH determines whether the applicant meets the statutory and rule requirements and issues a certificate to any person who meets such requirements, including those specific to training program completion, an oath of no addiction, an oath that there is no physical or mental impairment, application fee, application submission, and passage of a certification examination.[5]

A PST certification expires automatically if not renewed at the end of the two-year period and may be renewed if the certificate holder meets the DOH-established qualifications. The DOH establishes by rule a procedure that requires 20 hours of training for the biennial renewal certification of PSTs. The DOH may suspend or revoke a certificate at any time if it determines

[1] *See* http://www.floridahealth.gov/licensing-and-regulation/ems-system/index.html (last visited January 29, 2020).
[2] Section 401.465(1), F.S.
[3] Section 365.172 (3)(y), F.S., defines a "public safety answering point" as the public safety agency that receives incoming 911 requests for assistance and dispatches appropriate public safety agencies to respond to the requests in accordance with the state E911 plan.
[4] Section 365.171(3)(d), F.S., defines a "public safety agency" as a functional division of a public agency which provides firefighting, law enforcement, medical, or other emergency services.
[5] Section 401.465(2), F.S.

that the certificate holder does not meet the applicable qualifications. There is a process by which a certificate holder may request that his or her certificate be placed on inactive status.[6]

A person who was employed as a PST or a state-certified firefighter before April 1, 2012, must pass the examination approved by the DOH which measures the competency and proficiency in the subject material of the PST program, and upon passage of the examination, the completion of the PST training program is waived. In addition, the requirement for certification as a PST is waived for a person employed as a sworn, state-certified law enforcement officer, provided specified criteria are met.[7]

The following PST-related fees are specified in statute:
- Initial application for original certification: $50
- Examination fee, set by the DOH, not to exceed $75
- Biennial renewal certificate, set by the DOH, not to exceed $50
- Training program fee, set by the DOH, not to exceed $50
- Duplicate, substitute or replacement certificate fee, set by the DOH, not to exceed $25

Fees collected are deposited into the DOH EMS Trust Fund and used solely for administering this program.[8] The fees currently applied by the DOH are the maximum fees indicated above.[9]

The DOH has adopted three rules specific to its PST program responsibilities. These rules, which address PST certification, certification renewal, and PST course equivalency, were adopted in 2012.[10] These rules not only link to the DOH forms and reference documents but also link to the relevant DOE documents, such as PST curriculum framework.

The DOH website has extensive details specific to the PST program and includes links to all applicable forms for individuals who are seeking to become certified or re-certified as a PST, including PST examination details, training program requirements, and fees. Training programs must follow the DOE Public Safety Telecommunication Curriculum Framework and consist of not less than 232 hours in order to be approved as a PST training program. The DOH uses a vendor, Prometric,[11] to administer the testing for PST candidates.[12]

The DOH develops the learning objectives for the PST program, and these are reflected in the 142-page program study guide.[13] Until State Fiscal Year 2014-2015, the DOH learning objectives and the DOE curriculum framework included a requirement that PST training must

[6] *Id.*
[7] *Id.*
[8] Section 401.465(3), F.S.
[9] See the Department of Health, 911 Public Safety Telecommunicator Program, *available at* http://www.floridahealth.gov/licensing-and-regulation/911-public-safety-telecommunicator-program/index.html (last visited January 29, 2020).
[10] Fla. Adm. Code R. 64J-3 (2012).
[11] Prometric is a provider of technology-enabled testing and assessment solutions to many licensing and certification organizations, academic institutions, and government agencies.
[12] *Supra* note 9.
[13] *See* the Department of Health, Florida 911 Public Safety Telecommunicator Study Guide, *available at* http://www.floridahealth.gov/licensing-and-regulation/911-public-safety-telecommunicator-program/_documents/911-pst-studyguide-2017E4.pdf.pdf (last visited January 29, 2020).

include CPR training. In conjunction with the DOE and other stakeholders, the CPR element of required training was discontinued.[14]

According to the DOH, there are currently 115 active approved PST training programs in the state.[15]

Curriculum Framework for Public Safety Telecommunication

One of the divisions within the DOE is the Division of Adult and Community Education. Under this division is the DOE's Career & Technical Education (CTE) Programs section, which is responsible for developing and maintaining educational programs that prepare individuals for occupations important to Florida's economic development. These programs are organized into 17 different career clusters and are geared toward middle school, high school, district technical school, and Florida College System students throughout the state. Listed among the DOE's Career Clusters and Programs is Law, Public Safety, and Security. Among the certificate programs is the public safety telecommunicator program.[16]

The DOE Curriculum Framework for the PST program title indicates that the program offers a sequence of courses that:

- Provide coherent and rigorous content aligned with challenging academic standards and relevant technical knowledge and skills needed to prepare for further education and careers in DOE's Law, Public Safety and Security career cluster;
- Provide technical skill proficiency, and;
- Include competency-based applied learning that contributes to the academic knowledge, higher-order reasoning and problem-solving skills, work attitudes, general employability skills, technical skills, occupation-specific skills, and knowledge of all aspects of the Law, Public Safety and Security career cluster.[17]

Cardiopulmonary Resuscitation (CPR): First Aid

Cardiopulmonary resuscitation (CPR) is a lifesaving technique useful in many emergencies, including a heart attack or near drowning, in which someone's breathing or heartbeat has stopped. At its most basic, CPR is a technique which utilizes chest compressions when a patient has suffered from cardiac arrest. The American Heart Association recommends that everyone — untrained bystanders and medical personnel alike — begin CPR with chest compressions. CPR can keep oxygenated blood flowing to the brain and other vital organs until more definitive medical treatment can restore a normal heart rhythm. When the heart stops, the lack of

[14] Email from Department of Education to staff of the Senate Committee on Health Policy (January 30, 2020) (on file with the Senate Committee on Health Policy).
[15] Email from the Department of Health to staff of the Senate Committee on Health Policy (January 30, 2020) (on file with the Senate Committee on Health Policy).
[16] Department of Educations, Career and Technical Education, *available at* http://www.fldoe.org/academics/career-adult-edu/career-tech-edu/ (last visited January 29, 2020).
[17] *Id.*

oxygenated blood can cause brain damage in only a few minutes. A person may die within eight to 10 minutes.[18]

III. Effect of Proposed Changes:

Section 1 amends s. 401.465, F.S., relating to standards and requirements for 911 public safety telecommunicator certification, to:

- Add a definition of "telecommunicator cardiopulmonary resuscitation training" to mean specific training that is evidence based and contains nationally accepted guidelines for the recognition of out-of-hospital cardiac arrest over the telephone and the delivery of telephonic instructions for treating cardiac arrest and performing compression-only cardiopulmonary resuscitation.
- Incorporate a conforming cross-reference change.
- Add the requirement that 911 public safety telecommunicators who take telephone calls and provide dispatch functions for emergency medical conditions must receive "telecommunicator cardiopulmonary resuscitation training," as that term is defined above, every two years.
- Direct the DOH to establish a procedure to monitor adherence with the added training requirements and authority to adjust state grant and shared revenue funds to a public safety agency, as defined in s. 365.171(3), F.S., based on the agency's employees' adherence or failure to adhere with the added requirements.

Section 2 provides for 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.

[18] *See* Mayo Clinic: Cardiopulmonary resuscitation (CPR): First aid, *available at* https://www.mayoclinic.org/first-aid/first-aid-cpr/basics/art-20056600 (last visited January 29, 2020).

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Unknown.

C. Government Sector Impact:

Unknown.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Training in CPR was previously, but is not currently, part of the public safety telecommunicator core training competencies. When CPR was previously a required element in the training program, the CPR requirement was not specified in statute; it was part of the DOH program learning objectives. Elements for public telecommunicator training are not specified in statute. Training content is determined by the DOH and is reflected in the DOH learning objectives for the program. The DOH learning objectives are then reflected in the DOE curriculum framework, which is adopted by reference in rule.[19]

The approach proposed in the bill would require those who have undergone training and become certified in all other respects as a public safety telecommunicator to undergo another, separate level of training. The focus of this separate training requirement would be to prepare a public safety telecommunicator in performing CPR and in the delivery of telephonic instruction in the performance of CPR.

VIII. Statutes Affected:

This bill substantially amends the following section of the Florida Statutes: 401.465.

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.

[19] Fla. Adm. Code R. 64J-3.002 (2012).

By Senator Rouson

19-01419-20 20201014__

A bill to be entitled

An act relating to public safety telecommunicator training; amending s. 401.465, F.S.; defining the term "telecommunicator cardiopulmonary resuscitation training"; conforming cross-references; requiring certain 911 public safety telecommunicators to receive telecommunicator cardiopulmonary resuscitation training every 2 years; requiring the Department of Health to establish a procedure to monitor adherence to the training requirements; authorizing the department to adjust state grants or shared revenue funds to certain entities based on their employees' adherence or failure to adhere to the training requirements; providing an effective date.

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

Section 1. Present subsections (3) and (4) of section 401.465, Florida Statutes, are redesignated as subsections (4) and (5), respectively, paragraph (d) is added to subsection (1) of that section, a new subsection (3) is added to that section, and paragraphs (d) and (j) of subsection (2) of that section are amended, to read:

401.465 911 public safety telecommunicator certification.—

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

(d) "Telecommunicator cardiopulmonary resuscitation training" means specific training that is evidence based and contains nationally accepted guidelines for the recognition of out-of-hospital cardiac arrest over the telephone and the

delivery of telephonic instructions for treating cardiac arrest and performing compression-only cardiopulmonary resuscitation.

(2)PERSONNEL; STANDARDS AND CERTIFICATION.—

(d) The department shall determine whether the applicant meets the requirements specified in this section and in rules of the department and shall issue a certificate to any person who meets such requirements. Such requirements must include the following:

1. Completion of an appropriate 911 public safety telecommunication training program;

2. Certification under oath that the applicant is not addicted to alcohol or any controlled substance;

3. Certification under oath that the applicant is free from any physical or mental defect or disease that might impair the applicant’s ability to perform his or her duties;

4. Submission of the application fee prescribed in subsection (4) ~~(3)~~;

5. Submission of a completed application to the department which indicates compliance with subparagraphs 1., 2., and 3.; and

6. Effective October 1, 2012, passage of an examination approved by the department which measures the applicant’s competency and proficiency in the subject material of the public safety telecommunication training program.

(j)1. The requirement for certification as a 911 public safety telecommunicator is waived for a person employed as a sworn state-certified law enforcement officer, provided the officer:

a. Is selected by his or her chief executive to perform as

a 911 public safety telecommunicator;

b. Performs as a 911 public safety telecommunicator on an occasional or limited basis; and

c. Passes the department-approved examination that measures the competency and proficiency of an applicant in the subject material comprising the public safety telecommunication program.

2. A sworn state-certified law enforcement officer who fails an examination taken under subparagraph 1. must take a department-approved public safety telecommunication training program prior to retaking the examination.

3. The testing required under this paragraph is exempt from the examination fee required under subsection (4) ~~(3)~~.

(3) TELECOMMUNICATOR CARDIOPULMONARY RESUSCITATION TRAINING.—

(a) In addition to the certification and recertification requirements contained in this section, 911 public safety telecommunicators who take telephone calls and provide dispatch functions for emergency medical conditions shall also receive telecommunicator cardiopulmonary resuscitation training every 2 years.

(b) The department shall establish a procedure to monitor adherence to the training requirements of this subsection and may adjust state grant or shared revenue funds to a public safety agency as defined in s. 365.171(3) based on its employees' adherence or failure to adhere to these requirements.

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 23, 2020

I respectfully request that **Senate Bill #1014**, relating to Public Safety Telecommunicator Training, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Darryl E. Rouson

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)

2/4/20
Meeting Date

1014
Bill Number (if applicable)

Topic Telecommunicator CPR

Amendment Barcode (if applicable)

Name Mark Landreth

Job Title Gov Rel Dir

Address 2851 Remington Green Cir #A
Street
Tallahassee 32308
City *State* *Zip*

Phone 850.544.3376

Email mark.landreth@heart.org

Speaking: ☑ For ☐ Against ☐ Information

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

Representing American Heart Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

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)

2-4-2020
Meeting Date

1014
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic _____

Name Richard Pinsky

Job Title _____

Address 106 E. College Ave #1200 (*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 9-1-1 Emergency Dispatchers

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:	CS/SB 744
INTRODUCER:	Health Policy Committee and Senators Hooper and Gruters
SUBJECT:	Podiatric Medicine
DATE:	February 5, 2020
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 744 provides that a supervising allopathic or osteopathic physician of a physician assistant (PA) may authorize a licensed PA to perform services under the direction of a podiatric physician who is a partner, a shareholder, or an employee of the same group practice as the supervising physician and the PA. The supervising physician is liable for the performance, the acts, and omissions of the PA. The bill authorizes:

- A PA to perform services under the direction of a licensed podiatric physician;
- A podiatric physician to supervise a medical assistant;
- The Board of Podiatric Medicine (BPM) to make rules regarding a podiatric physician's continuing education for license renewal and to approve course and program criteria, including two hours related to safe and effective prescribing of controlled substances; and
- Authorizes individuals to directly contract with podiatric physicians through direct health care agreements, for the provision of health care services.

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

II. Present Situation:

The Department of Health

The Legislature created the Department of Health (DOH) to protect and promote the health of all residents and visitors in the state.[1] The DOH is charged with the regulation of health practitioners

[1] Section 20.43, F.S.

for the preservation of the health, safety, and welfare of the public. The Division of Medical Quality Assurance (MQA) is responsible for the boards[2] and professions within the DOH.[3]

Podiatric Medicine

Podiatric medicine is the diagnosis or medical, surgical, palliative, and mechanical treatment of ailments of the human foot or leg.[4] It also includes the amputation of toes or other parts of the foot but does not include the amputation of the entire foot or leg. A podiatric physician is authorized to prescribe drugs specifically related to his or her scope of practice.[5]

The BPM was established to ensure that every podiatric physician practicing in this state meets minimum requirements for safe practice. The BPM, through efficient and dedicated organization, licenses, monitors, disciplines, educates, and when appropriate, rehabilitates practitioners to assure their competence in the service of the people of Florida.

Licensure Requirements

Florida law requires a podiatric physician to meet the following requirements for licensure:[6]

- Be at least 18 years of age;
- Hold a degree from a school or college of podiatric medicine or chiropody recognized and approved by the Council on Podiatry Education of the American Podiatric Medical Association;
- Have successfully completed one of the following clinical experience requirements:
  - One year of residency in a program approved by the BPM;[7] or
  - Ten years of continuous, active licensed practice of podiatric medicine in another state immediately preceding application and completion of at least the same continuing education requirements during those 10 years as are required of podiatric physicians licensed in this state;
- Successfully complete a background screening; and
- Obtain passing scores on the national examinations administered by the National Board of Podiatric Medical Examiners.[8]

A license to practice podiatric medicine must be renewed biennially.

[2] Under s. 456.001(1), F.S., the term "board" is defined as any board, commission, or other statutorily created entity, to the extent such entity is authorized to exercise regulatory or rulemaking functions within the DOH or, in some cases, within the DOH, MQA.
[3] Section 20.43, F.S.
[4] Section 461.003(5), F.S.
[5] Id.
[6] Section 461.006, F.S.
[7] Id. If it has been more than four years since the completion of the residency, an applicant must have two years of active, licensed practice of podiatric medicine in another jurisdiction in the four years immediately preceding application or successfully complete a board-approved postgraduate program or board-approved course within the year preceding application.
[8] Fla. Adm. Code R. 64B18-11.002,(2019).

Continuing Education

A podiatric physician must complete 40 hours of continuing education as a part of the biennial licensure renewal, which must include:[9]

- One hour on risk management;
- One hour on the laws and rules related to podiatric medicine;
- Two hours on the prevention of medical errors;
- Two hours on HIV/AIDS (due for the first renewal only); and
- One hour on human trafficking (beginning January 1, 2021).[10]

Controlled Substance Prescribers

Effective July 1, 2018, every person registered with the U.S. Drug Enforcement Administration and authorized to prescribe controlled substances, must complete a two-hour continuing education course on prescribing controlled substances.[11] The course must include:

- Information on the current standards for prescribing controlled substances, particularly opiates;
- Alternatives to these standards;
- Non-pharmacological therapies;
- Prescribing emergency opioid antagonists; and
- The risks of opioid addiction following all stages of treatment in the management of acute pain.

The course can only be offered by a statewide professional association of physicians in this state that is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 Credit or the American Osteopathic Category 1-A medical continuing education on the safe and effective prescribing of controlled substances each biennial license renewal.[12] Currently the course is provided for podiatric physicians by:[13]

- The Florida Medical Association;
- The Florida Osteopathic Medical Association;
- InforMed;
- Emergency Medicine Learning and Resource Center; and
- Florida Academy of Family Physicians.

This requirement does not apply to a licensee who is required by his or her applicable practice act to complete a minimum of two hours of continuing education on the safe and effective prescribing of controlled substances.[14] The requirement applies to podiatric physicians because

[9] Section 461.007(3), F.S., and Fla. Adm. Code R. 64B18-17, (2019).
[10] Section 456.0341, F.S.
[11] Section 456.0301, F.S.
[12] Id.
[13] Department of Health, *Take Control of Controlled Substances*, available at http://www.flhealthsource.gov/FloridaTakeControl/ (last visited Jan. 30, 2020). To access the podiatric list of providers, select Podiatric Medicine.
[14] *See* note 11.

their practice act does not specifically require a two hours of continuing education on the safe and effective prescribing of controlled substances.

Physician Assistants (PAs)

Physician assistants (PAs) are regulated by the Board of Medicine (BOM) in conjunction with the Florida Council on Physician Assistants (PA Council) for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine (BOOM) for PAs licensed under ch. 459, F.S. The boards and PA Council are responsible for adopting the principles that a supervising physician must use for developing a PA's scope of practice, developing a formulary of drugs that may not be prescribed by a PA, and approving educational programs.[15]

Council on Physician Assistants

The PA Council consists of five members, including three physicians who are members of the BOM, one physician who is a member of the BOOM, and one licensed PA appointed by the Surgeon General.[16] Two of the physicians must be physicians who supervise physician assistants in their practice. The PA Council is responsible for:[17]

- Making recommendations to DOH regarding the licensure of PAs;
- Developing rules for the regulation of PAs for consideration for adoption by the boards;
- Making recommendations to the boards regarding all matters relating to PAs;
- Addressing concerns and problems of practicing PAs to ensure patient safety; and
- Denying, restricting, or placing conditions on the license of a PA who fails to meet the licensing requirements.

Licensure and Regulation of PAs

An applicant for a PA license must apply to the DOH. The DOH must issue a license to a person certified by the PA Council as having met all of the following requirements:[18]

- Completed an approved PA training program;
- Obtained a passing score on the National Commission on Certification of Physician Assistants examination;
- Acknowledged any prior felony convictions;
- Submitted to a background screening and have no disqualifying offenses;[19]
- Acknowledged any previous revocation or denial of licensure in any state; and
- Provided a copy of course transcripts and a copy of the course description from a PA training program describing the course content in pharmacotherapy if the applicant is seeking prescribing authority.

PAs must renew their licenses biennially. During each biennial renewal cycle, a PA must complete 100 hours of continuing medical education or must demonstrate current certification

[15] Sections 458.347(4) and (6), F.S., and 459.022(4) and (6), F.S.
[16] Sections 458.347(9), F.S., and 459.022(9), F.S. Members of the Board of Medicine and the Board of Osteopathic Medicine are appointed by the Governor and confirmed by the Senate. *See* ss. 458.307, F.S., and 459.004, F.S., respectively.
[17] Id.
[18] Sections 458.347(7), F.S., and 459.022(7), F.S.
[19] Section 456.0135, F.S.

issued by the National Commission on Certification of Physician Assistants.[20] To maintain certification, a PA must earn at least 100 hours of continuing medical education biennially and must take a re-certification examination every 10 years.[21]

PA Scope of Practice

PAs may practice only under the direct or indirect supervision of an allopathic or osteopathic physician with whom they have a clinical relationship.[22] A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[23] The supervising physician is responsible and liable for any acts or omissions of the PA and may not supervise more than four PAs at any time.[24]

The BOM and the BOOM have established by rule that "responsible supervision" of a PA means the ability of the supervising physician to exercise control and provide direction over the services or tasks performed by the PA. Whether the supervision of a PA is adequate is dependent upon the:[25]

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

A supervising physician decides whether to permit a PA to perform a task or procedure under direct or indirect supervision based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.[26] A supervising physician may delegate the authority for a PA to:

- Prescribe or dispense any medicinal drug used in the supervising physician's practice unless such medication is listed in the formulary established by the PA Council;[27]

[20] Sections 458.347(7)(c) and 459.022(7)(c), F.S.
[21] National Commission on Certification of Physician Assistants, *Maintaining Certification*, available at https://www.nccpa.net/CertificationProcess (last visited Jan. 31, 2020).
[22] Sections 458.347(2)(f), and 459.022(2)(f), F.S., define supervision as responsible supervision and control which requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.
[23] Fla. Adm. Code R. 64B8-30.012 and 64B15-6.010 (2019).
[24] Sections 458.347(15), F.S. and 459.022(15), F.S.
[25] Fla. Adm. Code R. 64B8-30.001 and 64B15-6.001 (2019).
[26] Id. "Direct supervision" refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed. "Indirect supervision" refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication.
[27] Sections 458.347(4)(f) and 459.022(e), F.S., directs the Council to establish a formulary listing the medical drugs that a PA may not prescribe. The formulary in Rules 64B8-30.008 and 64B15-6.0038, F.A.C., prohibits PAs from prescribing; general, spinal or epidural anesthetics; radiographic contrast materials; and psychiatric mental health controlled substances for children younger than 18 years of age. It also restricts the prescribing of Schedule II controlled substances to a seven-day supply. However, the rules authorize physicians to delegate to PAs the authority to order controlled substances in hospitals and other facilities licensed under ch. 395, F.S.

- Order any medication for administration to the supervising physician's patient in a hospital or other facility licensed under chapter 395, F.S., or at a health care clinic or nursing homes licensed under ch. 400, F.S.;[28] and
- Any other service that is not expressly prohibited in chs. 458 and 459, F.S., or the rules adopted under each.[29]

Currently, podiatric physicians are not authorized to supervise or delegate tasks or procedures to PAs.

Medical Assistants

Section 458.3485, F.S., define a "medical assistant" as a professional, multi-skilled person dedicated to assisting in all aspects of medical practice under the direct supervision and responsibility of a physician. This practitioner:
- Assists with patient care management;
- Executes administrative and clinical procedures; and
- Often performs managerial and supervisory functions.

Competence in the field also requires that a medical assistant adhere to ethical and legal standards of professional practice, recognize and respond to emergencies, and demonstrate professional characteristics.

A medical assistant performs his or her duties under the direct supervision and responsibility of a licensed physician. A medical assistant may undertake the following duties:
- Performing clinical procedures, including:
  - Performing aseptic procedures;
  - Taking vital signs;
  - Preparing patients for the physician's care and treatment;
  - Performing venipunctures and non-intravenous injections; and
  - Observing and reporting patients' signs or symptoms;
- Administering basic first aid;
- Assisting with patient examinations or treatments;
- Operating office medical equipment;
- Collecting routine laboratory specimens as directed by the physician;
- Administer medication as directed by the physician;
- Performing basic laboratory procedures;
- Performing office procedures, including all general administrative duties required by the physician;
- Performing dialysis procedures, including home dialysis.

Medical assistants are not required to be licensed, certified, or registered to practice in Florida but may obtain the designation of a certified medical assistant. However, a medical assistant may obtain the designation of certified medical assistant if he or she receives a certification from a

[28] Chapter 395, F.S., provides for the regulation and the licensure of hospitals and trauma centers, part II of ch. 400, F.S., provides for the regulation and licensure of nursing home facilities.
[29] Sections 458.347(4) and 459.022(e), F.S.

program accredited by the National Commission for Certifying Agencies, a national or state medical association, or an entity approved by the BOM.

Currently, podiatric physicians are not authorized to supervise or delegate tasks or procedures to medical assistants.

Direct Health Care Agreements

Section 624.27, F.S., authorizes the use of a direct health care agreements between a health care provider and his or patients. A direct health care agreement is a contract between a health care provider and a patient, a patient's legal representative, or a patient's employer, which must:

- Be in writing;
- Be signed by the health care provider, or his or her agent, and the patient, the patient's legal representative, or the patient's employer;
- Allow either party to terminate the agreement by giving the other party 30 days' advance written notice;
- Allow immediate termination of the agreement for a violation of physician-patient relationship or a breach of the terms of the agreement;
- Describe the scope of health care services that are covered by the monthly fee;
- Specify the monthly fee and any fees for health care services not covered under the agreement;
- Specify the duration of the agreement and any automatic renewal provisions;
- Offer a refund to the patient of monthly fees paid in advance if the health care provider stops offering health care services for any reason;
- State that the agreement is not health insurance and that the health care provider will not bill the patient's health insurance policy or plan for services covered under the agreement;
- State that the agreement does not qualify as minimum essential coverage to satisfy the individual responsibility provision of the federal Patient Protection and Affordable Care Act; and
- State that the agreement is not workers' compensation insurance and may not replace the employer's workers' compensation obligations.

A direct health care agreement is not considered health insurance and is exempt from the Florida Insurance Code, and the Office of Insurance Regulation does not have authority to regulate such agreements.[30]

Currently, s. 624.27, F.S., pertains to direct health care agreement contracts with allopathic physicians, osteopathic physicians, chiropractic physicians, nurses, or dentists, or a health care group practice, for health care services that are within the competency and training of the health care provider. Direct health care agreement contracts with a podiatric physician for the provision of health care services are not contemplated under the statute.

[30] Section 624.27(2), F.S.

III. Effect of Proposed Changes:

Podiatric Physician Direction of Physician Assistants and Medical Assistants

CS/SB 744 amends the practice acts for allopathic and osteopathic physicians in ss. 458.347 and 459.022, F.S., respectively, to provide that a supervising allopathic or osteopathic physician may authorize a licensed PA to perform services under the direction of a licensed podiatric physician who is a partner, a shareholder, or an employee of the same group practice, as defined in s. 456.053(3), F.S., as the supervising physician and the PA. Under the bill, the supervising physician is liable for the performance, the acts, and omissions of the PA.

The bill amends s. 458.3485, F.S., to authorize podiatric physicians to supervise medical assistants.

The bill creates ss. 461.0145 and 461.0155, F.S., within the podiatric medicine practice act, to provide that:

- A licensed PA may perform services under the direction of a podiatric physician; and
- A medical assistant may be supervised by a podiatric physician.

Direct Health Care Agreements

The bill authorizes individuals to directly contract with podiatric physicians through direct health care agreements for the provision of health care services without such contracts being considered insurance. The bill retains the contract requirements under current law for other health care practitioners offering direct health care agreements and applies them to such contracts with podiatric physicians.

Continuing Education

The bill amends s. 461.007, F.S., to provide that the continuing education hours the BPM is authorized to require of podiatrists for licensure renewal must include a minimum of two hours of continuing education related to the safe and effective prescribing of controlled substances. The criteria for such continuing education courses must be approved by the BPM.

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:

The bill defines "physician" in s. 458.4385, F.S., relating to medical assistants, as a person who is licensed as a physician under ch. 458 or as a podiatric physician under ch. 461, F.S. This definition excludes physicians licensed under ch. 459, F.S., and could be interpreted to specifically exclude osteopathic physicians from supervising medical assistants.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 458.347, 458.3485, 459.022, 461.007, and 624.27.

This bill creates the following sections of the Florida Statutes: 461.0145 and 461.0155.

IX. Additional Information:

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

CS by Health Policy on February 4, 2020:
The CS:

- Deletes the authority in the underlying bill of a podiatric physician, or group of podiatric physicians, to supervise up to four PAs and delegate tasks to PAs in the same manner as supervising allopathic and osteopathic physicians;

- Deletes the underlying bill's provision for podiatric physicians' independent and collective liability for any errors or omissions by the PA;
- Permits a podiatric physician, who is a partner, a shareholder, or an employee of the same group practice as the PA and the supervising allopathic or osteopathic physician, to "direct," not "supervise," a PA in the group practice;
- Imposes liability for the performance, errors, or omissions of the PA, while being directed by the podiatric physician, on the supervising allopathic or osteopathic physician;
- Eliminates any expansion of the number of members on the Council of PAs; and
- Deletes the underlying bill's authority for the BPM to develop the following for PAs working in a podiatric practice:
  - The scope of practice;
  - The formulary of drugs that PAs may not prescribe; and
  - PA educational programs.

B. Amendments:

None.

By Senator Hooper

16-00480-20 2020744__

A bill to be entitled

An act relating to podiatric medicine; amending s. 458.347, F.S.; providing and revising definitions; revising the membership, terms, and duties of the Council on Physician Assistants; amending s. 458.3485, F.S.; defining the term "physician" to include podiatric physicians; amending s. 459.022, F.S.; providing and revising definitions; revising the membership, terms, and duties of the Council on Physician Assistants; amending s. 461.007, F.S.; authorizing the Board of Podiatric Medicine to require as a condition for renewal of license a specified number of continuing education hours related to the safe and effective prescribing of controlled substances; creating s. 461.0145, F.S.; authorizing a podiatric physician or group of podiatric physicians to supervise a specified number of physician assistants; providing requirements for physician assistants under such supervision; providing for liability; creating s. 461.0155, F.S.; providing for governance of podiatric physicians who supervise medical assistants; amending s. 624.27, F.S.; revising the definition of the term "health care provider" to include podiatric physicians; providing an effective date.

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

Section 1. Paragraph (i) is added to subsection (2) of

section 458.347, Florida Statutes, and paragraphs (b) and (h) of that subsection and paragraphs (a) through (c) of subsection (9) of that section are amended, to read:

458.347 Physician assistants.—

(2) DEFINITIONS.—As used in this section:

(b) "Boards" means the Board of Medicine, ~~and~~ the Board of Osteopathic Medicine, and the Board of Podiatric Medicine.

(h) "Continuing medical education" means courses recognized and approved by the boards, the American Academy of Physician Assistants, the American Medical Association, the American Osteopathic Association, the American Podiatric Medical Association, or the Accreditation Council on Continuing Medical Education.

(i) "Physician" means a person who holds an active, unrestricted license as a physician under this chapter, an osteopathic physician under chapter 459, or a podiatric physician under chapter 461.

(9) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on Physician Assistants is created within the department.

(a) The council shall consist of seven ~~five~~ members appointed as follows:

1. The chairperson of the Board of Medicine shall appoint three members who are physicians and members of the Board of Medicine. One of the physicians must supervise a physician assistant in the physician's practice.

2. The chairperson of the Board of Osteopathic Medicine shall appoint two members ~~one member~~ who are physicians ~~is a physician~~ and members ~~a member~~ of the Board of Osteopathic Medicine.

3. The chairperson of the Board of Podiatric Medicine shall appoint one member who is a podiatric physician and a member of the Board of Podiatric Medicine.

4.~~3.~~ The State Surgeon General or his or her designee shall appoint one member who is a ~~fully licensed~~ physician assistant licensed under this chapter, ~~or~~ chapter 459, or chapter 461.

(b) Two of the members appointed to the council must be physicians who supervise physician assistants in their practice. Members shall be appointed to terms of 4 years, except that of the initial appointments, three ~~two~~ members shall be appointed to terms of 2 years, three ~~two~~ members shall be appointed to terms of 3 years, and one member shall be appointed to a term of 4 years, as established by rule of the boards. Council members may not serve more than two consecutive terms. The council shall annually elect a chairperson from among its members.

(c) The council shall:

1. Recommend to the department the licensure of physician assistants.

2. Develop all rules regulating the use of physician assistants by physicians under this chapter, ~~and~~ chapter 459, or chapter 461, except for rules relating to the formulary developed under paragraph (4)(f). The council shall also develop rules to ensure that the continuity of supervision is maintained in each practice setting. The boards shall consider adopting a proposed rule developed by the council at the regularly scheduled meeting immediately following the submission of the proposed rule by the council. A proposed rule submitted by the council may not be adopted by a ~~either~~ board unless all ~~both~~ boards have accepted and approved the identical language

contained in the proposed rule. The language of all proposed rules submitted by the council must be approved by all ~~both~~ boards pursuant to each respective board's guidelines and standards regarding the adoption of proposed rules. If a ~~either~~ board rejects the council's proposed rule, that board must specify its objection to the council with particularity and include any recommendations it may have for the modification of the proposed rule.

3. Make recommendations to the boards regarding all matters relating to physician assistants.

4. Address concerns and problems of practicing physician assistants in order to improve safety in the clinical practices of licensed physician assistants.

Section 2. Subsections (1) and (2) of section 458.3485, Florida Statutes, is amended to read:

458.3485 Medical assistant.—

(1) DEFINITIONS ~~DEFINITION~~.—As used in this section:~~,~~

(a) "Medical assistant" means a professional multiskilled person dedicated to assisting in all aspects of medical practice under the direct supervision and responsibility of a physician. This practitioner assists with patient care management, executes administrative and clinical procedures, and often performs managerial and supervisory functions. Competence in the field also requires that a medical assistant adhere to ethical and legal standards of professional practice, recognize and respond to emergencies, and demonstrate professional characteristics.

(b) "Physician" means a person who holds an active, unrestricted license as a physician under this chapter or a podiatric physician under chapter 461.

(2) DUTIES.—Under the direct supervision and responsibility of a ~~licensed~~ physician, a medical assistant may undertake the following duties:

(a) Performing clinical procedures, to include:

1. Performing aseptic procedures.

2. Taking vital signs.

3. Preparing patients for the physician's care.

4. Performing venipunctures and nonintravenous injections.

5. Observing and reporting patients' signs or symptoms.

(b) Administering basic first aid.

(c) Assisting with patient examinations or treatments.

(d) Operating office medical equipment.

(e) Collecting routine laboratory specimens as directed by the physician.

(f) Administering medication as directed by the physician.

(g) Performing basic laboratory procedures.

(h) Performing office procedures including all general administrative duties required by the physician.

(i) Performing dialysis procedures, including home dialysis.

Section 3. Paragraph (i) is added to subsection (2) of section 459.022, Florida Statutes, and paragraphs (b) and (h) of that subsection and paragraphs (a) through (c) of subsection (9) of that section are amended, to read:

459.022 Physician assistants.—

(2) DEFINITIONS.—As used in this section:

(b) "Boards" means the Board of Medicine<u>,</u> ~~and~~ the Board of Osteopathic Medicine<u>, and the Board of Podiatric Medicine</u>.

(h) "Continuing medical education" means courses recognized

and approved by the boards, the American Academy of Physician Assistants, the American Medical Association, the American Osteopathic Association, the American Podiatric Medical Association, or the Accreditation Council on Continuing Medical Education.

(i) "Physician" means a person who holds an active, unrestricted license as a physician under chapter 458, an osteopathic physician under this chapter, or a podiatric physician under chapter 461.

(9) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on Physician Assistants is created within the department.

(a) The council shall consist of seven ~~five~~ members appointed as follows:

1. The chairperson of the Board of Medicine shall appoint three members who are physicians and members of the Board of Medicine. One of the physicians must supervise a physician assistant in the physician's practice.

2. The chairperson of the Board of Osteopathic Medicine shall appoint two members ~~one member~~ who are physicians ~~is a physician~~ and members ~~a member~~ of the Board of Osteopathic Medicine.

3. The chairperson of the Board of Podiatric Medicine shall appoint one member who is a podiatric physician and a member of the Board of Podiatric Medicine.

4.~~3.~~ The State Surgeon General or her or his designee shall appoint one member who is a fully licensed physician assistant licensed under chapter 458, ~~or~~ this chapter, or chapter 461.

(b) Two of the members appointed to the council must be physicians who supervise physician assistants in their practice.

Members shall be appointed to terms of 4 years, except that of the initial appointments, three ~~two~~ members shall be appointed to terms of 2 years, three ~~two~~ members shall be appointed to terms of 3 years, and one member shall be appointed to a term of 4 years, as established by rule of the boards. Council members may not serve more than two consecutive terms. The council shall annually elect a chairperson from among its members.

(c) The council shall:

1. Recommend to the department the licensure of physician assistants.

2. Develop all rules regulating the use of physician assistants by physicians under chapter 458, ~~and~~ this chapter, and chapter 461, except for rules relating to the formulary developed under s. 458.347. The council shall also develop rules to ensure that the continuity of supervision is maintained in each practice setting. The boards shall consider adopting a proposed rule developed by the council at the regularly scheduled meeting immediately following the submission of the proposed rule by the council. A proposed rule submitted by the council may not be adopted by a ~~either~~ board unless all ~~both~~ boards have accepted and approved the identical language contained in the proposed rule. The language of all proposed rules submitted by the council must be approved by all ~~both~~ boards pursuant to each respective board's guidelines and standards regarding the adoption of proposed rules. If a ~~either~~ board rejects the council's proposed rule, that board must specify its objection to the council with particularity and include any recommendations it may have for the modification of the proposed rule.

3. Make recommendations to the boards regarding all matters relating to physician assistants.

4. Address concerns and problems of practicing physician assistants in order to improve safety in the clinical practices of licensed physician assistants.

Section 4. Subsection (3) of section 461.007, Florida Statutes, is amended to read:

461.007 Renewal of license.—

(3) The board may by rule prescribe continuing education, not to exceed 40 hours biennially, as a condition for renewal of a license, with a minimum of 2 hours of continuing education related to the safe and effective prescribing of controlled substances. The criteria for such programs or courses shall be approved by the board.

Section 5. Section 461.0145, Florida Statutes, is created to read:

461.0145 Physician assistants.—

(1) A podiatric physician or group of podiatric physicians may supervise up to four physician assistants licensed under s. 458.347 or s. 459.022. A physician assistant must be qualified in the medical areas in which the physician assistant is to perform.

(2) A physician assistant practicing under this chapter shall be governed by s. 458.347 or s. 459.022.

(3) A podiatric physician or group of podiatric physicians supervising a physician assistant shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant.

Section 6. Section 461.0155, Florida Statutes, is created

to read:

461.0155 Medical assistants.—A podiatric physician who is supervising a medical assistant shall be governed by s. 458.3485.

Section 7. Paragraph (b) of subsection (1) of section 624.27, Florida Statutes, is amended to read:

624.27 Direct health care agreements; exemption from code.—

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

(b) "Health care provider" means a health care provider licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 464, or chapter 466, or a health care group practice, who provides health care services to patients.

Section 8. This act shall take effect July 1, 2020.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR ED HOOPER
16th District

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

December 9th, 2019

Honorable Gayle Harrell, Chair
Committee on Health Policy
530 Knott Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Chair Harrell,

I am writing to request that SB 744, Podiatric Medicine, be placed on the agenda to be heard in the Health Policy Committee.

I appreciate your consideration in this matter.

Sincerely,

Ed Hooper

Cc: Staff Director, Allen Brown
Administrative Assistant, Celia Georgiades

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

Senate's Website: *www.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)

2/4/20
Meeting Date

744
Bill Number (if applicable)

892450
Amendment Barcode (if applicable)

Topic Podiatric Medicine

Name Chris Hansen

Job Title Ballard Partners

Address 201 E. Park Ave
Street

Tallahassee FL 32301
City *State* *Zip*

Phone 850/577-0444

Email Chansen@ballardpartners.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida Pediatric Medical 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)

2/4/20
Meeting Date

744
Bill Number (if applicable)

892450
Amendment Barcode (if applicable)

Topic Podiatric Medicine

Name Corinne Mixon

Job Title Lobbyist

Address 511 N. Adams
Street

Tallahassee FL 32301
City *State* *Zip*

Phone 850 766 5795

Email corinnemixon@gmail.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Academy of Physician Assistants

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)

2/4/20
Meeting Date

744
Bill Number (if applicable)

Topic Podiatric Medicine

Amendment Barcode (if applicable)

Name Scott Goldstein

Job Title Podiatric Foot and Ankle Surgeon

Address 2031 Twin Bridge Circle
Street

Phone (321) 331-0276

Ocala FL 34471
City *State* *Zip*

Email scottgoldstr@gmail.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)

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 1206
INTRODUCER:	Health Policy Committee and Senator Harrell
SUBJECT:	Applied Behavior Analysis Services
DATE:	February 5, 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 1206 exempts a group practice that provides applied behavior analysis (ABA) services from licensure and regulation as a health care clinic.

The bill requires the Agency for Persons with Disabilities (APD) to recognize the certification of registered behavior technicians (RBTs) by a nonprofit corporation in the same manner that the APD is currently required to recognize the certification of behavior analysts.

The bill authorizes certified RBTs who practice under the supervision of a certified behavior analyst or a mental health professional licensed under chapter 490 or chapter 491, to assist and support that professional in providing ABA services in the K-12 classroom setting.

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

II. Present Situation:

Health Care Clinics

The Health Care Clinic Act, ss. 400.990-400.995, F.S., was enacted in 2003 as part of the Florida Motor Vehicle insurance Affordability and Reform Act to address personal injury protection insurance exploitation.[1] Regulation of health care clinics was transferred from the Department of

[1] Chapter 2003-411, Laws of Fla.

Health (DOH) to the Agency for Health Care Administration (AHCA), to be funded by license application fees of $2,000 every two years.[2]

To be licensed as a health care clinic, an entity must submit a completed application form to the AHCA and must:

- Submit to a level-2 background screening for owners and certain employees and officers;
- Demonstrate its financial ability to operate;
- Pay the licensure application fee;
- Provide proof of the applicant's legal right to occupy the property; and
- Provide proof of any required insurance.

Each health care clinic must appoint a medical or clinical director. The medical director must be a physician licensed as an allopathic physician, an osteopathic physician, a chiropractic physician, or a podiatric physician.[3] If the clinic does not provide services pursuant to those physicians' respective practices acts, it may appoint a Florida-licensed health care practitioner to serve as a clinic director.[4]

Because ABA service providers are not licensed in Florida, an ABA practice licensed as a health care clinic would need to retain a state-licensed health care practitioner to act as its medical director or clinical director in order to comply with the Health Care Clinic Act.

The AHCA is responsible for licensing and regulating facilities that meet the definition of a health care clinic. Section 400.9905(4), F.S., defines the term "health care clinic" as 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. The subsection then lists fourteen exceptions from licensure that are not included in the definition of the term. Most of these exemptions are provided for entities that:[5]

- Are already regulated by the AHCA as a health care provider for licensure;
- Are federally-certified;
- Are otherwise regulated by the DOH or the Department of Children and Families or elsewhere in the Florida Statutes; or
- Have substantial financial commitment.

The AHCA licenses 2,454 health care clinics and 4,720 providers hold an active certificate of exemption.[6] An entity may apply for a certificate of an exemption, which costs $100 per biennium.[7]

Mental health professionals licensed under ch. 490, F.S., (psychological services) or under ch. 491, F.S., (clinical, counseling, and psychotherapy services) who provide services within

[2] Agency for Health Care Administration, *House Bill 575 Analysis* (November 13, 2019) (on file with the Senate Committee on Health Policy).
[3] Section 400.9905(5), F.S.
[4] *Id.*
[5] *Supra* note 2.
[6] *Id.*
[7] *Id.*

their scope of practice are granted such an exemption under s. 400.9905(4)(g), F.S., but there is no current exemption for persons or groups providing ABA services.

Applied Behavior Analysis Services

ABA is a therapeutic approach to dealing with behavioral disorders that is based on the science of learning and behavior.[8] The primary recipients of ABA services are individuals with autism spectrum disorder.[9] ABA seeks to reduce unwanted behavior patterns and to teach new, productive skills to help drive meaningful change.[10] Individuals participating in ABA strive to improve language capabilities and other communication skills, limit negative behavioral patterns, improve learning outcomes, and develop social skills.[11]

The AHCA covers behavior analysis services for children enrolled in Medicaid ages 0 through 20 with significant maladaptive behaviors, when medically necessary.[12] Before a child can receive ABA services, the child must be referred for a behavior assessment by his or her treating practitioner.[13]

Health insurers and health maintenance organizations are required to issue coverage for ABA services for individuals under 18 years of age, or individuals over 18 years of age who are in high school, who have been diagnosed as having a developmental disability at 8 years of age or younger.[14] Covered services must be provided by individuals certified as behavior analysts under s. 393.17, F.S., or licensed under chs. 490 or 491, F.S.[15]

ABA Service Providers and Certification

There are three provider types of ABA services:
- Board Certified Behavior Analyst (BCBAs) – These providers have either a masters or doctoral degree with a background in ABA.
- Board Certified Assistant Behavior Analysts (BCaBAs) – These providers have a bachelor's degree with a background in ABA.
- Registered Behavior Technicians (RBTs) – These providers have at least a high school diploma, have undergone 40 hours of training, and have passed an exam. RBTs can deliver ABA services under the supervision of a BCBA or a BCaBA.

Section 393.17(2), F.S., requires the APD to recognize a corporation for the certification of behavior analysts. It requires that the corporation:
- Adhere to the national standards of boards that determine professional credentials; and

[8] TEACH Make a Difference, *What is Applied Behavior Analysis (ABA)?*, https://teach.com/online-ed/psychology-degrees/what-is-aba/ (last visited Feb 2, 2020).
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] Agency for Health Care Administration, *Medicaid Behavior Analysis Overview* (January 2019) (on file with the Senate Committee on Health Policy).
[13] *Id.*
[14] Sections 627.6686 and 641.31098, F.S.
[15] *Id.*

- Have a mission to meet professional credentialing needs identified by behavior analysts, state governments, and consumers of behavior analysis services.

Further, the certification procedure recognized by the APD must undergo regular psychometric review and validation, pursuant to a job analysis survey of the profession and standards established by content experts in the field. In Rule 65G-4.0011 of the Florida Administrative Code, the APD recognizes the certification awarded by the Behavior Analyst Certification Board, Inc., which certifies the three provider types and recently added a fourth provider type: the BCBA-D for board certified behavior analysists who hold doctoral degrees.[16]

The APD reports that there are 173 certified ABA service providers.[17] The APD website provides a directory to identify certified behavioral analysis service providers.[18]

III. Effect of Proposed Changes:

Section 1 amends s. 393.17, F.S., to authorize the APD to establish a certification process for RBTs and to require the APD to recognize the certification of RBTs awarded by a nonprofit corporation that meets criteria established in current law, such as adhering to the national standards of boards that determine professional credentials relating to ABA.

Section 2 amends s. 400.9905(4), F.S., to exempt a group of certified behavior analysts or individuals licensed under chs. 490 or 491, F.S., from health care clinic licensure. The AHCA is not able to distinguish behavioral analysis providers from other types of health care clinics, so the AHCA is unable to determine how many behavior analysis providers are currently licensed as health care clinics.[19] The total number of providers affected by Section 2 of the bill is unknown.

Section 3 amends s. 1003.572, F.S., to expand the definition of "private instructional personnel" for purposes of allowing such personnel to provide services in a K-12 classroom. The definition is expanded to include certified RBTs who practice under the supervision of a certified behavior analyst or a mental health professional licensed under chapter 490 or chapter 491, and who assist and support such a provider in providing ABA services.

Sections 4-6 of the bill amend ss. 456.47, 627.6686, and 641.31098, F.S., to make conforming changes.

Section 7 provides an effective date of July 1, 2020.

[16] Behavior Analyst Certification Board https://www.bacb.com/ (last viewed Feb. 2, 2020).
[17] *Supra* note 2.
[18] Florida Developmental Disabilities Resources, *Provider Search* https://flddresources.qlarant.com/ProviderSearch.aspx (last visited Feb. 2, 2020).
[19] Supra note 2.

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:

CS/SB 1206 will have a positive fiscal impact on providers of ABA service providers that will be able to apply for a $100 certificate of exemption instead of a $2,000 health care clinic license.

C. Government Sector Impact:

The bill's exemption from health care clinic licensure should reduce workload within the AHCA's Division of Health Quality Assurance because the division will not have to license or survey exempted ABA service providers.

Under the bill, the AHCA will need to update Rule 5G-1.060 of the Florida Administrative Code to remove a reference to behavior analysis groups in regard to health care clinic licensure. The AHCA will experience minor operational cost that can be absorbed with existing resources.[20]

The APD may experience an operational impact because it will need to approve a nonprofit credentialing agency to certify RBTs.

[20] *Supra* note 2.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends sections 393.17, 400.9905, 1003.572, 456.47, 627.6686, and 641.31098 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.)

CS by Health Policy on February 4, 2020:

The CS:

- Requires the APD to recognize the certification of registered behavior technicians (RBTs) by a nonprofit corporation in the same manner that the APD is currently required to recognize the certification of behavior analysts.
- Reverts to the current law and removes a provision on lines 44-45 of the underlying bill that would require the Department of Education (DOE) to approve a nonprofit credentialing entity to certify behavior analysts. The CS keeps the certification of behavior analysts under s. 393.17, F.S., which currently requires the APD to recognize a corporation for the certification of behavior analysts.
- Replaces the word "paraprofessionals" on line 48 of the underlying bill with RBTs certified under s. 393.17, F.S., to narrow the scope of who may assist a behavior analyst in providing ABA services in K-12 classrooms and to ensure that those providers are qualified.
- Makes conforming changes.

B. Amendments:

None.

By Senator Harrell

25-01641-20 20201206__

A bill to be entitled

An act relating to applied behavior analysis services; amending s. 400.9905, F.S.; providing an exemption from licensure requirements for certain individuals who are employed or under contract with certain entities providing applied behavior analysis services; amending s. 1003.572, F.S.; redefining the term "private instructional personnel" to include certain behavior analysts and paraprofessionals providing applied behavior analysis services; providing an effective date.

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

Section 1. Paragraph (o) is added to subsection (4) of section 400.9905, Florida Statutes, 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:

(o) A group of individuals certified under s. 393.17 or licensed under chapter 490 or chapter 491, and who are employed by or under contract with a group practice, billing provider, or agency that provides applied behavior analysis services as defined in ss. 627.6686 and 641.31098.

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 2. Present paragraphs (b) through (f) of subsection (1) of section 1003.572, Florida Statutes, are redesignated as paragraphs (c) through (g), respectively, a new paragraph (b) is added to that subsection, and paragraph (a) of that subsection is amended, to read:

1003.572 Collaboration of public and private instructional personnel.—

(1) As used in this section, the term "private instructional personnel" means:

(a) Individuals ~~certified under s. 393.17 or~~ licensed under chapter 490 or chapter 491, or behavior analysts certified by a nonprofit credentialing entity approved by the department, for applied behavior analysis services as defined in ss. 627.6686 and 641.31098.

(b) Paraprofessionals who practice under the supervision of a professional authorized under paragraph (a) and who assist and support such professional in providing applied behavior analysis services.

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

2019 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

BILL INFORMATION	
BILL NUMBER:	HB 575
BILL TITLE:	Applied Behavior Analysis Services
BILL SPONSOR:	Representative Rene Plasencia
EFFECTIVE DATE:	July 1, 2020

COMMITTEES OF REFERENCE
1) Health Market Reform Subcommittee
2) Health Care Appropriations Subcommittee
3) Health & Human Services Committee
4)
5)

CURRENT COMMITTEE
Health Care Appropriations Subcommittee

SIMILAR BILLS	
BILL NUMBER:	
SPONSOR:	

PREVIOUS LEGISLATION	
BILL NUMBER:	
SPONSOR:	
YEAR:	

IDENTICAL BILLS	
BILL NUMBER:	SB 1206
SPONSOR:	Sen. Gayle Harrell

LAST ACTION:	

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

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	November 13, 2019
LEAD AGENCY ANALYST:	Noël Cronin Lawrence, Program Administrator, Hospital & Outpatient Services Unit
ADDITIONAL ANALYST(S):	Jack Plagge
LEGAL ANALYST:	Thomas M. Hoeler
FISCAL ANALYST:	

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

The bill creates an exemption from licensure as a health care clinic for applied behavior analysis service providers certified by the Agency for Persons with Disabilities (APD). Similarly the bill also appears to exempt a group of individuals licensed under chapter 490 or 491, F.S. providing applied behavior analysis services and being reimbursed by health insurers and health maintenance organizations from licensure as a health care clinic.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

The Health Care Clinic Act, Chapter 400, Part X, Florida Statutes (F.S.) provides for the licensure of entities where health care services are provided to individuals and which tender charges for reimbursement for such services. To reduce duplicative licensure requirements, the law provides 14 exemptions per s. 400.9905(4) (a) - (n), F.S. Most of these exemptions are provided to entities already regulated by the Agency as a health care provider for licensure and/or federal certification purposes, health care establishments or professions otherwise regulated by the Department of Health (DOH) or the Department of Children and Families (DCF), non-profit entities or entities with substantial financial commitment. Persons licensed under chapter 490, F.S. (Psychological Services) and chapter 491 (Clinical, Counseling, and Psychotherapy Services) providing services within their scope of practice are currently exempt from health care clinic licensure. There is no current exemption for persons or groups providing applied behavior analysis services.

An entity required to be licensed under Chapter 400, Part X, F.S. must apply for licensure on forms prescribed by the Agency. The licensure fee is $2,000 per biennium. The Agency also assesses each clinic $300 per biennium pursuant to s. 408.033, F.S. Additional clinic costs are associated with compliance with the background screening requirements of Chapters 435 and 408, Part II, F.S. Background screening costs vary based on the number of staff required to be screened and the vendor used. An entity meeting one or more exemption may apply for a certificate of exemption. The cost for a certificate of exemption is $100 per biennium. The Agency licenses 2,454 health care clinics and 4,720 providers have an active certificate of exemption. The Agency does not collect information that would distinguish if currently licensed health care clinics are applied behavior analysis providers.

Pursuant to s. 393.17, F.S., the Agency for Persons with Disabilities (APD) certifies behavior analysts who provide applied behavior analysis services to clients of APD. Certification procedures are established by rule and include criteria for scope of practice, qualifications for certification including training and testing requirements, continuing education requirements and standards of performance. The procedures also include a decertification process to determine if individuals continue to meet certification requirements. Behavior treatment programs implemented by certified behavior analysts must be designed, approved, implemented and monitored according to a system of oversight also established by rule. The APD website provides a resource directory to identify certified Behavioral Health Services providers.

The Steven A. Geller Autism Coverage Act, enacted in 2008, directs health insurers (s. 627.6686, F.S.) and health maintenance organizations (641.31098, F.S.) to issue coverage for applied behavior analysis services provided to eligible individuals diagnosed with developmental disabilities including autism spectrum disorders. An “eligible individual” is an individual under 18 years of age or an individual 18 years of age or older who is in high school who has been diagnosed as having a developmental disability at 8 years of age or younger. Covered services must be provided by individuals certified as behavior analysts under s. 393.17, F.S. or licensed under chapters 490 or 491, F.S.

2. EFFECT OF THE BILL:

This bill creates an exemption from licensure as a health care clinic for APD certified applied behavior analysis service providers. This would align these providers with other entities currently eligible for an exemption due to licensure by the Agency, DOH, DCF or federal certification. APD certification requirements and ongoing treatment program oversight are more stringent than health care clinic licensure standards. Not all providers offering applied behavioral analysis will meet this exemption.

In addition, the bill also appears to exempt a group of individuals licensed under chapter 490 or 491, F.S. providing applied behavior analysis services and being reimbursed by health insurers and health maintenance organizations from licensure as a health care clinic. Chapter 490 or 491, F.S. addresses licensing individuals. It is not clear if the exemption would apply to an individual or only a group of individuals.

Currently there are 665 Behavior Analysis Medicaid providers (Groups only) and 1,226 Community Behavioral Health Services Medicaid providers. APD reports there are currently 173 APD certified applied behavior analysis service providers. Health care clinic licensing regulations do not distinguish behavioral analysis providers from other types of

health care clinics, so we are unable to determine how many behavior analysis providers are currently licensed as health care clinics. Thus, the total number of providers affected by this bill is unknown.

The Agency tracks average staff hours required to conduct inspections. Average staff inspection time required to conduct an inspection includes pre-survey preparation, travel to and from the site, onsite investigation, post-inspection reporting writing and distribution, data management and analysis, communication with complainants and providers, and quality assurance review. Staff on average conduct survey tasks 40 weeks per year, 4.5 days per week or 184.5 days per year; this excludes holidays, leave time, and office days for training, legal case prep and depositions for sanctions cases.

Based on an estimate that one surveyor may conduct approximately 15 inspections per week (or 3 per day). We estimate the total behavior analysis related health care clinics would be 1,891 (665+1,226). Inspections are completed biennially, so this would require 946 inspections each year; which would require two FTEs. Therefore, the bill would avoid the need for the Agency to add 1.7 FTEs.

This bill also redefines the term "private instructional personnel" to include certain behavior analysts and paraprofessionals providing applied behavior analysis services as referenced in Part V, Specialized Instruction for Certain Public K-12 Students, of the K-20 Education Code.

The bill will have minor operational impacts to the Florida Medicaid program, which can be completed within existing resources. Currently, the Agency requires providers seeking enrollment in Florida Medicaid to comply with all applicable state licensure requirements. Rule 59G-1.060, Provider Enrollment Policy, was recently adopted by the Agency with an effective date of 12/25/19. Within Rule 59G-1.060, Appendix E (attached) includes a list of providers who are required to show proof of health care clinic licensure or proof of exemption from licensure as a health care clinic. Behavior Analysis groups are included in this list. If this bill were to pass the Agency would need to amend the rule remove the reference to Behavior Analysis providers. Updating Medicaid rules is a routine function performed by the Agency.

The bill provides for an effective date of 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 _X__ N ___

If yes, explain:	Adding an exemption to the Health Care Clinic Act will require the Agency to update the certificate of exemption application.
Is the change consistent with the agency's core mission?	Y _X__ N ___
Rule(s) impacted (provide references to F.A.C., etc.):	59A-33.006, F.A.C., AHCA Form 3110-0014

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 ___

Revenues:	The Agency will not have to license and survey service providers already regulated by APD. The providers may apply for an exemption certificate rather than a license.
Expenditures:	
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:	APD certified behavior analysis service providers will experience a reduced regulatory cost if they are able to apply for a $100 health care clinic exemption instead of a $2,000 health care clinic license.
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 _X__ N ___

If yes, describe the anticipated impact to the agency including any fiscal impact.	Minor system changes to track the new health care clinic exemption in the Agency's database.

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 other than those stated above.

Agency for Health Care Administration

Medicaid Behavior Analysis Overview

Overview of Behavior Analysis Services

The Agency for Health Care Administration (Agency) covers behavior analysis (BA) services for children enrolled in Medicaid ages 0 through 20 with significant maladaptive behaviors, when medically necessary. These services are highly structured interventions, strategies, and approaches provided to decrease maladaptive behaviors and increase or reinforce appropriate behaviors. For example, a child with an autism spectrum disorder may receive BA services to redirect maladaptive behavior such as self-injurious behavior and reinforce positive behaviors.

Services are generally provided during one-to-one sessions between the provider and child in the child's home. Services may also be provided in the provider's office. Depending on the level of need, a child may receive up to 40 hours a week of BA services.

Currently, BA services are paid on a fee-for-service basis, meaning that they are paid for directly by the Agency, rather than being covered by health plans participating in the Statewide Medicaid Managed Care (SMMC) program. This is true even if the child is enrolled in an SMMC health plan for his or her other Medicaid services.

Who Provides BA Services

BA services can be delivered by one of three provider types. All provider types must enroll with Florida Medicaid to provide services.

- **Behavior Analyst Certification Board (BACB) Certified Lead Analysts:** These providers have either a master's or doctoral degree with a background in BA. Lead Analysts can complete behavior assessments and reassessments, deliver BA services directly, and supervise BCaBAs and RBTs.
- **BCaBAs:** These providers have a bachelor's degree with a background in BA. Like the Lead Analysts, they must also receive certification from the BACB. BCaBAs can deliver BA services and supervise RBTs.
- **Registered Behavior Technicians (RBTs):** These providers have at least a high school diploma, have undergone 40 hours of training, and have passed an exam. RBTs are the most numerous provider type and can deliver BA services under the supervision of a Lead Analyst or BCaBA.

Who Can Receive BA Services

BA services are available to Florida Medicaid recipients who are under the age of 21. Children receiving the services are not required to have a specific diagnosis but must exhibit maladaptive behaviors. Over 90% of the children who receive BA services are diagnosed with Autism Spectrum Disorder.

Before a child can receive BA services, they must be referred for a behavior assessment by their treating practitioner. The assessment determines whether BA services are needed and assists the BA Lead Analyst in determining the appropriate number of hours of service. Before Florida Medicaid will reimburse for BA services, providers must first request authorization from the Agency's contracted Quality Improvement Organization vendor, which reviews the requests to determine whether they are medically necessary and then issues an authorization or denial.

Agency for Health Care Administration

Historical Overview

In March 2012, the Agency was directed by a federal judge to begin coverage of BA services for children on Medicaid diagnosed with Autism Spectrum Disorder within 7 days of the court order. In addition, the Agency was required to cover the service without regard for medical necessity. To quickly implement payment for this service, the Agency used established rates and procedure codes that were already in use for similar Medicaid covered services, without adopting a separate BA fee schedule and coverage policy. Use of the BA service grew significantly year over year. Nearly three years after the initial court order, the Agency was successful with the legal appeal, which overturned the judge's ruling, in part. While the Agency was still required to cover the service, it could now implement a utilization management process (e.g., prior authorization of services) for determining medical necessity.

The Agency then quickly moved to promulgate in administrative rule a coverage policy and fee schedule specifically for BA services and also competitively bid a contract, awarded to Beacon Health Options, to implement prior authorization for BA services. The Agency used Beacon's expertise to develop the coverage policy and fee schedule. They recommended that the Agency incentivize the provision of services at the BA technician level (the lowest practitioner type), whenever services can safely be provided at that level. Beacon advised that our current rates for the BA technician levels were insufficient, causing increased use of higher-level, higher cost practitioner types. Beacon recommended a two-pronged strategy for ensuring utilization levels were appropriate:

- Significantly increase the BA technician rates to support increased use of services at that level
- Ensure the utilization management processes (for which they were responsible) assessed whether services that were previously provided at higher practitioner levels could be redirected to the BA technician level without jeopardizing safety.

The Agency incorporated Beacon's recommendations and other suggestions obtained from stakeholders through the public rulemaking process into the BA fee schedule.

The Agency quickly experienced an unprecedented surge in utilization after implementing the utilization management process and the revised fee schedule. We also identified a host of aberrant, fraudulent, and abusive billing practices. In addition, after experiencing a repeated pattern of non-compliance, the Agency terminated its contract with Beacon and entered into a new contract with eQHealth Solutions to conduct utilization management services.

Reducing and Preventing BA Fraud and Abuse

In January 2018, the Agency intensified its investigation of suspected fraud and abuse in the delivery of BA services. A review of records obtained from Beacon and multiple BA provider claims revealed that fraud and abuse were prevalent across the state, particularly in Miami-Dade and Broward counties. This prompted the Agency to take more direct and immediate action.

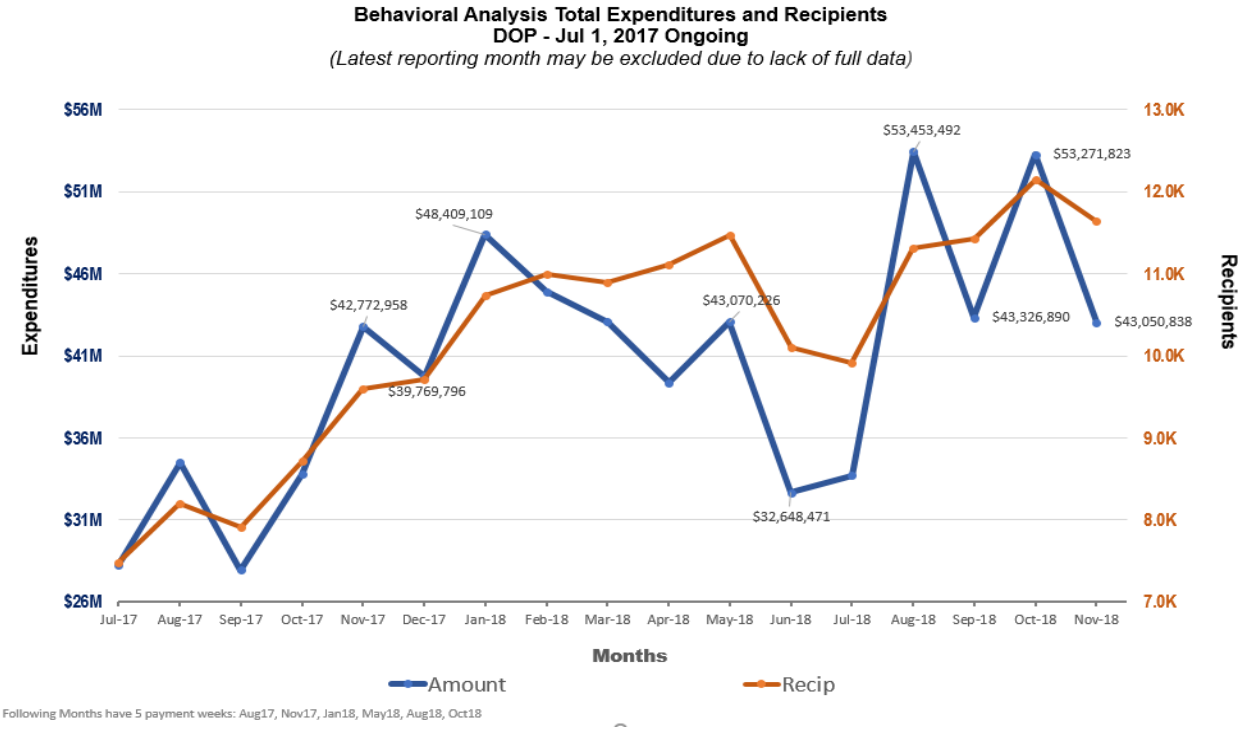
Since February 2018, the Agency has taken the following actions to reduce and prevent BA fraud and abuse:

- Terminated the contract with the previous QIO vendor, Beacon Health Options, in February 2018.

- Implemented a contract with a new QIO vendor, eQHealth Solutions, in March 2018.
- Instituted payment suspensions and terminated BA providers suspected of fraud.
- Implemented a more rigorous screening process for individuals enrolling in Florida Medicaid as BA providers.
- Imposed a maximum of 10 hours per day/70 hours per week limit on the amount of services that a single BA provider can deliver.
- Placed a 6-month moratorium on enrollment of new BA providers in Broward and Miami-Dade and then extended the moratorium for 6 more months (through mid-May 2019). These moratoria required approval from the federal Centers for Medicare and Medicaid Services.

Growth in Use of BA Services and Cost Continues

Despite these actions, growth in both the number of children receiving BA services and the cost continue to rise.



The numbers of enrolled providers has remained stable, ensuring that there is access to services for children.

Date	Enrolled BA Providers
May 2018	14,042
January 2019	14,239

Agency for Health Care Administration

Additional Actions the Agency is Taking to Reduce BA Fraud and Abuse

In an effort to continue to control expenditures and ensure appropriate utilization, the Agency is in the process of taking these additional actions:

- Registered Behavior Technician (RBT) Certification Requirements
  - The Agency required all RBT BA providers to provide proof of RBT certification by December 31, 2018. All RBT providers who have not provided documentation of RBT certification are on prepayment review (i.e., are suspended from receiving reimbursement from the Medicaid program) and will be terminated from the Medicaid program if they cannot provide proof of certification.
- Rule changes
  - Revise the Behavior Analysis Services Coverage Policy rule to strengthen coverage requirements to ensure that BA services that are reimbursed are medically necessary and delivered as prescribed.
  - Revise the Medicaid enrollment requirements to allow for more rigorous screening of BA provider applicants.
- Statute change
  - Drafting a legislative proposal to require providers delivering BA services to be licensed by the Department of Health.
- Budget request
  - Requesting appropriation to extend electronic visit verification to BA providers. This type of verification is currently in place for Medicaid home health providers.

CourtSmart Tag Report

Room: KN 412 **Case No.:** **Type:**
Caption: Senate Health Policy Committee **Judge:**

Started: 2/4/2020 9:01:13 AM
Ends: 2/4/2020 11:00:38 AM Length: 01:59:26

9:01:12 AM Meeting called to order
9:01:26 AM Chair
9:01:33 AM Roll Call - Quorum is present
9:01:49 AM Tab 1 - Confirmation of Dr. Scott Rivkees as State Surgeon General, Department of Health
9:02:12 AM Oath of affirmation
9:02:41 AM Opening Statement by Dr. Rivkees
9:06:32 AM Questions?
9:10:36 AM Senator Rouson
9:11:50 AM Dr. Rivkees
9:12:13 AM Senator Rouson
9:12:22 AM Dr. Rivkees
9:12:35 AM Senator Rouson
9:13:00 AM Dr. Rivkees
9:14:45 AM Senator Rouson
9:14:54 AM Dr. Rivkees
9:15:21 AM Chair
9:15:50 AM Senator Rouson
9:16:00 AM Dr. Rivkees
9:16:53 AM Chair
9:16:58 AM Senator Cruz
9:17:19 AM Dr. Rivkees
9:19:59 AM Senator Cruz
9:20:04 AM Dr. Rivkees
9:22:23 AM Senator Cruz
9:22:29 AM Dr. Rivkees
9:24:13 AM Senator Cruz
9:24:19 AM Dr. Rivkees
9:24:43 AM Senator Book
9:25:01 AM Dr. Rivkees
9:27:01 AM Senator Book
9:27:10 AM Dr. Rivkees
9:28:55 AM Senator Baxley
9:29:05 AM Dr. Rivkees
9:30:45 AM Appearance Forms?
9:31:45 AM Ron Watson, waives in support
9:31:54 AM Ronald Giffler, President, FMA, waives in support
9:32:03 AM Stephen Winn, Exec. Dir., FOMA, speaking in support
9:34:10 AM Tazia Stagg, Tampa, representing self, speaking against
9:38:39 AM Debate?
9:39:38 AM Senator Bean
9:39:56 AM Senator Baxley
9:42:56 AM Senator Berman
9:44:32 AM Senator Hooper
9:46:46 AM Senator Cruz
9:46:53 AM Senator Rouson
9:49:08 AM Chair
9:50:35 AM Dr. Rivkees closing remarks
9:53:07 AM Is there a motion to recommend confirmation?
9:54:07 AM Senator Baxley moves to recommend Dr. Rivkees as Surgeon General
9:54:17 AM Roll Call on confirmation of Dr. Rivkees as State Surgeon General and Secretary of the Department of Health. Recommended favorably.
9:54:42 AM Tab 5 - SB 1650 By Senator Simmons -Medicaid Provider Agreements for Charter and Private Schools

9:57:15 AM Questions? None
9:57:36 AM Appearance Cards?
9:57:42 AM Debate? None
9:57:45 AM Senator Simmons waives close
9:57:53 AM Roll Call on SB 1650 - Favorable
9:58:35 AM Tab 6 SB 512 by Senator Hutson - Nonembryonic Stem Cells
9:58:47 AM Amendment 846704 by Senator Hutson
9:59:58 AM Questions on amendment?
10:00:04 AM Senator Berman
10:00:09 AM Senator Hutson
10:00:24 AM Senator Berman
10:01:04 AM Senator Hutson
10:01:45 AM Allen Brown, Committee Staff Director responds
10:02:02 AM Senator Berman
10:02:26 AM Senator Hutson
10:02:54 AM Appearance Cards? None
10:03:06 AM Debate? None
10:03:11 AM Amendment is adopted
10:03:19 AM Back on bill as amended
10:03:25 AM Appearance Cards? None
10:03:34 AM Debate? None
10:03:37 AM Chair
10:04:12 AM Senator Hutson to close
10:04:19 AM Roll Call SB 512 - Favorable
10:04:41 AM Tab 7 - SB 1014 by Senator Rouson - Public Safety Telecommunicator Training
10:05:55 AM Questions? None
10:06:12 AM Appearance Cards?
10:06:20 AM Mark Landreth, Gov. Rel. Director, American Heart Association, speaking in support
10:07:30 AM Richard Pinsky, 911 Emergency Dispatches, speaking in support
10:08:34 AM Chair
10:09:24 AM Debate? None
10:09:31 AM Senator Rouson waives close
10:09:37 AM Roll Call on SB 1014 - Favorable
10:10:07 AM Tab 3 - SB 1676 by Senator Albritton - Direct Care Workers
10:10:27 AM Delete-all amendment 414062 by Senator Albritton
10:11:48 AM Questions on amendment?
10:12:53 AM Appearance Cards?
10:12:57 AM Jack McRay, waives in support
10:13:06 AM Susan waives in support
10:13:11 AM Markus, waives in support
10:13:24 AM Debate on amendment?
10:13:37 AM Senator Berman
10:13:49 AM Senator Book
10:14:24 AM Senator Albritton to close on amendment
10:14:36 AM Amendment is adopted
10:15:36 AM Questions on bill as amended?
10:15:43 AM Appearance Cards?
10:15:47 AM Jennifer Ungell, Health Care Association of America, waives in support
10:15:50 AM Bob Azztablos, Chief Lobbyist, FL Health Care Association, waives in support
10:15:56 AM Bob Lolley, Exec. Dir., Home CARE Industry, waives in support
10:16:07 AM Debate? None
10:16:35 AM Senator Albritton to close on bill as amended
10:17:04 AM Roll Call on SB 1676 - Favorable
10:17:18 AM Tab 4 - SB 1544 by Senator Albritton - Elderly Care
10:17:56 AM Amendment 858654 by Senator Albritton
10:19:55 AM Questions on amendment? None
10:20:56 AM Appearance Cards?
10:21:00 AM Jack McCray, AARP, waives in support
10:21:05 AM Susan Langston, VP of Advocacy, Leading Age Florida, waives in support
10:21:09 AM Robert Beck, FL Association of Area Agencies on Aging, waives in support
10:21:20 AM Marcus Dixon, SEIU 1199, Healthcare Workers, waives in support
10:21:26 AM Debate? None

10:21:32 AM Delete-all is adopted
10:21:40 AM Back on bill as amended?
10:21:46 AM Appearance Cards?
10:21:52 AM Bob Asztalos, Chief Lobbyist, FL Health Care Association, waives in support
10:21:57 AM Debate?
10:22:02 AM Senator Albritton waives close
10:22:09 AM Roll Call on CS/SB 1544 - Favorable
10:22:36 AM Tab 8 - SB 744 by Senator - Podiatric Medicine
10:23:09 AM Late filed Substitute amendment 892450 by Senator Hooper
10:23:15 AM No objections to late filed
10:23:25 AM Late filed amendment 892450 by Senator Hooper
10:24:26 AM Questions on amendment? None
10:24:31 AM Appearance Cards on Amendment?
10:24:39 AM Chris Hanson, Ballard Partners, Florida Podiatric Medical Association, waives in support
10:25:44 AM Corinee Miiker, FL Academy of Physician Assistants, waive in support
10:25:48 AM Debate on delete-all? None
10:25:56 AM Senator Hooper to close on amendment
10:26:39 AM Amendment is adopted
10:26:49 AM Back on bill as amended
10:26:54 AM Questions?
10:26:56 AM Appearance Cards, Dr. Scott Goldstein, self
10:28:27 AM Debate? None
10:28:35 AM Roll Call SB 744 - Favorable
10:29:04 AM Gavel to Senator Baxley
10:29:31 AM Tab 9 - SB 1206 by Senator Harrell - Applies Behavior Analysis Services
10:30:16 AM Amendment 455434 by Senator Harrell
10:30:19 AM Scott Goldstein, self, speaking for
10:32:10 AM Questions? None
10:33:10 AM Appearance Cards? None
10:33:28 AM Debate? None
10:33:33 AM Senator Harrell to close
10:33:39 AM Amendment is adopted
10:33:43 AM Back on bill as amended
10:33:49 AM Appearance Cards?
10:33:55 AM Krista Cayer, CEO & Founder- Cayer Behavioral Group, waive in support
10:33:59 AM John Parker, Integration Engineer Public Health Information, speaking in support of Justin Parker and Andrew Pogar
10:40:13 AM Leigh Ellen Nettles, parent, Florida educator, speaking for daughter
10:44:25 AM Steve Coleman, Public Policy Director, FL Association for Behavior Analysis, waives in support
10:45:27 AM Marucci Guzman, ED, Santiago and Friends/Family Center for Autism, speaking for
10:47:08 AM Brooke Marion, Learning Leaps Behavioral Services, speaking for
10:49:20 AM Senator Harrell waives close
10:50:19 AM Roll Call on SB 1206 - Favorable
10:50:34 AM Gavel to Chair Harrell
10:50:48 AM Tab 2 - SB 1764 by Senator Flores - Childbirth
10:51:03 AM Amendment 591062 is withdrawn
10:51:09 AM Amendment 921390 by Senator Flores
10:52:49 AM Questions on amendment? None
10:53:17 AM Debate on amendment? None
10:53:20 AM Appearance Cards on amendment?
10:53:23 AM Ron Watson, Lobbyist, Midwives Association of Florida, speaking for information
10:54:44 AM Mary Thomas, Assistant General Counsel, FMA, waives in support
10:54:57 AM Debate? None
10:55:03 AM Senator Flores to waive close on amendment
10:55:13 AM Amendment is adopted
10:55:20 AM Questions on bill as amended? None
10:55:32 AM Riva Majeciuski, speaking for self, speaking for
10:57:48 AM Debate? None
10:58:49 AM Senator Flores to close
10:59:11 AM Roll Call SB 1764- Favorable
10:59:11 AM Senator Diaz Motion to vote affirmative on Tabs 5, 6, 7 and 3. Senator Berman Tabs 3, 8, 7, and 14. Senator Baxley SB 1650

10:59:48 AM No objections. Show adopted.
10:59:59 AM Senator Baxley moves to adjourn. No objections to motion.
11:00:05 AM We are adjourned