Tab 2	**SB 768** by **Rodriguez**; (Similar to CS/H 00693) Department of Health					
709032	PCS	S	RCS	HP		01/26 01:12 PM
Tab 3	**SB 718** by **Bradley**; (Similar to CS/H 00469) Patient Care in Health Care Facilities					
430722	D	S	RCS	HP, Bradley	Delete everything after	01/26 01:12 PM
~~883280~~	T	S	WD	HP, Bradley	In title, delete L.2 -	01/24 10:09 AM
Tab 4	**SB 1770** by **Book**; (Identical to H 01333) Donor Human Milk Bank Services					
Tab 5	**SB 836** by **Brodeur**; (Similar to H 01403) Medication Technicians					
811990	D	S	RCS	HP, Brodeur	Delete everything after	01/26 01:12 PM
Tab 6	**SB 1258** by **Jones**; (Identical to H 00855) Managed Care Plan Performance					
Tab 7	**SB 842** by **Brodeur**; (Identical to H 01449) Invalid Restrictive Covenants in Health Care					
720062	A	S	RCS	HP, Brodeur	Delete L.42 - 47:	01/26 01:12 PM
Tab 8	**SB 1950** by **Brodeur**; (Compare to H 00607) Statewide Medicaid Managed Care Program					
591072	A	S	RCS	HP, Brodeur	Delete L.856 - 876:	01/26 01:12 PM
Tab 9	**SB 1184** by **Broxson**; (Similar to H 00687) Free Speech of Health Care Practitioners					
646934	D	S	RCS	HP, Broxson	Delete everything after	01/26 01:12 PM
Tab 10	**SB 1260** by **Gruters**; (Identical to H 00897) Conversion of a Public Health Care System					

The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Diaz, Chair
Senator Brodeur, Vice Chair

MEETING DATE: Wednesday, January 26, 2022
TIME: 10:00 a.m.—12:00 noon
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Diaz, Chair; Senator Brodeur, Vice Chair; Senators Albritton, Baxley, Bean, Book, Cruz, Garcia, Jones, and Powell

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	Ladapo, Joseph ()	Pleasure of Governor	Recommend Confirm Yeas 6 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
	A proposed committee substitute for the following bill (SB 768) is expected to be considered:		
2	**SB 768** Rodriguez (Identical CS/H 693, Compare CS/H 343, H 679, H 1321, CS/S 566, S 1144, S 1268)	Department of Health; Revising the purpose of the Department of Health's targeted outreach program for certain pregnant women; requiring the department to encourage high-risk pregnant women of unknown status to be tested for sexually transmissible diseases; removing the Children's Medical Services office from parties required to coordinate in the development of local emergency management plans for special needs shelters; revising functions paramedics and emergency medical technicians may perform in nonemergency environments; deleting a requirement that certain nursing program graduates complete a specified preparatory course; defining the terms "doctoral degree from an American Psychological Association accredited program" and "doctoral degree in psychology", etc. HP 01/26/2022 Fav/CS AHS AP	Fav/CS Yeas 10 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
3	**SB 718** Bradley (Similar CS/H 469)	Patient Care in Health Care Facilities; Revising provisions relating to medications and devices with which unlicensed individuals may assist patients in self-administration under certain circumstances; specifying staffing requirements for advanced life support ambulances during interfacility transfers; revising the list of medications that a registered nurse may delegate the administration of to a certified nursing assistant or home health aide, etc. HP 01/19/2022 Temporarily Postponed HP 01/26/2022 Fav/CS AP RC	Fav/CS Yeas 9 Nays 0
4	**SB 1770** Book (Identical H 1333)	Donor Human Milk Bank Services; Authorizing the Agency for Health Care Administration to pay for donor human milk bank services as an optional Medicaid service if certain conditions are met; adding donor human milk bank services to the list of Medicaid services authorized for reimbursement on a fee-for-service basis; adding donor human milk bank services to the list of minimum benefits required to be covered by Medicaid managed care plans, etc. HP 01/26/2022 Favorable AHS AP	Favorable Yeas 10 Nays 0
5	**SB 836** Brodeur (Similar H 1403)	Medication Technicians; Defining the term "medication technician"; providing minimum requirements and specifications for training of medication technicians, etc. HP 01/19/2022 Temporarily Postponed HP 01/26/2022 Fav/CS AHS AP	Fav/CS Yeas 10 Nays 0
6	**SB 1258** Jones (Identical H 855)	Managed Care Plan Performance; Requiring managed care plans to collect and report specified measures beginning with a certain data reporting period; requiring plans to stratify reported measures by specified categories beginning with a certain data reporting period; requiring a plan's performance to be published on its website in a specified manner; requiring the Agency for Health Care Administration to use the measures to monitor plan performance, etc. HP 01/26/2022 Favorable BI RC	Favorable Yeas 10 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
7	**SB 842** Brodeur (Identical H 1449)	Invalid Restrictive Covenants in Health Care; Defining the terms “hospital” and “physician”; specifying that certain restrictive covenants in employment agreements between physicians and hospitals do not support a legitimate business interest; authorizing a party to an employment agreement to elect to have a mutually agreed upon arbitrator make a specified binding determination, etc. CM 01/10/2022 Favorable HP 01/19/2022 Temporarily Postponed HP 01/26/2022 Fav/CS RC	Fav/CS Yeas 7 Nays 3
8	**SB 1950** Brodeur (Compare H 607, CS/S 1080)	Statewide Medicaid Managed Care Program; Requiring, rather than authorizing, that the reimbursement method for provider service networks be on a prepaid basis; deleting a requirement that the Agency for Health Care Administration provide the opportunity for public feedback on a certain waiver application; revising requirements relating to the databook published by the agency consisting of Medicaid utilization and spending data; revising provisions relating to agency-defined quality measures under the achieved savings rebate program for Medicaid prepaid plans; providing that cancer hospitals meeting certain criteria are statewide essential providers, etc. HP 01/26/2022 Fav/CS AHS AP	Fav/CS Yeas 9 Nays 0
9	**SB 1184** Broxson (Similar H 687)	Free Speech of Health Care Practitioners; Prohibiting certain entities from reprimanding, sanctioning, or revoking or threatening to revoke a license, certificate, or registration of a health care practitioner for specified use of his or her right of free speech without specified proof; requiring certain entities to provide to a health care practitioner any complaints within a specified timeframe, etc. HP 01/26/2022 Fav/CS JU AP	Fav/CS Yeas 6 Nays 3

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
10	**SB 1260** Gruters (Identical H 897)	Conversion of a Public Health Care System; Authorizing the governing body of a public health care system to evaluate the potential conversion of the public health care system to a nonprofit entity; requiring such governing body to publish notice of its completed evaluation in a specified manner; authorizing a public health care system and local governing authority to negotiate an agreement for such conversion; requiring members of the governing body of the public health care system to disclose whether they intend to serve on the board of the successor nonprofit entity; requiring the public health care system and local governing authority to jointly submit a notice of completion of such conversion to the Legislature after certain requirements are met, etc. HP 01/26/2022 Favorable CA RC	Favorable Yeas 9 Nays 0

Other Related Meeting Documents

HAND DELIVERED

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2021 OCT 29 PM 2:43

DIVISION OF ELECTIONS
TALLAHASSEE, FL

RON DESANTIS
GOVERNOR

September 21, 2021

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

Dear Secretary Lee:

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

Dr. Joseph Ladapo
4052 Bald Cypress Way
Tallahassee, Florida 32399

as State Surgeon General, succeeding Scott Rivkees, subject to confirmation by the Senate. This appointment is effective September 21, 2021 for a term ending at the pleasure of the Governor.

Sincerely,

Ron DeSantis
Governor

RD/kk

HAND DELIVERED

OATH OF OFFICE

(Art. II. § 5(b), Fla. Const.)

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DEPARTMENT OF STATE
2021 NOV 19 PM 4:43
DIVISION OF ELECTIONS
TALLAHASSEE, FL

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
(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 by means of ✓ *physical presence or* ___ *online notarization, this* 17th *day of* November, 2021.

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 California Driver Lic#

ACCEPTANCE

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

Mailing Address: ☐ Home ☒ Office

4052 Bald Cypress Way
Street or Post Office Box

Tallahassee FL 32399
City, State, Zip Code

Joseph Ladapo
Print Name

Signature

DS-DE 56 (Rev. 02/20)

1030

STATE OF FLORIDA
DEPARTMENT OF STATE

Division of Elections

I, Laurel M. Lee, Secretary of State,
do hereby certify that

Joseph Ladapo

is duly appointed

**State Surgeon General and Secretary,
Department of Health**

for a term beginning on the Twenty-First day of September, A.D., 2021, to serve at the pleasure of the Governor and is subject to be confirmed by the Senate during the next regular session of the Legislature.

Given under my hand and the Great Seal of the State of Florida, at Tallahassee, the Capital, this the Twenty-Second day of November, A.D., 2021.

Laurel M. Lee

Secretary of State

DSDE 99 (3/03)

The Florida Senate

Committee Notice Of Hearing

IN THE FLORIDA SENATE
TALLAHASSEE, FLORIDA

IN RE: Executive Appointment of

Joseph Ladapo

State Surgeon General

NOTICE OF HEARING

TO: Dr. Joseph Ladapo

YOU ARE HEREBY NOTIFIED that the Committee on Health Policy of the Florida Senate will conduct a hearing on your executive appointment on Wednesday, January 26, 2022, in the Pat Thomas Committee Room, 412 Knott Building, commencing at 10:00 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 20th day of January, 2022

Committee on Health Policy

Senator Manny Diaz, Jr.
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: Joseph Ladapo

ANSWER: Yes

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

COMMITTEE NAME: Senate Health Policy Committee

DATE: 1/26/2022

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:	PCS/SB 768 (709032)
INTRODUCER:	Health Policy Committee
SUBJECT:	Department of Health
DATE:	January 25, 2022
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Vanwinkle and Looke	Brown	HP	**Pre-meeting**
2.			AHS	
3.			AP	

I. Summary:

PCS/SB 768 addresses numerous health care-related issues regulated by the Department of Health (DOH). The PCS:

- Updates the "Targeted Outreach for Pregnant Women Act of 1998;"
- Amends s. 381.0303, F.S., to specify that for pediatric special needs shelters, the DOH is the lead agency to coordinate local medical and health care providers for the staffing and management of the shelters and is the decision-making authority for determining the medical supervision in each special needs shelter;
- Allows the DOH to collect samples of marijuana and marijuana delivery devices, in general, from a medical marijuana treatment center (MMTC) for specified testing, rather than only samples of edibles;
- Expands MMTC recall requirements to all marijuana products and delivery devices, rather than only edibles;
- Provides an exception from criminal laws for DOH employees to acquire, possess, test, transport, and lawfully dispose of marijuana and marijuana delivery devices;
- Amends statutes regulating several types of health care professions, including allopathic and osteopathic physicians, nurses, midwives, psychologists, orthotists, prosthetists, clinical lab personnel, chiropractors, mental health counselors, clinical social workers, and marriage and family therapists;
- Amends ss. 460.406, 468.803, 483.824, 490.005, F.S., to delete references to the term "regional" and replace it with the term "institutional" to conform with the U.S. Department of Education accreditation nomenclature for approving health care-related educational institutions; and
- Amends s. 766.314, F.S., authorizing the Florida Birth-Related Neurological Injury Compensation Association (NICA) to collect and enforce physician assessments in circuit

court, if necessary, and requires the NICA to notify the DOH and the appropriate board of any unpaid final judgments against a physician within a specific timeframe.

The PCS provides an effective date of July 1, 2022, except as otherwise provided.

II. Present Situation:

Targeted Outreach for Pregnant Women

The Targeted Outreach for Pregnant Women Act (TOPWA) was enacted by the Florida Legislature in 1998. The TOPWA program is designed to establish targeted outreach to high-risk pregnant women who may not be receiving proper prenatal care, who suffer from substance abuse problems, or who may be infected with the human immunodeficiency virus (HIV). The goal of the program is to provide these high-risk pregnant women with referrals for information and services.

In 2019, there were 453 HIV-exposed births in Florida. While there were no known perinatal HIV transmissions in 2019, the DOH does not have a definitive status on roughly 25 percent of the 453 HIV-exposed births.

Without proper care for both mother and newborn, each of these births risks vertical transmission. The TOPWA supports outreach programs aimed at preventing vertical HIV transmission and other health issues by linking high-risk pregnant women with services that can help them have healthier pregnancies and deliveries and can aid them in ensuring their newborn gets a healthy start.[1]

Many of the women targeted by TOPWA programs may not otherwise receive prenatal care or know their HIV status. In 2021, there were eight TOPWA programs in Florida.[2] The TOPWA programs, which are funded through General Revenue (GR) dollars and grant funds from the federal Centers for Disease Control and Prevention (CDC), provided services to 7,703 women from January 2016 to July 2020. Women living with HIV made up just under 10 percent of TOPWA program enrollments.[3]

If a pregnant woman tests positive for HIV, medical interventions and prevention, such as the following, can greatly reduce her risk of transmitting the virus to her baby during childbirth:

- Antiretroviral medication to the mother;
- Delivery by caesarian section;
- Avoiding breastfeeding; and
- Antiretroviral medication to the newborn.

[1] Section 381.0045(2), F.S.
[2] Florida Department of Health, Diseases and Conditions, AIDS, Prevention, *TOWPA Map*, available at http://www.floridahealth.gov/diseases-and-conditions/aids/prevention/_documents/topwa/TOPWAProviderMap2021.pdf (last visited Nov. 2, 2021).
[3] Department of Health, *Senate Bill 768 2022 Agency Legislative Bill Analysis* (July 23, 2021) (on file with the Senate Committee on Health Policy).

The DOH has developed a GR-funded program, Baby Rxpress, which provides a six-week course of ARV medication to HIV-exposed newborns at no cost to the mother. In 2019, this program filled 304 prescriptions to 264 HIV-exposed newborns at a cost of $10,801.96, or $40.92 per baby.[4]

Special Needs Shelter Program

Section 381.0303, F.S., was enacted in 2000 to create the Special Needs Shelter Program to provide for the operation and closure of special needs shelters (shelters). The shelters are designed for persons with a physical impairment, mental impairment, cognitive impairment, or sensory disability who, during periods of evacuation or emergency, require sheltering assistance to have a safe and secure place to go during an emergency or disaster. In s. 381.0303(1), F.S., the Legislature designates the DOH, through its county health departments, as the lead agency for coordinating and recruiting health care practitioners to staff the shelters during emergencies or disasters.[5]

In s. 381.0303(2), F.S., the Legislature delineates the responsibilities for the shelters as follows:

- The DOH has the lead responsibility for coordinating local medical and health care providers, the American Red Cross, and other interested parties and in developing a plan for the staffing and medical management of the shelters;
- The DOH's local Children's Medical Services (CMS) offices have responsible for the coordination of local medical and health care providers, the American Red Cross, and other interested parties, and for developing a plan for the staffing and medical management of the shelters;
- The county health departments, in conjunction with the local emergency management agencies, have lead responsibility for the coordination and recruitment of the health care practitioners to staff local shelters;
- Local emergency management agencies have responsibility for the designation and operation of the shelters during an emergency or disaster and the closure of the facilities following the event; and
- The local county health department, local CMS office, and local emergency management agency are jointly responsible for deciding who is responsible for the medical supervision in each shelter.[6]

According to the DOH, this shared lead responsibility between the DOH, through its local county health departments, and CMS, through its local offices was, in large part, due to the large local CMS workforce of health care practitioners with specialized training and experience in the provision of services for children with special needs. Through a series of program and organizational changes at the DOH, toward a more effective operation and cost savings, the CMS workforce has been reduced by more than 70 percent since 2018. Due to this change in CMS workforce, the DOH advises that CMS is unable to fulfill its responsibilities under s. 381.3030, F.S.[7]

[4] *Id.*
[5] Section 381.0303(1), F.S.
[6] Section 381.0303(2), F.S.
[7] Department of Health, 2022 *Senate Bill 768 Fiscal Analysis* (July 23, 2021) (on file with the Senate Committee on Health Policy).

Medical Marijuana

Amendment 2

On November 4, 2016, Amendment 2 was approved by the statewide electorate and established Article X, section 29 of the Florida Constitution. This section of the constitution became effective on January 3, 2017, and created several exemptions from criminal and civil liability for:

- Qualifying patients who medically use marijuana in compliance with the amendment;
- Physicians, solely for issuing physician certifications with reasonable care and in compliance with the amendment; and
- MMTCs and their agents and employees for actions or conduct under the amendment and in compliance with rules promulgated by the DOH.

Implementation

Subsequently, the Legislature passed SB 8-A in Special Session A of 2017.[8] The bill revised the Compassionate Medical Cannabis Act of 2014[9] in s. 381.986, F.S., to implement Article X, section 29 of the State Constitution.

Testing Marijuana and Exemption from Criminal Offenses

Pursuant to s. 381.986(8)(11)d., F.S., the DOH may select a random sample from edibles available for purchase in an MMTC's DOH-approved dispensing facility for testing. The DOH must test the random samples for potency, safety for human consumption, and accuracy of Tetrahydrocannabinol (THC) and Cannabidiol (CBD) labeling.

MMTCs are required to recall all edibles, including all edibles made from the same batch of marijuana, which fail to meet potency requirements, which are unsafe for human consumption, or for which the labeling of the THC and CBD concentration is inaccurate.

Presently, the DOH and its employees are not expressly exempt from criminal prosecution under ss. 893.13, 893.135, and 893.147, F.S., when acquiring, possessing, testing, transporting, and disposing of marijuana and delivery devices under certain circumstances when acting within the scope of their duties.[10]

Additional Disclosure for Physician Licensure and Renewal

Section 456,039, F.S., requires each physician,[11] chiropractor, and podiatrist seeking initial licensure, or license renewal, in Florida, in addition to normal required licensure information, to submit the following to the DOH:

[8] Chapter 2017-232, Laws of Fla.
[9] Chapter 2014-157, Laws of Fla.
[10] Department of Health, *Senate Bill 1568 Fiscal Analysis* (Mar. 12, 2021) (on file with the Senate Committee on Health Policy).
[11] *See* ss. 458.345 and 459 021, F.S., Registered medical and osteopathic, residents are exempt from the requirement of 456.039, F.S.

- Name of each medical school attended, including dates of attendance, graduation, and a description of all graduate medical education completed, except continuing education (CE) requirements;
- Name of each hospital where the applicant has privileges;
- Primary practice address;
- Specialty board certifications, if any;
- Date applicant began practicing medicine;
- Medical school faculty appointments currently held and whether the applicant has had the responsibility for graduate medical education within the past 10 years;
- Any criminal offenses, felony or misdemeanor, of which the applicant has been found guilty, regardless of whether adjudication was withheld, or to which the applicant has pled guilty or nolo contendere, including those committed in another jurisdiction which would constitute a felony or misdemeanor in Florida;
- Any final professional disciplinary action within the previous 10 years in Florida or any other jurisdiction, or by any specialty board, similar national organization, licensed hospital, health maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home;
- Any claim or action for damages in Florida, in another jurisdiction or in a foreign country, for personal injury alleged to have been caused by error, omission, or negligence in the performance of licensee's professional services; and
- Fingerprints.

Any change in the above information must be updated within 45 days after the occurrence of an event or change in status that is required to be reported. The DOH compiles this information and submits it to the practitioner profile of the applicant.[12]

Educational Institution Accreditation

Each profession includes the requirement of completion of a program from a "regionally accredited" institution. The U.S. Department of Education issued a letter of guidance on February 26, 2020, specifying that final regulations published that year omit references to "regional" and "national" accreditation. The letter specifies, "Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded." Provisions implemented in 34 C.F.R. § 602.32(d), relating to the recognition of accrediting agencies, will become effective January 1, 2021.[13]

Nursing

Licensure by Examination

Part I of ch. 464, F.S., the Nurse Practice Act, governs the licensure and regulation of nurses in Florida. Nurses are licensed by the DOH[14] and are regulated by the Board of Nursing (BON).[15]

[12] Section 456.041, F.S.
[13] U.S. Department of Education, Office of the Under Secretary, *Final Accreditation and State Authorization Regulations*, February 26, 2020, (on file with the Senate Committee on Health Policy).
[14] Section 464.008, F.S.
[15] The BON is composed of 13 members appointed by the Governor and confirmed by the Senate who serve four-year terms. All members must be residents of the state. Seven members must be registered nurses who are representative of the diverse

Currently, a person desiring to practice nursing in the state of in Florida must obtain a Florida license by examination, endorsement[16]or have a multistate license.[17]

Applicants for licensure by examination as a registered nurse (RN) or licensed practical nurse (LPN) must, among other requirements:

- Graduate from an approved program or its equivalent as determined by the BON.[18]
- Submit an application to the DOH;
- Pay a fee;
- Submit information for a criminal background check;[19] and
- Pass the National Council Licensure Examination (NCLEX).[20]

Any applicant who fails the NCLEX three consecutive times, regardless of the jurisdiction where the examination is taken, must complete a board-approved remedial course before the applicant will be approved to re-take the NCLEX. After taking the remedial course, the applicant may be approved to retake the examination up to three additional times before the applicant must retake remediation. The applicant must apply for reexamination within 6 months after completion of remediation.[21]

If an applicant who graduates from an approved program does not take the licensure examination within six months after graduation, he or she must enroll in and successfully complete a BON-approved licensure examination preparatory course. The applicant is responsible for all costs associated with the course and may not use state or federal financial aid for such costs. The BON is directed to, by rule, establish guidelines for licensure examination preparatory courses.[22]

Disciplinary Actions

Once an individual is licensed to practice nursing in Florida, he or she has a professional responsibility to practice nursing at a minimum level of competency to ensure the safety of the public. The safe practice of nursing also requires that a nurse not commit any of the hundreds of acts that would constitute grounds for the denial of a license, disciplinary action, or even criminal prosecution, as set out under ss. 456.072(2), 464.0095, and 464.018, F.S.

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areas of practice within the nursing profession. Three members must be licensed practical nurses and three members must be laypersons. At least one member of the board must be 60 years of age or older. *See* Section 464.004, F.S.

[16] Section 464.009, F.S., provides the requirements for licensure by endorsement, and requires an applicant to submit an application and fee, passing a criminal background screening, and 1) Hold a valid license to practice professional or practical nursing in another state or territory of the United States which, when issued, met or exceeded those in Florida at that time; 2) Meet the requirements for licensure in Florida and having successfully completed an examination in another state which is substantially equivalent to the examination in Florida; or 3) Have actively practiced nursing in another state, jurisdiction, or territory of the United States for two of the preceding three years without having his or her license acted against by the licensing authority of any jurisdiction.

[17] Section 464.0095, F.S., A "Multistate license" is a license to practice as a registered nurse (RN) or a licensed practical/vocational nurse (LPN/VN) issued by another Nurse Licensure Compact state's licensing board which authorizes the licensed nurse to practice in all party states under a multistate licensure privilege.

[18] Section 464.008(1)(c), F.S.

[19] Section 464.008(1)(b), F.S.

[20] Section 464.008(2), F.S.

[21] Section 464.008(3), F.S.

[22] Section 464.008 (4), F.S.

Section 464.018(1)(c)-(e), F.S., as currently written, uses the modifying phrase, "regardless of adjudication;" but where the phrase is placed in subsections (c) and (d) verses subsection (e) has a significant impact on its application in law.

In s. 464.018(1)(e), F.S., the placement of the phrase, "regardless of adjudication," only applies to licensees "having been found guilty of," offenses listed in s. 435.04, F.S., or an offense of domestic violence under s. 741.20, F.S. "Regardless of adjudication" does not apply to those "entering a plea of guilty or nolo contendere to" listed offenses. This interpretation could result in those licensees entering a plea of nolo contendere or guilty and not being found guilty (i.e. adjudication is withheld), therefore not being subject to professional disciplinary action.

Midwifery

"Midwifery" is the practice of supervising the conduct of a normal labor and childbirth, with the informed consent of the parent; the practice of advising the parents as to the progress of the childbirth; and the practice of rendering prenatal and postpartal care.[23]

Chapter 467, F.S., is the Midwifery Practice Act. Any person who seeks to practice midwifery in Florida must be at least 21 years of age and be:

- Licensed under s. 464.012, F.S., as an Advanced Practice Registered Nurse (APRN) nurse midwife; or
- Licensed as a midwife under ch. 467, F.S.

Section 467.009, F.S., governs midwifery programs and education and training requirements which are a minimum of three years in an approved program. An applicant must have:

- A high school diploma or the equivalent.
- Taken at least three college-level credits such as math and English.

It is unclear under current law whether both a high school diploma and three college level credits are required for admission, or whether one or the other will satisfy the admission requirement.

Section 467.009, F.S., also requires a student midwife, during training, to undertake the care of 50 women in each of the prenatal, intrapartal, and postpartal periods, and observe an additional 25 women in the intrapartal period under the supervision of a preceptor, but the same women need not be seen through all periods. Prenatal, intrapartal, and postpartal periods are not defined, and the statute is unclear as to whether this requires 150 patients prenatal, intrapartal, and postpartal periods, or just 50 patients in any one of the three phases of pregnancy and delivery. The statute is also unclear as to whether the two references to intrapartal care and observation may be the same patient or require different patient contacts.

Section 467.009, F.S., uses the terms, "applicant" and "student midwife" interchangeably, which is inaccurate. These sections frame standards for admission, education, and clinical training in the context of student requirements. Preceptors direct, teach, supervise, and evaluate the learning experiences of the student midwife and may be physicians, licensed midwives, or a certified

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

nurse midwife, who have a minimum of three years professional experience.[24] Persons with previous midwifery education, RNs, and LPNs may have a reduced training period, but in no case less than two years.

Chapter 467.009, F.S., does not include any provisions explicitly allowing a new midwifery program to be provisionally approved nor does it provide guidance to schools regarding the circumstances under which the DOH may rescind the approval of program.

Section 467.011, F.S., licensure by examination, requires the DOH to:
- Administer the licensure examination to test the proficiency of applicants in the core competencies required to practice midwifery as specified in s. 467.009, F.S.;
- Develop, publish, and make available to interested parties at a reasonable cost a bibliography and guide for the examination; and
- Issue a license to practice midwifery to an applicant who has graduated from an approved midwifery program, successfully completed the examination, and paid a licensure fee.

The DOH no longer administers midwifery examinations, and, pursuant to s. 456.017(c), F.S., the DOH has approved the use of a national examination for midwives seeking to become licensed.[25]

In lieu of examination, an applicant may apply for a license by endorsement based on verification that the applicant holds a current valid license to practice midwifery in another jurisdiction that has equivalent or more stringent licensure requirements than those in Florida.[26]

A midwife may accept and provide care only for those women who are expected to have a normal pregnancy, labor, and delivery and must ensure that:
- The patient has signed an informed consent form; and
- If the patient is delivering at home, the home is safe and hygienic.

The statute does not define "normal delivery," "low risk pregnancy," or "high risk pregnancy."

A midwife licensed under ch. 467, F.S., may administer the following:
- Prophylactic ophthalmic medication;
- Oxygen;
- Postpartum oxytocin;
- Vitamin K;
- Rho immune globulin (human); and
- Local anesthetic and other medications prescribed by a practitioner.[27]

A midwife's care of mothers and infants throughout the prenatal, intrapartal, and postpartal periods must be in conformity with DOH rules and the health laws of Florida. The midwife must:

[24] Section 467.003(12), F.S.
[25] Department of Health, *Senate Bill 678 2022 Agency Legislative Bill Analysis -Midwifery* (July 23, 2021) (on file with the Senate Committee on Health Policy).
[26] Section 467.0125, F.S.
[27] Section 467.015, F.S.

- 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;
- Instruct the patient and family regarding the preparation of the environment and ensure availability of equipment and supplies needed for delivery and infant care;
- Instruct the patient in the hygiene of pregnancy and nutrition as it relates to prenatal care;
- Maintain equipment and supplies;
- Determine the progress of labor and, when birth is imminent, be immediately available until delivery is accomplished, and must:
  - Maintain a safe and hygienic environment;
  - Monitor the progress of labor and the status of the fetus;
  - Recognize early signs of distress or complications; and
  - Enact the written emergency plan when indicated;
- Remain with the postpartal mother until the conditions of the mother and the neonate are stabilized; and
- Instill into each eye of the newborn infant a prophylactic in accordance with s. 383.04, F.S.

Section 467.0125, F.S., also includes provisions for licensure by endorsement and temporary certification of a midwife who is qualifying for endorsement to practice in an area of critical need. This statute defines the term "area of critical need" differently from every other profession which has temporary certification that allows practice in an area of critical need. In addition, the current provisions for temporary certification of midwives require revocation if the area in which they practice loses its designation as an area of critical need.

Section 467.205, F.S., provides that any accredited or state-licensed institution of higher learning, public or private, may provide midwifery education and training. The statute sets out the DOH approval requirements for programs desiring to conduct an approved midwifery education program. Under the application and recertification process:

- The applicant must submit evidence of the program's compliance with the requirements in s. 467.009, F.S.
- The DOH must survey the organization applying for approval. If the DOH is satisfied that the program meets the requirements of s. 467.009, F.S., it must approve the program.
- The DOH must certify whether each approved midwifery program complies with the standards developed under s. 467.009, F.S., at least every three years.
  - If the DOH finds that an approved program no longer meets the required standards, it may place the program on probation until such time as the standards are restored.
  - If a program fails to correct these conditions within a specified period of time, the DOH may rescind the approval.
  - Any program having its approval rescinded has the right to reapply.
- Provisional approval of a new program may be granted pending the licensure results of the first graduating class.[28]

[28] Section 467.205, F.S.

Practice of Orthotics, Prosthetics, and Pedorthics

The practice of orthotics, prosthetics, and pedorthics is governed by part XIV of ch. 468, F.S., and all three professions evaluate, measure, design, fabricate, assemble, fit, adjust, service, or provide the initial training necessary to accomplish the fitting of an orthosis or pedorthic device.[29]

Section 468.803, F.S., provides minimum qualifications for licensure to practice orthotics, prosthetics, and pedorthics. An applicant must be 18 years of age or older and must:

- Submit an application and fee;
- Submit fingerprint forms and the cost of the state and national criminal background checks;
- Be of good moral character;
- Have completed a one year residency or internship in orthotics or prosthetics approved by the Board of Orthotists and Prosthetists (BOAP); and
- Meet the following degree requirements to take the appropriate BOAP-approved examination:
  - *Orthoptist*: A bachelor of science or higher-level postgraduate degree in orthotics and prosthetics from a regionally accredited college or university, or a bachelor's degree with a certificate in orthotics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the BOAP.
  - *Prosthetist:* A bachelor of science or higher-level postgraduate degree in orthotics and prosthetics from a regionally accredited college or university, or a bachelor's degree with a certificate in prosthetics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the BOAP; and
- Pass the BOAP-approved examination.

Clinical Lab Personnel

Part I of ch. 483, F.S., regulates clinical laboratory personnel. "Clinical laboratory personnel" includes a clinical laboratory director, supervisor, technologist, blood gas analyst, or technician who performs or is responsible for laboratory test procedures, but the term does not include trainees, persons who perform screening for blood banks or plasmapheresis centers, phlebotomists, or persons employed by a clinical laboratory to perform manual pretesting duties or clerical, personnel, or other administrative responsibilities.[30]

Section 483.824(2), F.S., requires that the doctoral degree held by a clinical laboratory director must be from a regionally-accredited institution in a chemical, physical, or biological science.

Psychologists

Chapter 490, F.S., regulates the practice of psychology by psychologists. A psychologist is a person licensed by examination under s. 490.005(1), F.S., or endorsement under s. 490.006, F.S.

[29] Section 468.80, F.S.
[30] Section 483.803(4), F.S.

Section 490.003. F.S., defines a "doctoral-level psychological education" and "doctoral degree in psychology" as of July 1, 1999, to include a Psy.D., an Ed.D. in psychology, or a Ph.D. in psychology from a psychology program at an educational institution that, at the time the applicant was enrolled and graduated:

- Had institutional accreditation from an agency recognized and approved by the U.S. Department of Education or was recognized as a member in good standing with the Association of Universities and Colleges of Canada; and
- Had programmatic accreditation from the American Psychological Association (APA).

Section 490.005, F.S., provides that any person desiring to be licensed by examination as a psychologist must apply to the DOH to take the licensure examination. The DOH will license each applicant who the Board of Psychology (BOP) certifies has:

- Completed an application and submitted a fee;
- Submitted proof satisfactory to the BOP that the applicant has received:
  - Doctoral-level psychological education; or
  - The equivalent of a doctoral-level psychological education from a program at a school or university located outside the U.S.;
- Had at least two years or 4,000 hours of experience in the field of psychology; and
- Passed the licensing examination.

Section 490.0051, F.S., also requires the DOH to issue a provisional psychology license to each applicant who the BOP certifies has:

- Completed the application form and paid the fee;
- Earned a doctoral degree in psychology as defined in s. 490.003(3); and
- Met any additional requirements established by BOP rule.

Provisional licensees must practice under the supervision of a licensed psychologist until the provisional licensee receives a license or a letter from the DOH stating that he or she is licensed as a psychologist. A provisional license expires 24 months after the date it is issued and may not be renewed or reissued.

Mental Health Professionals

Section 491.005, F.S., sets out the educational and examination requirements for a clinical social worker, marriage and family therapist, and mental health counselor to obtain a license by examination in Florida. An individual applying for licensure by examination who has satisfied the clinical experience requirements of s. 491.005, F.S., or an individual applying for licensure by endorsement pursuant to s. 491.006, F.S., intending to provide clinical social work, marriage and family therapy, or mental health counseling services in Florida, while satisfying coursework or examination requirements for licensure, must obtain a provisional license in the profession for which he or she is seeking licensure prior to beginning practice.[31]

An individual who has not satisfied the postgraduate or post-master's level of experience requirements under s. 491.005, F.S., must register as an intern in the profession for which he or she is seeking licensure before commencing the post-master's experience requirement. An

[31] Section 491.0046, F.S.

individual who intends to satisfy part of the required graduate-level practicum, internship, or field experience outside the academic arena, must register as an intern in the profession for which he or she is seeking licensure before commencing the practicum, internship, or field experience.[32]

Clinical Social Workers

Section 491.005(1), F.S., relates to licensure by examination for clinical social workers. The DOH must issue a license to an applicant as a clinical social worker if the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling (Board) certifies that the applicant:

- Has submitted an application and appropriate fees;
- Has earned a doctoral degree in social work from a graduate school of social work accredited by an accrediting agency recognized by the U.S. Department of Education, or a master's degree in social work from a graduate school of social work which:
  - Was accredited by the Council on Social Work Education (CSWE);
  - Was accredited by the Canadian Association of Schools of Social Work (CASSW); or
  - Has been determined to be an equivalent program to programs approved by the CSWE by the Foreign Equivalency Determination Service of the CSWE;
  - Completed all of the following coursework:
    - A supervised field placement during which the applicant provided clinical services directly to clients; and
    - Twenty-four semester hours or 32 quarter hours in theory of human behavior and practice methods as courses in clinically oriented services, with a minimum of one course in psychopathology and no more than one course in research;
- Has completed at least two post graduate years of clinical social work experience under the supervision of a licensed clinical social worker or the equivalent supervisor as determined by the Board;[33]
- Has passed a theory and practice examination; and
- Demonstrates, in a manner designated by Board rule, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.

Marriage and Family Therapists

Section 491.005(3), F.S., relates to licensure by examination for marriage and family therapists. The DOH must issue a license to an applicant as a marriage and family therapist if the Board certifies that the applicant has:

- Submitted an application and appropriate fee;
- A minimum of a master's degree with major emphasis in marriage and family therapy or a closely related field from a:
  - Program accredited by the Commission on Accreditation for Marriage and Family Therapy Education (CAMFTE); or

[32] Section 491.0045, F.S.

[33] Section 491.005(1)(c), F.S. An individual who intends to practice in Florida to satisfy clinical experience requirements must register with the DOH pursuant to s. 491.0045, F.S., before commencing practice.

    - Florida university program accredited by the Council for Accreditation of Counseling and Related Educational Programs (CACREP);
- Documentation of the completion of graduate courses approved by the Board;[34]
- Completed at least two years of clinical experience during which 50 percent of the applicant's clients were receiving marriage and family therapy services:
    - At the post-master's level; and
    - Under the supervision of a licensed marriage and family therapist with at least five years of experience, or the equivalent, and whom the Board determines is a qualified supervisor;
- Passed a theory and practice examination provided by the DOH;[35]
- Demonstrated, in a manner designated by Board rule, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.[36]

The required master's degree must have been earned at an institution of higher education that, at the time the applicant graduated, was fully accredited by a regional accrediting body recognized by:

- The Commission on Recognition of Postsecondary Accreditation (CORPA);
- A member in good standing with the Association of Universities and Colleges of Canada; or
- An institution of higher education located outside the United States and Canada which, at the time the applicant attended and graduated, maintained a standard of training substantially equivalent to the standards of training of those institutions in the United States which are accredited by a regional accrediting body recognized by the CORPA.[37]

The applicant has the burden of establishing that all above requirements for licensure are met.

An applicant who has a master's degree from a program that did not emphasize marriage and family therapy may complete the coursework requirement in an institution fully accredited by the CAMFTE, and recognized by the U.S. Department of Education.

To satisfy the clinical experience requirements, an individual who intends to practice in Florida must register with the DOH before he or she may commence practice.

A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting.

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[34] Section 491.005(3)(b), F.S. If the course title that appears on the applicant's transcript does not clearly identify the content of the coursework, the applicant must provide additional documentation, including, but not limited to, a syllabus or catalog description published for the course.

[35] *See* s. 491.004(5), F.S., and Fla. Admin. Code R. 64B4-3.003(2)(c) and 3, (2021). The DOH no longer provides the theory and practice examination for Marriage and Family Therapists. The examination used is the one developed by the Examination Advisory Committee of the Association of Marital and Family Therapy Regulatory Board (AMFTRB). The minimum passing score is established by that provider as well.

[36] *See* Fla. Admin. Code R. 64B4-3.0035, (2021).

[37] *Id.* Such foreign education and training must have been received in an institution or program of higher education officially recognized by the government of the country in which it is located as an institution or program to train students to practice as professional marriage and family therapists or psychotherapists.

The DOH must issue a dual license to persons licensed as psychologists, clinical social workers, mental health counselors, and psychiatric advanced practice registered nurses, if the candidate has:

- A valid, active license for at least three years; and
- Passed the examination provided by the DOH for marriage and family therapy.

Mental Health Counselors

Section 491.005(4), F.S., relates to licensure by examination for mental health counselors. Education and training in mental health counseling must have been received in an institution of higher education that, at the time the applicant graduated, was fully accredited by:

- A regional accrediting body recognized by the Council for Higher Education Accreditation (CHEA) or its successor;
- A publicly recognized member in good standing with the Association of Universities and Colleges of Canada; or
- An institution of higher education located outside the United States and Canada which, at the time the applicant was enrolled and at the time the applicant graduated, was officially recognized by the government of the country in which it is located as an institution or program, to train students to practice as mental health counselors that maintained a standard of training substantially equivalent to the standards of training of those institutions in the United States which are accredited by a regional accrediting body recognized by the CHEA or its successor.

The DOH must issue a license to an applicant as a mental health counselor if the Board certifies that the applicant has:

- Submitted an application and appropriate fees;
- Earned a minimum of a master's degree from:
  - A mental health counseling program accredited by the CACREP[38] which includes clinical and didactic instruction, including courses in human sexuality and substance abuse; or
  - A non-CACREP accredited program related to the practice of mental health counseling, but with coursework and practicum, internship, or fieldwork that meet all of the following:
    - Thirty-three semester hours, or 44 quarter hours, which must include a minimum of three semester hours, or four quarter hours, of graduate-level coursework in 11 specified content areas;[39]or
    - A minimum of one graduate level course emphasizing the diagnostic processes, including differential diagnosis and the use of the current diagnostic tools, such as the current edition of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders. the common core curricular experience; or

[38] Council for Accreditation of Counseling & Related Educational Programs, *2016 CACREP Standards, available at* http://www.cacrep.org/wp-content/uploads/2018/05/2016-Standards-with-Glossary-5.3.2018.pdf (last visited Nov. 20, 2021).
[39] *See* s. 491.005(4)(b)1.a., F.S. The graduate course work must include the following 11 content areas: counseling theories and practice; human growth and development; diagnosis and treatment of psychopathology; human sexuality; group theories and practice; individual evaluation and assessment; career and lifestyle assessment; research and program evaluation; social and cultural foundations; substance abuse; and legal, ethical, and professional standards issues in the practice of mental health counseling. Courses in research, thesis or dissertation work, practicums, internships, or fieldwork may not be applied toward this requirement.

    - An equivalent program to the two previously described options, as determined by the Board, including at least 700 hours of university-sponsored supervised clinical practicum, internship, or field work, that includes at least 280 hours of direct client services, as required by CACREP accrediting standards for mental health counseling programs. This experience may not be used to satisfy the post-master's clinical experience requirement;
- Had at least two years of clinical experience in mental health counseling, which must be at the post-master's level under the supervision of a licensed mental health counselor or the equivalent who is a Board qualified supervisor;[40]
- Passed a theory and practice examination provided by the DOH;[41] and
- Demonstrated, in a manner designated by Board rule, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.[42]

Beginning July 1, 2025, an applicant for mental health counseling licensure must have a master's degree from a program that is accredited by the CACREP which consists of at least 60 semester hours or 80 quarter hours.

A licensed mental health professional is required to be on the premises when clinical services are provided by a registered intern in a private practice setting. Section 491.005, F. S., contains the same provision for registered clinical social worker interns.

Recent Legislative History of Section 491.005, F.S.

The current program accreditation and licensure requirements in s. 491.005, F.S., for social workers, marriage and family therapists and mental health counselors were enacted during the 2020 legislative session.

As of July 1, 2020 an applicant seeking licensure under current s. 491.005(4), F.S., as a mental health counselor was required to have a master's degree from an a program accredited by the CACREP beginning July 1, 2025. Until July 1, 2025, mental health counseling students in programs related to the practice of mental health counseling that were not accredited by the CACREP could still obtain a license as a mental health counselor by satisfying the additional statutory requirements in s. 491.005(4), F.S., which required coursework and practicum,

[40] Section 491.005(4), F.S., An individual who intends to practice in Florida to satisfy the clinical experience requirements must register pursuant to s. 491.0045, F.S., before commencing practice. If a graduate has a master's degree with a major related to the practice of mental health counseling which did not include all the coursework required under sub-subparagraphs (b)1.a. and b., credit for the post-master's level clinical experience may not commence until the applicant has completed a minimum of seven of the courses required under sub-subparagraphs (b)1.a. and b., as determined by the Board, one of which must be a course in psychopathology or abnormal psychology. A doctoral internship may be applied toward the clinical experience requirement.

[41] *See* s. 491.004(5), F.S., and Fla. Admin Code R. 64B4-3.003(2)(b) and 3, (2021). The DOH no longer provides the theory and practice examination for mental health counselors. The examination used is the National Clinical Mental Health Counseling Examination (NCMHCE), clinical simulation examination developed by the National Board for Certified Counselors (NBCC). Applicants for licensure by endorsement may use the National Counselor Examination for Licensure and Certification (NCE) if the exam was taken prior to the year 2000. The minimum passing score is established by the test provider.

[42] Fla. Admin. Code R. 64B4-3.0035, (2021).

internship, or fieldwork consisting of at least 60 semester hours or 80 quarter hours and meeting other specific requirements. This window of time also gave those non-CACREP accredited programs time to apply for and obtain CACREP accreditation.

However, for marriage and family therapy licensure candidates, the current s. 491.005(3), F.S., contains no similar window of time for students to obtain licensure, or programs to obtain CAMFTE or CACREP accreditation. On July 1, 2020, students who had satisfied the previous requirements of s. 491.005(3), F.S., for licensure in programs not accredited by the CAMFTE, or who were in a Florida program not accredited by the CACREP, became immediately unable to obtain a license to practice marriage and family therapy without seeking a variance from the Board.

Currently, there are six universities in Florida with a marriage and family program that are not accredited by either COAMFTE or CACREP. They are: Carlos Albizu, Jacksonville University, Palm Beach Atlantic University, St. Thomas University, University of Miami, and University of Phoenix. As a result, students who are presently enrolled in a marriage and family program at one of the specified universities will not meet minimum requirements for Florida licensure upon graduation, although the programs did meet the requirements at the time of the student's enrollment.[43]

Regional Accreditation

The minimum qualifications for licensure specified in s. 491.005(3), F.S., includes the requirement of completion of a graduate program from a "regionally accredited body recognized by the Commission on Recognition of Postsecondary Accreditation." The U.S. Department of Education issued a letter of guidance on February 26, 2020, specifying that final regulations published that year omit references to "regional" and "national" accreditation. The letter specifies, "Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded." Provisions implemented in 34 C.F.R. s. 602.32(d), relating to the recognition of accrediting agencies, will become effective January 1, 2021.[44]

Department Examination

The DOH has discontinued the practice of conducting examinations or purchasing examinations for licensure. Applicants are presently responsible for coordinating the completion of an examination with an approved vendor and submitting passing scores to the applicable board to meet minimum qualifications. Current statutory references to the DOH collecting fees for examinations or conducting examinations is not consistent with current practice.[45]

Florida Birth-Related Neurological Injury Compensation Association (NICA)

In 1988 the Florida Legislature created the Florida Birth-Related Neurological Injury Compensation Association (NICA), to provide compensation, long-term medical care, and other

[43] Department of Health, *Senate Bill 768 2022 Agency Legislative Bill Analysis - Mental Health Professionals* (July 23, 2021) (on file with the Senate Committee on Health Policy.)
[44] *Id.*
[45] *Id.*

services to persons with birth-related neurological injuries.[46] If an infant suffers such an injury, and the physician participates in NICA and delivers obstetrical services in connection with the birth, then an administrative award for a compensable injury is the infant's sole and exclusive remedy for the injury, with exceptions.[47] Although the benefits paid under the Florida Birth-Related Neurological Injury Compensation Plan (the Plan) are limited, the Plan does not require the claimant to prove malpractice and provides a streamlined administrative hearing process to resolve the claim.[48]

A "birth-related neurological injury" is an injury to the brain or spinal cord of a live infant who weighs at least 2,500 grams for a single gestation or, in the case of a multiple gestation, a live infant who weighs at least 2,000 grams at birth caused by oxygen deprivation or by mechanical injury occurring in the course of labor, delivery, or resuscitation in the immediate post-delivery period in a hospital.[49] Such an injury addressed by this statute renders the infant permanently and substantially mentally and physically impaired.[50]

The NICA is an independent association, and was created by the Legislature to manage the Plan. Although it is not a state agency, NICA is subject to regulation and oversight by the Office of Insurance Regulation (OIR) and the Joint Legislative Auditing Committee. Directors on the NICA's board are appointed by the Chief Financial Officer for staggered terms of three years or until their successor is appointed, but there is no limit on the number of terms a director may serve.[51] The five-member board of directors of NICA administers the Plan.[52] The board of directors is composed of:

- One citizen representative;
- One representative of participating physicians;
- One representative of hospitals;
- One representative of casualty insurers; and
- One representative of physicians other than participating physicians.[53]

The duties of the NICA board of directors include:

- Administering the Plan;
- Administering the funds collected on behalf of the Plan;
- Reviewing and paying claims;
- Directing the investment and reinvestment of any surplus funds over losses and expenses, provided that any investment income generated thereby remains credited to the Plan;
- Reinsuring the risks of the Plan in whole or in part;
- Suing and being sued, appearing and defending, in all actions and proceedings in its name;

[46] Chapter 88-1, ss. 60-75, Laws of Fla., was enacted by the Legislature to stabilize and reduce malpractice insurance premiums for physicians practicing obstetrics. The intent of the Legislature is to provide compensation, on a no-fault basis, for a limited class of high costs catastrophic injuries, specifically birth-related neurological injuries, that result in unusually high costs for custodial care and rehabilitation. Section 766.301, F.S.
[47] Section 766.31(1), F.S.
[48] See *Florida Birth-Related Neurological Injury Compensation Ass'n v. McKaughan*, 668 So.2d 974, 977 (Fla. 1996).
[49] Section 766.302(2), F.S.
[50] *Id.*
[51] Section 766.315, F.S., and ch. 88-1, s. 74, Laws of Fla.
[52] Sections 766.315(1) and (2), F.S.
[53] Section 766.315, F.S., and ch. 88-1, s. 74, Laws of Fla.

- Exercising all powers necessary or convenient to effect any or all of the purposes for which the Plan was created;
- Entering into such contracts as are necessary or proper to administer the Plan;
- Employing or retaining such persons as are necessary to perform the administrative and financial transactions and responsibilities of the Plan;
- Taking such legal action as may be necessary to avoid payment of improper claims; and
- Indemnifying any person acting on behalf of the Plan in an official capacity, provided that such person acted in good faith.[54]

Annually, the NICA must furnish audited financial reports to:
- Any Plan participant upon request;
- The OIR; and
- The Joint Legislative Auditing Committee.[55]

The reports must be prepared in accordance with accepted accounting procedures. The OIR or the Joint Legislative Auditing Committee may conduct an audit of the Plan at any time.[56]

NICA Funding

The initial funding for the Plan is derived from an appropriation of $20 million by the Legislature at the time the Plan was created[57] and annual assessments paid by physicians and hospitals.[58] A participating physician is required to pay a $5,000 fee each year for coverage which runs January 1 through December 31.[59] All licensed Florida physicians pay a mandatory fee of $250, regardless of specialty. Hospitals pay $50 for each live birth during the previous calendar year. Certain exemptions apply to all of these categories, including resident physicians, retired physicians, government physicians, and facilities.[60] In 2019, NICA collected $26,989,960 in hospital and physician assessments. In 2020, NICA collected $27,000,000.[61]

Section 766.314, F.S., requires the OIR to maintain a $20 million reserve in the Insurance Regulatory Trust Fund. If the assessments collected and the appropriation of funds provided by ch. 88-277, s. 41, Laws of Florida, to the Plan from the trust fund are insufficient to maintain the Plan on an actuarially sound basis, the OIR is authorized to transfer an additional amount up to $20 million to the NICA from the Insurance Regulatory Trust Fund reserve.[62]

Obsolete Statutory References and Provisions

Currently, s. 766.314, F.S., contains numerous references to the Department of Business and Professional Regulation (DBPR) as the agency housing the Florida Board of Medicine and the

[54] Section 766.315(4), F.S.
[55] Section 766.315(5)(e), F.S.
[56] *Id*.
[57] Section 766.314(5)(b), F.S.
[58] Section 766.314, F.S.
[59] *Id*.
[60] *Id*.
[61] Turner Consulting, Inc., *Proposed Increase in Parental Award – Section 766.31 (1) (b) (1), Florida Statutes* (Jan. 14, 2020).
[62] Section 766.314(5)(b), F.S.

Florida Board of Osteopathic Medicine. All medical boards were moved to the DOH in the early 2000s. DOH accepted all of the responsibilities in this statute when the boards moved; however, the statute still indicates that these functions should be performed by the DBPR. In addition, the statute contains obsolete language related to how the initial NICA assessment was collected in 1988. This language is no longer needed.

"Following Year" Assessments

The statute requires the DBPR to collect the initial NICA assessment (fee) from all applicants. The statute also requires that if a license is being issued between October 1 and December 31, the DBPR is to collect the fee for the following year.

Currently, the DOH is not collecting the "following year" fees from individuals licensed during the specified period. Every licensee pays the initial NICA assessment (ranging from $0 to $5,000) at the time of application. The "following year" fees have been collected directly by NICA since the boards were moved to the DOH. NICA requires fees to be paid by January 31 of the calendar year.

Data Sharing with NICA

The statute requires the DBPR to provide a listing in a computer-readable format of the names and addresses of physicians licensed under chs. 458 and 459, F.S., as often "as determined to be necessary."

Currently, the DOH provides NICA with a list of newly licensed physicians each month, including their license numbers, the date they were licensed, and the fees collected. Any additional information that NICA may need can be downloaded from DOH's website. This coincides with the transfer of those fees collected by the DOH to NICA, allowing NICA to reconcile the amount received with the fees listed in the monthly report.

III. Effect of Proposed Changes:

Targeted Outreach for Pregnant Women

The PCS amends s. 381.0045, F.S., to:

- Add pregnant women who are suffering from mental health problems to the list of outreach targets;
- Encourage high risk pregnant women to get tested for other sexually transmissible diseases, as well as HIV, per DOH rule;
- Provide pregnant women with information on:
  - The need for antiretroviral medications, deleting reference to a single type of antiretroviral (AZT), for themselves and their newborn; and
  - How to access antiretroviral medications after discharge from the hospital;
- Link women to mental health services; and
- Require additional follow up for HIV-exposed newborns to determine final HIV status and ensure continued linkages to care, if needed.

Special Needs Shelters

The PCS amends s. 381.0303, F.S., and removes CMS from responsibility for coordinating local medical and health care providers, the American Red Cross, and other interested parties in developing a plan for the staffing and medical management of pediatric special needs shelters. The PCS instead specifies that the DOH has the sole lead-agency responsibility in the coordination of local medical and health care providers for the staffing and management of pediatric special needs shelters and is the decision-making authority for determining the medical supervision in each special needs shelter. Under the bill, the DOH will no longer share that duty with CMS.

Medical Marijuana Sampling and Testing

The PCS amends s. 381.986, F.S., related to the medical use of marijuana to:

- Allow the DOH to collect samples of marijuana and marijuana delivery devices from a MMTC for specified testing. Currently, the DOH may only collect samples of edibles;
- Expand MMTC recall requirements to all marijuana products and delivery devices, rather than only edibles; and
- Provide an exception from criminal laws for DOH employees to acquire, possess, test, transport, and lawfully dispose of marijuana and marijuana delivery devices.

Additional Disclosure Requirement for Physician Licensure and Renewal

The PCS amends s. 456.039, F.S., requiring require each physician seeking licensure, or license renewal, under chs, 458 or 459, F.S., to provide, in addition to the other requirements, proof of payment of the NICA assessment required under s. 766.314, F.S., if applicable.

Chiropractic Licensure

The PCS amends s. 460.406, F.S., to deletes references to the term "regional" and replaces it with the term "institutional" to conform with the U.S. Department of Education accreditation nomenclature for approving educational institutions.

Nursing Licensure and Disciplinary Actions

The PCS amend s. 464.008, F.S., and deletes the requirement that graduates from an approved nursing program who do not take the licensure examination within six months after graduation, must successfully complete and pay for a board-approved licensure examination preparatory course.

The PCS also amends s. 464.018(1)(e), F.S., and moves the placement of the phrase, "regardless of adjudication," after the phrase "[h]aving been found guilty of, or entered a plea of nolo contendere or guilty to", to clarify that "regardless of adjudication" does not apply only to guilty pleas but to any plea to offenses listed in ss. 435.04, F.S., or 741.28, F.S.

Midwifery

The PCS amends s. 467.003(12) to clearly define "preceptor" in the midwifery education process. Specifically, the PCS provides that a preceptor may not supervise an individual as a midwifery student unless the student has been enrolled in an approved midwifery program.

The PCS defines "prelicensure course" to mean a course of study, offered by an accredited midwifery program and approved by the DOH, which an applicant for licensure must complete before a license may be issued, and which provides instruction in the laws and rules of Florida and demonstrates the student's competency to practice midwifery. The PCS clarifies language to promote consistency in terminology and that midwifery programs must incorporate all required standards, guidelines, and education objectives.

The PCS also clarifies that both a high school diploma or the equivalent and three college-level credits in math and English or demonstration of competency in communication and computation may be required for admission to a midwifery program. The PCS amends s. 467.009, F.S., and requires, for the accreditation and approval of midwifery programs, that a program's clinical training must include all of the following:

- Care for 50 women in each of the prenatal, intrapartal, and postpartal periods under the supervision of a preceptor;
- Observation of an additional 25 women in the intrapartal period before qualifying for a license;
- Training in a hospital and alternate birth settings or both; and
- Assessment and differentiation between a high-risk and low-risk pregnancy.

The PCS amends s. 467.011, F.S., to require the following for the issuance of a midwifery license:

- Application and fee;
- Graduation from:
    - An accredited and approved midwifery program;
    - A medical or midwifery program offered in another jurisdiction whose graduation requirements were equivalent to or exceeded those required in Florida;
    - Completion of a prelicensure course offered by an accredited and approved midwifery program; and
    - A passing score on the examination specified by the DOH.

The PCS amends s. 467.0125, F.S, to repeal the abbreviated oral examination to determine the applicant's competency without a written examination for temporary certificates and clarifies the criteria for obtaining a license by endorsement and temporary certificate to practice in areas of critical need. The PCS does not specifically define "areas of critical need" for temporary certificates but requires the applicant to:

- Specify that he or she will only practice in one or more of the following areas:
    - A county health department;
    - A correctional facility;
    - A U.S. Department of Veterans' Affairs clinic;
    - A community health center funded by s. 329, s. 330, or s. 340 of the United States Public Health Service Act;

    - Any other agency or institution that is approved by the state Surgeon General that provides health care to meet the needs of an underserved populations in this state; or
    - Areas of critical need determined by the state Surgeon General, which areas include, but are not be limited to, health professional shortage areas designated by the U.S. Department of Health and Human Services.
- Practice only under the supervision of a physician, an APRN certified nurse midwife or a midwife licensed under ch. 467, F.S., who has a minimum of three years professional experience; and
- Voluntarily relinquish the temporary certificate, or report a new practice area of critical need to the DOH, if his or her current practice area ceases to be an area of critical need.

The PCS amends s. 467.205, F.S., to update the DOH's approval process of midwifery programs to allow such programs to be provisionally approved for five years. This conforms to the five-year period provisional licensure period the Florida Department of Education's Commission for Independent Education uses when seeking accreditation status. For private institutions, the PCS adds to the CHEA, an accrediting agency approved by the U.S. Department of Education, as an institutional accrediting agency for direct-entry midwifery education programs and its licensing or provisional licensing by the Commission for Independent Education. The DOH will be able to give provisional approval to a new program that has meet all requirements except for showing its students have an 80-percent passage rate on the national exam. Programs provisionally approved will have five years to demonstrate the required exam approval rate after they are preliminary approved. This time period should allow completion the three-year education program for at least one cohort of students and for those students to take the exam before the DOH tries to determine the passing rate.[63]

The PCS requires the DOH to certify every three years whether each approved midwifery program is compliant and has maintained compliance with the requirements of s. 467.009, F.S., or has lost its accreditation status. The DOH must provide its finding to the program in writing and may place the program on probationary status for a specified period of time, not to exceed three years. If a program on probationary status does not come into compliance or regain its accreditation status within the specified time, the DOH may rescind the program's approval.

Practice of Orthotics, Prosthetics, and Pedorthics

The PCS amends part XIV of ch. 468, F.S., to reflect current procedures for applicants to obtain a criminal history check and the method of transmission to the DOH for review. The DOH no longer collects fingerprint forms or fees from applicants to process the initial criminal history check for licensure. Applicants are required to complete fingerprinting electronically through independent vendors and provide an originating agency identifier number specific to the profession for the results to be submitted to the DOH. If a criminal history is indicated, the BOAP will review the application for consideration of licensure.[64]

The PCS also amends the educational requirements for orthotists and prosthetists. The orthoptist

[63] Department of Health, *Senate Bill 768 2022 Agency Legislative Bill Analysis - Midwifery* (July 23, 2021) (on file with the Senate Committee on Health Policy).
[64] Department of Health, *Senate Bill 768 Fiscal Analysis - Practice of Orthotics, Prosthetics, and Pedorthics* (July 23, 2021) (on file with the Senate Committee on Health Policy).

and prosthetists acceptable bachelor of science or higher-level postgraduate degree in orthotics and prosthetics from an accredited college or university must now also specifically be recognized by the Commission on Accreditation of Allied Health Education Programs.

The PCS deletes references to the term "regionally accredited" and replaces it with the term "institutionally accredited" or simply references the programmatic accrediting body to conform with the U.S. Department of Education accreditation nomenclature for approving educational institutions.[65]

Clinical Lab Personnel

The PCS amends s. 483.824(2), F.S., to delete the reference to the term "regionally" and replace it with "institutionally" in regard to the accredited institution at which a clinical laboratory director is required to have earned a doctoral degree in a chemical, physical, or biological science.

Psychologists

The PCS amends ss. 490.003, 490.005, and 490.0051, F.S., to clarify definitions and the educational requirements for psychologists applying for licensure by examination or provisional licensure.

The PCS defines a "doctoral degree from an APA accredited program" as a Psy.D., an Ed.D. in psychology, or a Ph.D. in psychology from a psychology program at an educational institution that, at the time the applicant was enrolled and graduated had both an institutional accreditation from an agency recognized and approved by the U.S. Department of Education or was as recognized as a member in good standing with the Association of Universities and Colleges of Canada, and had programmatic accreditation from the APA.

The PCS further defines "doctoral degree in psychology" as a Psy.D., an Ed.D. in psychology, or a Ph.D. in psychology from a psychology program at an educational institution that, at the time the applicant was enrolled and graduated, had institutional accreditation from an agency recognized and approved by the U.S. Department of Education or was recognized as a member in good standing with the Association of Universities and Colleges of Canada.

The PCS requires psychologists applying for licensure to have obtained a doctoral degree from:
- An APA accredited program; or
- The equivalent of a degree from APA-accredited program from a school or university located outside the United States which was officially recognized by the government of the country in which it is located as an institution or program to train students to practice professional psychology.

Provisional licensure applicants must have earned a degree from an APA accredited program.

[65] Department of Health, *Senate Bill 768 2022 Agency Legislative Bill Analysis - Practice of Orthotics, Prosthetics, and Pedorthics* (July 23, 2021) (on file with the Senate Committee on Health Policy).

Lack of a degree from an APA-accredited program would be grounds for denial of licensure under the PCS.

Mental Health Professionals

The PCS amends s. 491.005, F.S., effective upon the bill becoming law, to create three pathways to licensure for applicants for a marriage and family therapy license to meet the minimum educational requirements by one of the following methods:

- A minimum of a master's degree in marriage and family therapy from a college or university that is accredited by the CAMFTE;
- A minimum of a master's degree with an emphasis in marriage and family therapy from a college or university that is accredited by the CACREP and graduate courses approved by the board; or
- A minimum of a master's degree with an emphasis in marriage and family therapy or a closely related field, with a degree conferred date before September 1, 2027, from an institutionally accredited college or university.

The PCS updates the education requirements for marriage and family therapists, including current law's obsolete reference to accreditation by CORPA, which was dissolved in 1997. The PCS replaces the CORPA with the CHEA or its successors.

The PCS deletes references to the term "regional" in s. 491.005(3), F.S., and replaces it with the term "institutional" to conform with the U.S. Department of Education accreditation nomenclature for approving educational institutions and deletes obsolete statutory references to the DOH collecting fees for examinations or conducting examinations.

Florida Birth-Related Neurological Injury Compensation Association (NICA)

The PCS amends s. 766.314, F.S., deleting references to the DBPR and revising the frequency and content of certain reports which the DOH must submit to the NICA. The PCS eliminates unnecessary and obsolete language regarding the initial fees collected in 1988.

The PCS deletes obsolete language and updates provisions to conform to current law. The PCS authorizes the NICA to enforce the collection of physician assessments in circuit court under certain circumstances and requires the NICA to notify the DOH and the appropriate regulatory board of any unpaid final judgments against a physician within seven days of the issuance of a final judgment.

The PCS updates the provisions regarding data sharing with the NICA to reflect current DOH practice and requires DOH to continue providing NICA with an electronic monthly report of physicians licensed in the previous month, including their license numbers, the date they were licensed, and the fees collected.

The PCS provides an effective date of July 1, 2022, except as otherwise provided.

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 DOH indicates it will experience a non-recurring workload increase associated with updating online applications and websites; limited costs associated with rule making; limited costs associated with updating licensure databases and the License and Enforcement System; and minimal costs associated with testing from MMTCs. According to the DOH, current resources are adequate to absorb these costs.[66]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

[66] Department of Health, *Senate Bill 768 2022 Agency Legislative Bill Analysis- Practice of Orthotics, Prosthetics, and Pedorthics* (July 23, 2021) (on file with the Senate Committee on Health Policy)

VIII. Statutes Affected:

This PCS substantially amends the following sections of the Florida Statutes: 381.0045, 381.0303, 381.986, 456.039, 460.406, 464.008, 464.018, 467.003, 467.009, 467.011, 467.0125, 467.205, 468.803, 483.824, 490.003, 490.005, 490.0051, 491.005, and 766.314.

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.

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Proposed Committee Substitute by the Committee on Health Policy

A bill to be entitled

An act relating to the Department of Health; amending s. 381.0045, F.S.; revising the purpose of the department's targeted outreach program for certain pregnant women; requiring the department to encourage high-risk pregnant women of unknown status to be tested for sexually transmissible diseases; requiring the department to provide specified information to pregnant women who have human immunodeficiency virus (HIV); requiring the department to link women with mental health services when available; requiring the department to educate pregnant women who have HIV on certain information; requiring the department to provide, for a specified purpose, continued oversight of newborns exposed to HIV; amending s. 381.0303, F.S.; removing the Children's Medical Services office from parties required to coordinate in the development of local emergency management plans for special needs shelters; amending s. 381.986, F.S.; authorizing the department to select samples of marijuana from medical marijuana treatment center facilities for certain testing; authorizing the department to select samples of marijuana delivery devices from medical marijuana treatment centers to determine whether such devices are safe for use; requiring medical marijuana treatment centers to recall marijuana and marijuana delivery devices, instead of just edibles, under certain circumstances; exempting the department and

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its employees from criminal provisions if they acquire, possess, test, transport, or lawfully dispose of marijuana and marijuana delivery devices under certain circumstances; amending s. 456.039, F.S.; requiring certain applicants for licensure as physicians to provide specified documentation to the department at the time of application; amending s. 460.406, F.S.; revising provisions related to chiropractic physician licensing; amending s. 464.008, F.S.; deleting a requirement that certain nursing program graduates complete a specified preparatory course; amending s. 464.018, F.S.; revising grounds for disciplinary action against licensed nurses; amending s. 467.003, F.S.; revising and defining terms; amending s. 467.009, F.S.; revising provisions related to accredited and approved midwifery programs; amending s. 467.011, F.S.; revising requirements for licensure of midwives; amending s. 467.0125, F.S.; revising requirements for licensure by endorsement of midwives; revising requirements for temporary certificates to practice midwifery in this state; amending s. 467.205, F.S.; revising provisions relating to approval, continued monitoring, probationary status, provisional approval, and approval rescission of midwifery programs; amending s. 468.803, F.S.; revising provisions related to orthotist and prosthetist registration, examination, and licensing; amending s. 483.824, F.S.; revising educational requirements for clinical laboratory

directors; amending s. 490.003, F.S.; defining the terms "doctoral degree from an American Psychological Association accredited program" and "doctoral degree in psychology"; amending ss. 490.005 and 490.0051, F.S.; revising education requirements for psychologist licensure and provisional licensure, respectively; amending s. 491.005, F.S.; revising requirements for licensure of clinical social workers, marriage and family therapists, and mental health counselors; amending s. 766.314, F.S.; deleting obsolete language and updating provisions to conform to current law; revising the frequency with which the department must submit certain reports to the Florida Birth-Related Neurological Injury Compensation Association; revising the content of such reports; authorizing the association to enforce the collection of certain assessments in circuit court under certain circumstances; requiring the association to notify the department and the applicable regulatory board of any unpaid final judgment against a physician within a specified timeframe; providing effective dates.

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

Section 1. Subsections (2) and (3) of section 381.0045, Florida Statutes, are amended to read:

381.0045 Targeted outreach for pregnant women.—

(2) It is the purpose of this section to establish a targeted outreach program for high-risk pregnant women who may

not seek proper prenatal care, who suffer from substance abuse or mental health problems, or who have acquired ~~are infected with~~ human immunodeficiency virus (HIV), and to provide these women with links to much-needed ~~much needed~~ services and information.

(3) The department shall:

(a) Conduct outreach programs through contracts with, grants to, or other working relationships with persons or entities where the target population is likely to be found.

(b) Provide outreach that is peer-based, culturally sensitive, and performed in a nonjudgmental manner.

(c) Encourage high-risk pregnant women of unknown status to be tested for HIV and other sexually transmissible diseases as specified by department rule.

(d) Educate women not receiving prenatal care as to the benefits of such care.

(e) Provide ~~HIV-infected~~ pregnant women who have HIV with information on the need for antiretroviral medication for their newborn, their medication options, and how they can access the medication after their discharge from the hospital ~~so they can make an informed decision about the use of Zidovudine (AZT)~~.

(f) Link women with substance abuse treatment and mental health services, when available, and act as a liaison with Healthy Start coalitions, children's medical services, Ryan White-funded providers, and other services of the Department of Health.

(g) Educate pregnant women who have HIV on the importance of engaging in and continuing HIV care.

(h) Provide continued oversight of any newborn exposed to

HIV to determine the newborn's final HIV status and ensure continued linkage to care if the newborn is diagnosed with HIV ~~to HIV exposed newborns~~.

Section 2. Paragraphs (a) and (c) of subsection (2) of section 381.0303, Florida Statutes, are amended to read:

381.0303 Special needs shelters.—

(2) SPECIAL NEEDS SHELTER PLAN; STAFFING; STATE AGENCY ASSISTANCE.—If funds have been appropriated to support disaster coordinator positions in county health departments:

(a) The department shall assume lead responsibility for the coordination of local medical and health care providers, the American Red Cross, and other interested parties in developing a plan for the staffing and medical management of special needs shelters and~~. The local Children's Medical Services offices shall assume lead responsibility for the coordination of local medical and health care providers, the American Red Cross, and other interested parties in developing a plan for the staffing and medical management of~~ pediatric special needs shelters. Plans must conform to the local comprehensive emergency management plan.

(c) The appropriate county health department~~, Children's Medical Services office,~~ and local emergency management agency shall jointly decide who has responsibility for medical supervision in each special needs shelter.

Section 3. Present paragraphs (e) through (h) of subsection (14) of section 381.986, Florida Statutes, are redesignated as paragraphs (f) through (i), respectively, a new paragraph (e) is added to that subsection, and paragraph (e) of subsection (8) of that section is amended, to read:

381.986 Medical use of marijuana.—

(8) MEDICAL MARIJUANA TREATMENT CENTERS.—

(e) A licensed medical marijuana treatment center shall cultivate, process, transport, and dispense marijuana for medical use. A licensed medical marijuana treatment center may not contract for services directly related to the cultivation, processing, and dispensing of marijuana or marijuana delivery devices, except that a medical marijuana treatment center licensed pursuant to subparagraph (a)1. may contract with a single entity for the cultivation, processing, transporting, and dispensing of marijuana and marijuana delivery devices. A licensed medical marijuana treatment center must, at all times, maintain compliance with the criteria demonstrated and representations made in the initial application and the criteria established in this subsection. Upon request, the department may grant a medical marijuana treatment center a variance from the representations made in the initial application. Consideration of such a request shall be based upon the individual facts and circumstances surrounding the request. A variance may not be granted unless the requesting medical marijuana treatment center can demonstrate to the department that it has a proposed alternative to the specific representation made in its application which fulfills the same or a similar purpose as the specific representation in a way that the department can reasonably determine will not be a lower standard than the specific representation in the application. A variance may not be granted from the requirements in subparagraph 2. and subparagraphs (b)1. and 2.

1. A licensed medical marijuana treatment center may

transfer ownership to an individual or entity who meets the requirements of this section. A publicly traded corporation or publicly traded company that meets the requirements of this section is not precluded from ownership of a medical marijuana treatment center. To accommodate a change in ownership:

a. The licensed medical marijuana treatment center shall notify the department in writing at least 60 days before the anticipated date of the change of ownership.

b. The individual or entity applying for initial licensure due to a change of ownership must submit an application that must be received by the department at least 60 days before the date of change of ownership.

c. Upon receipt of an application for a license, the department shall examine the application and, within 30 days after receipt, notify the applicant in writing of any apparent errors or omissions and request any additional information required.

d. Requested information omitted from an application for licensure must be filed with the department within 21 days after the department's request for omitted information or the application shall be deemed incomplete and shall be withdrawn from further consideration and the fees shall be forfeited.

e. Within 30 days after the receipt of a complete application, the department shall approve or deny the application.

2. A medical marijuana treatment center, and any individual or entity who directly or indirectly owns, controls, or holds with power to vote 5 percent or more of the voting shares of a medical marijuana treatment center, may not acquire direct or

indirect ownership or control of any voting shares or other form of ownership of any other medical marijuana treatment center.

3. A medical marijuana treatment center may not enter into any form of profit-sharing arrangement with the property owner or lessor of any of its facilities where cultivation, processing, storing, or dispensing of marijuana and marijuana delivery devices occurs.

4. All employees of a medical marijuana treatment center must be 21 years of age or older and have passed a background screening pursuant to subsection (9).

5. Each medical marijuana treatment center must adopt and enforce policies and procedures to ensure employees and volunteers receive training on the legal requirements to dispense marijuana to qualified patients.

6. When growing marijuana, a medical marijuana treatment center:

a. May use pesticides determined by the department, after consultation with the Department of Agriculture and Consumer Services, to be safely applied to plants intended for human consumption, but may not use pesticides designated as restricted-use pesticides pursuant to s. 487.042.

b. Must grow marijuana within an enclosed structure and in a room separate from any other plant.

c. Must inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state in accordance with chapter 581 and any rules adopted thereunder.

d. Must perform fumigation or treatment of plants, or remove and destroy infested or infected plants, in accordance

with chapter 581 and any rules adopted thereunder.

7. Each medical marijuana treatment center must produce and make available for purchase at least one low-THC cannabis product.

8. A medical marijuana treatment center that produces edibles must hold a permit to operate as a food establishment pursuant to chapter 500, the Florida Food Safety Act, and must comply with all the requirements for food establishments pursuant to chapter 500 and any rules adopted thereunder. Edibles may not contain more than 200 milligrams of tetrahydrocannabinol, and a single serving portion of an edible may not exceed 10 milligrams of tetrahydrocannabinol. Edibles may have a potency variance of no greater than 15 percent. Edibles may not be attractive to children; be manufactured in the shape of humans, cartoons, or animals; be manufactured in a form that bears any reasonable resemblance to products available for consumption as commercially available candy; or contain any color additives. To discourage consumption of edibles by children, the department shall determine by rule any shapes, forms, and ingredients allowed and prohibited for edibles. Medical marijuana treatment centers may not begin processing or dispensing edibles until after the effective date of the rule. The department shall also adopt sanitation rules providing the standards and requirements for the storage, display, or dispensing of edibles.

9. Within 12 months after licensure, a medical marijuana treatment center must demonstrate to the department that all of its processing facilities have passed a Food Safety Good Manufacturing Practices, such as Global Food Safety Initiative

or equivalent, inspection by a nationally accredited certifying body. A medical marijuana treatment center must immediately stop processing at any facility which fails to pass this inspection until it demonstrates to the department that such facility has met this requirement.

10. A medical marijuana treatment center that produces prerolled marijuana cigarettes may not use wrapping paper made with tobacco or hemp.

11. When processing marijuana, a medical marijuana treatment center must:

a. Process the marijuana within an enclosed structure and in a room separate from other plants or products.

b. Comply with department rules when processing marijuana with hydrocarbon solvents or other solvents or gases exhibiting potential toxicity to humans. The department shall determine by rule the requirements for medical marijuana treatment centers to use such solvents or gases exhibiting potential toxicity to humans.

c. Comply with federal and state laws and regulations and department rules for solid and liquid wastes. The department shall determine by rule procedures for the storage, handling, transportation, management, and disposal of solid and liquid waste generated during marijuana production and processing. The Department of Environmental Protection shall assist the department in developing such rules.

d. Test the processed marijuana using a medical marijuana testing laboratory before it is dispensed. Results must be verified and signed by two medical marijuana treatment center employees. Before dispensing, the medical marijuana treatment

center must determine that the test results indicate that low-THC cannabis meets the definition of low-THC cannabis, the concentration of tetrahydrocannabinol meets the potency requirements of this section, the labeling of the concentration of tetrahydrocannabinol and cannabidiol is accurate, and all marijuana is safe for human consumption and free from contaminants that are unsafe for human consumption. The department shall determine by rule which contaminants must be tested for and the maximum levels of each contaminant which are safe for human consumption. The Department of Agriculture and Consumer Services shall assist the department in developing the testing requirements for contaminants that are unsafe for human consumption in edibles. The department shall also determine by rule the procedures for the treatment of marijuana that fails to meet the testing requirements of this section, s. 381.988, or department rule. The department may select samples of marijuana ~~a random sample~~ from ~~edibles available for purchase in~~ a medical marijuana treatment center ~~dispensing~~ facility which shall be tested by the department to determine whether ~~that~~ the marijuana ~~edible~~ meets the potency requirements of this section, is safe for human consumption, and is accurately labeled with ~~the labeling of~~ the tetrahydrocannabinol and cannabidiol concentration or to verify the result of marijuana testing conducted by a marijuana testing laboratory. The department may also select samples of marijuana delivery devices from a medical marijuana treatment center to determine whether the marijuana delivery device is safe for use by qualified patients ~~is accurate~~. A medical marijuana treatment center may not require payment from the department for the sample. A medical marijuana

treatment center must recall marijuana ~~edibles~~, including all marijuana and marijuana products ~~edibles~~ made from the same batch of marijuana, that fails ~~which fail~~ to meet the potency requirements of this section, that is ~~which are~~ unsafe for human consumption, or for which the labeling of the tetrahydrocannabinol and cannabidiol concentration is inaccurate. A medical marijuana treatment center must also recall all marijuana delivery devices determined to be unsafe for use by qualified patients. The medical marijuana treatment center must retain records of all testing and samples of each homogenous batch of marijuana for at least 9 months. The medical marijuana treatment center must contract with a marijuana testing laboratory to perform audits on the medical marijuana treatment center's standard operating procedures, testing records, and samples and provide the results to the department to confirm that the marijuana or low-THC cannabis meets the requirements of this section and that the marijuana or low-THC cannabis is safe for human consumption. A medical marijuana treatment center shall reserve two processed samples from each batch and retain such samples for at least 9 months for the purpose of such audits. A medical marijuana treatment center may use a laboratory that has not been certified by the department under s. 381.988 until such time as at least one laboratory holds the required certification, but in no event later than July 1, 2018.

e. Package the marijuana in compliance with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.

f. Package the marijuana in a receptacle that has a firmly

affixed and legible label stating the following information:

(I) The marijuana or low-THC cannabis meets the requirements of sub-subparagraph d.

(II) The name of the medical marijuana treatment center from which the marijuana originates.

(III) The batch number and harvest number from which the marijuana originates and the date dispensed.

(IV) The name of the physician who issued the physician certification.

(V) The name of the patient.

(VI) The product name, if applicable, and dosage form, including concentration of tetrahydrocannabinol and cannabidiol. The product name may not contain wording commonly associated with products marketed by or to children.

(VII) The recommended dose.

(VIII) A warning that it is illegal to transfer medical marijuana to another person.

(IX) A marijuana universal symbol developed by the department.

12. The medical marijuana treatment center shall include in each package a patient package insert with information on the specific product dispensed related to:

a. Clinical pharmacology.

b. Indications and use.

c. Dosage and administration.

d. Dosage forms and strengths.

e. Contraindications.

f. Warnings and precautions.

g. Adverse reactions.

13. In addition to the packaging and labeling requirements specified in subparagraphs 11. and 12., marijuana in a form for smoking must be packaged in a sealed receptacle with a legible and prominent warning to keep away from children and a warning that states marijuana smoke contains carcinogens and may negatively affect health. Such receptacles for marijuana in a form for smoking must be plain, opaque, and white without depictions of the product or images other than the medical marijuana treatment center's department-approved logo and the marijuana universal symbol.

14. The department shall adopt rules to regulate the types, appearance, and labeling of marijuana delivery devices dispensed from a medical marijuana treatment center. The rules must require marijuana delivery devices to have an appearance consistent with medical use.

15. Each edible shall be individually sealed in plain, opaque wrapping marked only with the marijuana universal symbol. Where practical, each edible shall be marked with the marijuana universal symbol. In addition to the packaging and labeling requirements in subparagraphs 11. and 12., edible receptacles must be plain, opaque, and white without depictions of the product or images other than the medical marijuana treatment center's department-approved logo and the marijuana universal symbol. The receptacle must also include a list of all the edible's ingredients, storage instructions, an expiration date, a legible and prominent warning to keep away from children and pets, and a warning that the edible has not been produced or inspected pursuant to federal food safety laws.

16. When dispensing marijuana or a marijuana delivery

device, a medical marijuana treatment center:

a. May dispense any active, valid order for low-THC cannabis, medical cannabis and cannabis delivery devices issued pursuant to former s. 381.986, Florida Statutes 2016, which was entered into the medical marijuana use registry before July 1, 2017.

b. May not dispense more than a 70-day supply of marijuana within any 70-day period to a qualified patient or caregiver. May not dispense more than one 35-day supply of marijuana in a form for smoking within any 35-day period to a qualified patient or caregiver. A 35-day supply of marijuana in a form for smoking may not exceed 2.5 ounces unless an exception to this amount is approved by the department pursuant to paragraph (4)(f).

c. Must have the medical marijuana treatment center's employee who dispenses the marijuana or a marijuana delivery device enter into the medical marijuana use registry his or her name or unique employee identifier.

d. Must verify that the qualified patient and the caregiver, if applicable, each have an active registration in the medical marijuana use registry and an active and valid medical marijuana use registry identification card, the amount and type of marijuana dispensed matches the physician certification in the medical marijuana use registry for that qualified patient, and the physician certification has not already been filled.

e. May not dispense marijuana to a qualified patient who is younger than 18 years of age. If the qualified patient is younger than 18 years of age, marijuana may only be dispensed to the qualified patient's caregiver.

f. May not dispense or sell any other type of cannabis, alcohol, or illicit drug-related product, including pipes or wrapping papers made with tobacco or hemp, other than a marijuana delivery device required for the medical use of marijuana and which is specified in a physician certification.

g. Must, upon dispensing the marijuana or marijuana delivery device, record in the registry the date, time, quantity, and form of marijuana dispensed; the type of marijuana delivery device dispensed; and the name and medical marijuana use registry identification number of the qualified patient or caregiver to whom the marijuana delivery device was dispensed.

h. Must ensure that patient records are not visible to anyone other than the qualified patient, his or her caregiver, and authorized medical marijuana treatment center employees.

(14) EXCEPTIONS TO OTHER LAWS.—

(e) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other law, but subject to the requirements of this section, the department, including an employee of the department acting within the scope of his or her employment, may acquire, possess, test, transport, and lawfully dispose of marijuana and marijuana delivery devices as provided in this section, in s. 381.988, and by department rule.

Section 4. Subsection (1) of section 456.039, Florida Statutes, is amended to read:

456.039 Designated health care professionals; information required for licensure.—

(1) Each person who applies for initial licensure or license renewal as a physician under chapter 458, chapter 459, chapter 460, or chapter 461, except a person applying for

registration pursuant to ss. 458.345 and 459.021, must furnish the following information to the department~~,~~ at the time of application or~~, and each physician who applies for license renewal under chapter 458, chapter 459, chapter 460, or chapter 461, except a person registered pursuant to ss. 458.345 and 459.021, must,~~ in conjunction with the renewal of such license ~~and~~ under procedures adopted by the department ~~of Health,~~ and in addition to any other information that may be required from the applicant~~, furnish the following information to the Department of Health~~:

(a)1. The name of each medical school that the applicant has attended, with the dates of attendance and the date of graduation, and a description of all graduate medical education completed by the applicant, excluding any coursework taken to satisfy medical licensure continuing education requirements.

2. The name of each hospital at which the applicant has privileges.

3. The address at which the applicant will primarily conduct his or her practice.

4. Any certification that the applicant has received from a specialty board that is recognized by the board to which the applicant is applying.

5. The year that the applicant began practicing medicine.

6. Any appointment to the faculty of a medical school which the applicant currently holds and an indication as to whether the applicant has had the responsibility for graduate medical education within the most recent 10 years.

7. A description of any criminal offense of which the applicant has been found guilty, regardless of whether

adjudication of guilt was withheld, or to which the applicant has pled guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony or misdemeanor if committed in this state must be reported. If the applicant indicates that a criminal offense is under appeal and submits a copy of the notice for appeal of that criminal offense, the department must state that the criminal offense is under appeal if the criminal offense is reported in the applicant's profile. If the applicant indicates to the department that a criminal offense is under appeal, the applicant must, upon disposition of the appeal, submit to the department a copy of the final written order of disposition.

8. A description of any final disciplinary action taken within the previous 10 years against the applicant by the agency regulating the profession that the applicant is or has been licensed to practice, whether in this state or in any other jurisdiction, by a specialty board that is recognized by the American Board of Medical Specialties, the American Osteopathic Association, or a similar national organization, or by a licensed hospital, health maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home. Disciplinary action includes resignation from or nonrenewal of medical staff membership or the restriction of privileges at a licensed hospital, health maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home taken in lieu of or in settlement of a pending disciplinary case related to competence or character. If the applicant indicates that the disciplinary action is under appeal and submits a copy of the document initiating an appeal of the disciplinary action,

the department must state that the disciplinary action is under appeal if the disciplinary action is reported in the applicant's profile.

9. Relevant professional qualifications as defined by the applicable board.

(b) In addition to the information required under paragraph (a), for each applicant seeking ~~who seeks~~ licensure under chapter 458, chapter 459, or chapter 461~~, and~~ who has practiced previously in this state or in another jurisdiction or a foreign country, ~~must provide~~ the information required of licensees under those chapters pursuant to s. 456.049. An applicant for licensure under chapter 460 who has practiced previously in this state or in another jurisdiction or a foreign country must provide the same information as is required of licensees under chapter 458, pursuant to s. 456.049.

(c) For each applicant seeking licensure under chapter 458 or chapter 459, proof of payment of the assessment required under s. 766.314, if applicable.

Section 5. Subsection (1) of section 460.406, Florida Statutes, is amended to read:

460.406 Licensure by examination.—

(1) Any person desiring to be licensed as a chiropractic physician must apply to the department to take the licensure examination. There shall be an application fee set by the board not to exceed $100 which shall be nonrefundable. There shall also be an examination fee not to exceed $500 plus the actual per applicant cost to the department for purchase of portions of the examination from the National Board of Chiropractic Examiners or a similar national organization, which may be

refundable if the applicant is found ineligible to take the examination. The department shall examine each applicant whom ~~who~~ the board certifies has met all of the following criteria:

(a) Completed the application form and remitted the appropriate fee.

(b) Submitted proof satisfactory to the department that he or she is not less than 18 years of age.

(c) Submitted proof satisfactory to the department that he or she is a graduate of a chiropractic college which is accredited by or has status with the Council on Chiropractic Education or its predecessor agency. However, any applicant who is a graduate of a chiropractic college that was initially accredited by the Council on Chiropractic Education in 1995, who graduated from such college within the 4 years immediately preceding such accreditation, and who is otherwise qualified is ~~shall be~~ eligible to take the examination. An ~~No~~ application for a license to practice chiropractic medicine may not ~~shall~~ be denied solely because the applicant is a graduate of a chiropractic college that subscribes to one philosophy of chiropractic medicine as distinguished from another.

(d)1. For an applicant who has matriculated in a chiropractic college before ~~prior to~~ July 2, 1990, completed at least 2 years of residence college work, consisting of a minimum of one-half the work acceptable for a bachelor's degree granted on the basis of a 4-year period of study, in a college or university accredited by an institutional accrediting agency recognized and approved by the United States Department of Education. However, before ~~prior to~~ being certified by the board to sit for the examination, each applicant who has matriculated

in a chiropractic college after July 1, 1990, must ~~shall~~ have been granted a bachelor's degree, based upon 4 academic years of study, by a college or university accredited by an institutional ~~a regional~~ accrediting agency that ~~which~~ is a member of the Commission on Recognition of Postsecondary Accreditation.

2. Effective July 1, 2000, completed, before ~~prior to~~ matriculation in a chiropractic college, at least 3 years of residence college work, consisting of a minimum of 90 semester hours leading to a bachelor's degree in a liberal arts college or university accredited by an institutional accrediting agency recognized and approved by the United States Department of Education. However, before ~~prior to~~ being certified by the board to sit for the examination, each applicant who has matriculated in a chiropractic college after July 1, 2000, must ~~shall~~ have been granted a bachelor's degree from an institution holding accreditation for that degree from an institutional ~~a regional~~ accrediting agency that ~~which~~ is recognized by the United States Department of Education. The applicant's chiropractic degree must consist of credits earned in the chiropractic program and may not include academic credit for courses from the bachelor's degree.

(e) Successfully completed the National Board of Chiropractic Examiners certification examination in parts I, II, III, and IV, and the physiotherapy examination of the National Board of Chiropractic Examiners, with a score approved by the board.

(f) Submitted to the department a set of fingerprints on a form and under procedures specified by the department, along with payment in an amount equal to the costs incurred by the

Department of Health for the criminal background check of the applicant.

The board may require an applicant who graduated from an institution accredited by the Council on Chiropractic Education more than 10 years before the date of application to the board to take the National Board of Chiropractic Examiners Special Purposes Examination for Chiropractic, or its equivalent, as determined by the board. The board shall establish by rule a passing score.

Section 6. Subsection (4) of section 464.008, Florida Statutes, is amended to read:

464.008 Licensure by examination.—

~~(4) If an applicant who graduates from an approved program does not take the licensure examination within 6 months after graduation, he or she must enroll in and successfully complete a board-approved licensure examination preparatory course. The applicant is responsible for all costs associated with the course and may not use state or federal financial aid for such costs. The board shall by rule establish guidelines for licensure examination preparatory courses.~~

Section 7. Paragraph (e) of subsection (1) of section 464.018, Florida Statutes, is amended 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:

(e) Having been found guilty of~~, regardless of adjudication,~~ or entered a plea of nolo contendere or guilty to,

regardless of adjudication, any offense prohibited under s. 435.04 or similar statute of another jurisdiction; or having committed an act which constitutes domestic violence as defined in s. 741.28.

Section 8. Present subsections (13) and (14) of section 467.003, Florida Statutes, are redesignated as subsections (14) and (15), respectively, a new subsection (13) is added to that section, and subsections (1) and (12) of that section are amended, to read:

467.003 Definitions.—As used in this chapter, unless the context otherwise requires:

(1) "Approved midwifery program" means ~~a midwifery school or~~ a midwifery training program ~~which is~~ approved by the department pursuant to s. 467.205.

(12) "Preceptor" means a physician licensed under chapter 458 or chapter 459, a ~~licensed~~ midwife licensed under this chapter, or a certified nurse midwife licensed under chapter 464~~,~~ who has a minimum of 3 years' professional experience~~,~~ and who directs, teaches, supervises, and evaluates the learning experiences of a ~~the~~ student midwife as part of an approved midwifery program.

(13) "Prelicensure course" means a course of study, offered by an accredited midwifery program and approved by the department, which an applicant for licensure must complete before a license may be issued and which provides instruction in the laws and rules of this state and demonstrates the student's competency to practice midwifery under this chapter.

Section 9. Section 467.009, Florida Statutes, is amended to read:

467.009 Accredited and approved midwifery programs; education and training requirements.—

(1) The department shall adopt standards for accredited and approved midwifery programs which must include, but need not be limited to, standards for all of the following:

(a) ~~. The standards shall encompass~~ Clinical and classroom instruction in all aspects of prenatal, intrapartal, and postpartal care, including all of the following:

1. Obstetrics.~~;~~
2. Neonatal pediatrics.~~;~~
3. Basic sciences.~~;~~
4. Female reproductive anatomy and physiology.~~;~~
5. Behavioral sciences.~~;~~
6. Childbirth education.~~;~~
7. Community care.~~;~~
8. Epidemiology.~~;~~
9. Genetics.~~;~~
10. Embryology.~~;~~
11. Neonatology.~~;~~
12. Applied pharmacology.~~;~~
13. The medical and legal aspects of midwifery.~~;~~
14. Gynecology and women's health.~~;~~
15. Family planning.~~;~~
16. Nutrition during pregnancy and lactation.~~;~~
17. Breastfeeding.~~; and~~
18. Basic nursing skills~~; and any other instruction determined by the department and council to be necessary~~.

(b) ~~The standards shall incorporate the~~ Core competencies, incorporating those established by the American College of Nurse

Midwives and the Midwives Alliance of North America, including knowledge, skills, and professional behavior in all of the following areas:

1. Primary management, collaborative management, referral, and medical consultation.~~;~~

2. Antepartal, intrapartal, postpartal, and neonatal care.~~;~~

3. Family planning and gynecological care.~~;~~

4. Common complications.~~; and~~

5. Professional responsibilities.

(c) Noncurricular ~~The standards shall include noncurriculum~~ matters under this section, including, but not limited to, staffing and teacher qualifications.

(2) An accredited and approved midwifery program must offer ~~shall include~~ a course of study ~~and clinical training~~ for a minimum of 3 years which incorporates all of the standards, curriculum guidelines, and educational objectives provided in this section and the rules adopted hereunder.

(3) An accredited and approved midwifery program may reduce ~~If the applicant is a registered nurse or a licensed practical nurse or has previous nursing or midwifery education,~~ the required period of training ~~may be reduced~~ to the extent of the student's ~~applicant's~~ qualifications as a registered nurse or licensed practical nurse or based on prior completion of equivalent nursing or midwifery education, as determined ~~under rules adopted~~ by ~~the~~ department rule~~. In no case shall the training be reduced to a period of less than 2 years~~.

(4)~~(3)~~ An accredited and approved midwifery program may accept students who ~~To be accepted into an approved midwifery program, an applicant shall~~ have both:

(a) A high school diploma or its equivalent.

(b) Taken three college-level credits each of math and English or demonstrated competencies in communication and computation.

(5)~~(4)~~ As part of its course of study, an accredited and approved midwifery program must require clinical training that includes all of the following:

(a) ~~A student midwife, during training, shall undertake, under the supervision of a preceptor,~~ The care of 50 women in each of the prenatal, intrapartal, and postpartal periods under the supervision of a preceptor.~~, but~~ The same women need not be seen through all three periods.

(b)~~(5)~~ Observation of ~~The student midwife shall observe~~ an additional 25 women in the intrapartal period ~~before qualifying for a license~~.

(6) Clinical ~~The~~ training required under this section must include all of the following:

(a) ~~shall include~~ Training in ~~either~~ hospitals or alternative birth settings, or both.

(b) A requirement that students demonstrate competency in the assessment of and differentiation~~, with particular emphasis on learning the ability to differentiate~~ between low-risk pregnancies and high-risk pregnancies.

(7) A hospital or birthing center receiving public funds shall be required to provide student midwives access to observe labor, delivery, and postpartal procedures, provided the woman in labor has given informed consent. The Department of Health shall assist in facilitating access to hospital training for accredited and approved midwifery programs.

(8) ~~(7)~~ The Department of Education shall adopt curricular frameworks for midwifery programs offered by ~~conducted within~~ public educational institutions under ~~pursuant to~~ this section.

~~(8) Nonpublic educational institutions that conduct approved midwifery programs shall be accredited by a member of the Commission on Recognition of Postsecondary Accreditation and shall be licensed by the Commission for Independent Education.~~

Section 10. Section 467.011, Florida Statutes, is amended to read:

467.011 Licensed midwives; qualifications; examination ~~Licensure by examination~~.—

~~(1) The department shall administer an examination to test the proficiency of applicants in the core competencies required to practice midwifery as specified in s. 467.009.~~

~~(2) The department shall develop, publish, and make available to interested parties at a reasonable cost a bibliography and guide for the examination.~~

~~(3)~~ The department shall issue a license to practice midwifery to an applicant who meets all of the following criteria:

(1) Demonstrates that he or she has graduated from one of the following:

(a) An accredited and approved midwifery program.

(b) A medical or midwifery program offered in another state, jurisdiction, territory, or country whose graduation requirements were equivalent to or exceeded those required by s. 467.009 and the rules adopted thereunder at the time of graduation.

(2) Demonstrates that he or she has ~~and~~ successfully

completed a prelicensure course offered by an accredited and approved midwifery program. Students graduating from an accredited and approved midwifery program may meet this requirement by showing that the content requirements for the prelicensure course were covered as part of their course of study.

(3) Submits an application for licensure on a form approved by the department and pays the appropriate fee.

(4) Demonstrates that he or she has received a passing score on an ~~the~~ examination specified by the department~~, upon payment of the required licensure fee~~.

Section 11. Section 467.0125, Florida Statutes, is amended to read:

467.0125 Licensed midwives; qualifications; ~~Licensure by~~ endorsement; temporary certificates.—

(1) The department shall issue a license by endorsement to practice midwifery to an applicant who, upon applying to the department, demonstrates to the department that she or he meets all of the following criteria:

(a) ~~1. Holds a valid certificate or diploma from a foreign institution of medicine or midwifery or from a midwifery program offered in another state, bearing the seal of the institution or otherwise authenticated, which renders the individual eligible to practice midwifery in the country or state in which it was issued, provided the requirements therefor are deemed by the department to be substantially equivalent to, or to exceed, those established under this chapter and rules adopted under this chapter, and submits therewith a certified translation of the foreign certificate or diploma; or~~

~~2.~~ Holds an active, unencumbered ~~a valid certificate or~~ license to practice midwifery in another state, jurisdiction, or territory ~~issued by that state~~, provided the licensing requirements of that state, jurisdiction, or territory at the time the license was issued were ~~therefor are deemed by the department to be~~ substantially equivalent to~~,~~ or exceeded ~~to exceed,~~ those established under this chapter and the rules adopted hereunder ~~under this chapter~~.

(b) Has successfully completed a ~~4-month~~ prelicensure course conducted by an accredited and approved midwifery program ~~and has submitted documentation to the department of successful completion~~.

(c) Submits an application for licensure on a form approved by the department and pays the appropriate fee ~~Has successfully passed the licensed midwifery examination~~.

(2) The department may issue a temporary certificate to practice in areas of critical need to an applicant ~~any midwife who is~~ qualifying for a midwifery license ~~licensure by endorsement~~ under subsection (1) who meets all of the following criteria~~, with the following restrictions~~:

(a) Submits an application for a temporary certificate on a form approved by the department and pays the appropriate fee, which may not exceed $50 and is in addition to the fee required for licensure by endorsement under subsection (1).

(b) Specifies on the application that he or she will ~~The Department of Health shall determine the areas of critical need, and the midwife so certified shall~~ practice only in one or more of the following locations:

1. A county health department.

2. A correctional facility.

3. A United States Department of Veterans Affairs clinic.

4. A community health center funded by s. 329, s. 330, or s. 340 of the Public Health Service Act.

5. Any other agency or institution that is approved by the State Surgeon General and provides health care to meet the needs of an underserved population in this state.

(c) Will practice only ~~those specific areas,~~ under the supervision ~~auspices~~ of a physician licensed under ~~pursuant to~~ chapter 458 or chapter 459, a certified nurse midwife licensed under ~~pursuant to~~ part I of chapter 464, or a midwife licensed under this chapter~~,~~ who has a minimum of 3 years' professional experience.

(3) The department may issue a temporary certificate under this section with the following restrictions:

(a) A requirement that a temporary certificateholder practice only in areas of critical need. The State Surgeon General shall determine the areas of critical need, which ~~Such areas shall~~ include, but are not ~~be~~ limited to, health professional shortage areas designated by the United States Department of Health and Human Services.

(b) A requirement that if a temporary certificateholder's practice area ceases to be an area of critical need, within 30 days after such change the certificateholder must either:

1. Report a new practice area of critical need to the department; or

2. Voluntarily relinquish the temporary certificate.

(4) The department shall review a temporary certificateholder's practice at least annually to determine

whether the certificateholder is meeting the requirements of subsections (2) and (3) and the rules adopted thereunder. If the department determines that a certificateholder is not meeting these requirements, the department must revoke the temporary certificate.

(5) A temporary certificate issued under this section is ~~shall be~~ valid ~~only as long as an area~~ for ~~which it is issued remains an area of critical need, but no longer than~~ 2 years~~,~~ and is ~~shall~~ not ~~be~~ renewable.

~~(c) The department may administer an abbreviated oral examination to determine the midwife's competency, but no written regular examination shall be necessary.~~

~~(d) The department shall not issue a temporary certificate to any midwife who is under investigation in another state for an act which would constitute a violation of this chapter until such time as the investigation is complete, at which time the provisions of this section shall apply.~~

~~(e) The department shall review the practice under a temporary certificate at least annually to ascertain that the minimum requirements of the midwifery rules promulgated under this chapter are being met. If it is determined that the minimum requirements are not being met, the department shall immediately revoke the temporary certificate.~~

~~(f) The fee for a temporary certificate shall not exceed $50 and shall be in addition to the fee required for licensure.~~

Section 12. Section 467.205, Florida Statutes, is amended to read:

467.205 Approval of midwifery programs.—

(1) The department must approve an accredited or state-licensed public or private institution seeking to provide midwifery education and training as an approved midwifery program in this state if the institution meets all of the following criteria:

(a) Submits an application for approval on a form approved by the department.

(b) Demonstrates to the department's satisfaction that the proposed midwifery program complies with s. 467.009 and the rules adopted thereunder.

(c) For a private institution, demonstrates its accreditation by a member of the Council for Higher Education Accreditation or an accrediting agency approved by the United States Department of Education as an institutional accrediting agency for direct-entry midwifery education programs and its licensing or provisional licensing by the Commission for Independent Education ~~An organization desiring to conduct an approved program for the education of midwives shall apply to the department and submit such evidence as may be required to show that it complies with s. 467.009 and with the rules of the department. Any accredited or state-licensed institution of higher learning, public or private, may provide midwifery education and training.~~

~~(2) The department shall adopt rules regarding educational objectives, faculty qualifications, curriculum guidelines, administrative procedures, and other training requirements as are necessary to ensure that approved programs graduate midwives competent to practice under this chapter.~~

~~(3) The department shall survey each organization applying for approval. If the department is satisfied that the program~~

~~meets the requirements of s. 467.009 and rules adopted pursuant to that section, it shall approve the program~~.

(2)~~(4)~~ The department shall, at least once every 3 years, certify whether each approved midwifery program is currently compliant, and has maintained compliance, ~~complies~~ with the requirements of ~~standards developed under~~ s. 467.009 and the rules adopted thereunder.

(3)~~(5)~~ If the department finds that an approved midwifery program is not in compliance with the requirements of s. 467.009 or the rules adopted thereunder, or has lost its accreditation status, the department must provide its finding to the program in writing and ~~no longer meets the required standards, it~~ may place the program on probationary status for a specified period of time, which may not exceed 3 years ~~until such time as the standards are restored~~.

(4) If a program on probationary status does not come into compliance with the requirements of s. 467.009 or the rules adopted thereunder, or regain its accreditation status, as applicable, within the period specified by the department ~~fails to correct these conditions within a specified period of time~~, the department may rescind the program's approval.

(5) A ~~Any~~ program that has ~~having~~ its approval rescinded has ~~shall have~~ the right to reapply for approval.

(6) The department may grant provisional approval of a new program seeking accreditation status, for a period not to exceed 5 years, provided that all other requirements of this section are met.

(7) The department may rescind provisional approval of a program that fails to meet the requirements of s. 467.009, this

section, or the rules adopted thereunder, in accordance with procedures provided in subsections (3) and (4) ~~may be granted pending the licensure results of the first graduating class~~.

Section 13. Subsections (2), (3), and (4) and paragraphs (a) and (b) of subsection (5) of section 468.803, Florida Statutes, are amended to read:

468.803 License, registration, and examination requirements.—

(2) An applicant for registration, examination, or licensure must apply to the department on a form prescribed by the board for consideration of board approval. Each initial applicant shall submit ~~a set of~~ fingerprints to the department in accordance with ~~on a form and under~~ procedures specified by the department~~, along with payment in an amount equal to the costs incurred by the department~~ for state and national criminal history checks of the applicant. ~~The department shall submit the fingerprints provided by an applicant to the Department of Law Enforcement for a statewide criminal history check, and the Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check of the applicant.~~ The board shall screen the results to determine if an applicant meets licensure requirements. The board shall consider for examination, registration, or licensure each applicant whom ~~who~~ the board verifies:

(a) Has submitted the completed application and completed the fingerprinting requirements ~~fingerprint forms~~ and has paid the applicable application fee, not to exceed $500~~, and the cost of the state and national criminal history checks~~. The

application fee is ~~and cost of the criminal history checks shall be~~ nonrefundable;

(b) Is of good moral character;

(c) Is 18 years of age or older; and

(d) Has completed the appropriate educational preparation.

(3) A person seeking to attain the orthotics or prosthetics experience required for licensure in this state must be approved by the board and registered as a resident by the department. Although a registration may be held in both disciplines, for independent registrations the board may not approve a second registration until at least 1 year after the issuance of the first registration. Notwithstanding subsection (2), a person who has been approved by the board and registered by the department in one discipline may apply for registration in the second discipline without an additional state or national criminal history check during the period in which the first registration is valid. Each independent registration or dual registration is valid for 2 years after the date of issuance unless otherwise revoked by the department upon recommendation of the board. The board shall set a registration fee not to exceed $500 to be paid by the applicant. A registration may be renewed once by the department upon recommendation of the board for a period no longer than 1 year, as such renewal is defined by ~~the~~ board ~~by~~ rule. The renewal fee may not exceed one-half the current registration fee. To be considered by the board for approval of registration as a resident, the applicant must have one of the following:

(a) A Bachelor of Science or higher-level postgraduate degree in orthotics and prosthetics from an institutionally ~~a~~

~~regionally~~ accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs.

(b) A minimum of a bachelor's degree from an institutionally ~~a regionally~~ accredited college or university and a certificate in orthotics or prosthetics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board.

(c) A minimum of a bachelor's degree from an institutionally ~~a regionally~~ accredited college or university and a dual certificate in both orthotics and prosthetics from programs recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board.

(4) The department may develop and administer a state examination for an orthotist or a prosthetist license, or the board may approve the existing examination of a national standards organization. The examination must be predicated on a minimum of a baccalaureate-level education and formalized specialized training in the appropriate field. Each examination must demonstrate a minimum level of competence in basic scientific knowledge, written problem solving, and practical clinical patient management. The board shall require an examination fee not to exceed the actual cost to the board in developing, administering, and approving the examination, which fee must be paid by the applicant. To be considered by the board for examination, the applicant must have:

(a) For an examination in orthotics:

1. A Bachelor of Science or higher-level postgraduate

degree in orthotics and prosthetics from an institutionally ~~a~~ ~~regionally~~ accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs or, at a minimum, a bachelor's degree from an institutionally ~~a~~ ~~regionally~~ accredited college or university and a certificate in orthotics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board; and

2. An approved orthotics internship of 1 year of qualified experience, as determined by the board, or an orthotic residency or dual residency program recognized by the board.

(b) For an examination in prosthetics:

1. A Bachelor of Science or higher-level postgraduate degree in orthotics and prosthetics from an institutionally ~~a~~ ~~regionally~~ accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs or, at a minimum, a bachelor's degree from an institutionally ~~a~~ ~~regionally~~ accredited college or university and a certificate in prosthetics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board; and

2. An approved prosthetics internship of 1 year of qualified experience, as determined by the board, or a prosthetic residency or dual residency program recognized by the board.

(5) In addition to the requirements in subsection (2), to be licensed as:

(a) An orthotist, the applicant must pay a license fee not to exceed $500 and must have:

1. A Bachelor of Science or higher-level postgraduate degree in orthotics and prosthetics from an institutionally ~~a~~ ~~regionally~~ accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs, or a bachelor's degree from an institutionally accredited college or university and ~~with~~ a certificate in orthotics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board;

2. An approved ~~appropriate~~ internship of 1 year of qualified experience, as determined by the board, or a residency program recognized by the board;

3. Completed the mandatory courses; and

4. Passed the state orthotics examination or the board-approved orthotics examination.

(b) A prosthetist, the applicant must pay a license fee not to exceed $500 and must have:

1. A Bachelor of Science or higher-level postgraduate degree in orthotics and prosthetics from an institutionally ~~a~~ ~~regionally~~ accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs, or a bachelor's degree from an institutionally accredited college or university and ~~with~~ a certificate in prosthetics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board;

2. An internship of 1 year of qualified experience, as determined by the board, or a residency program recognized by the board;

3. Completed the mandatory courses; and

4. Passed the state prosthetics examination or the board-approved prosthetics examination.

Section 14. Section 483.824, Florida Statutes, is amended to read:

483.824 Qualifications of clinical laboratory director.—A clinical laboratory director must have 4 years of clinical laboratory experience with 2 years of experience in the specialty to be directed or be nationally board certified in the specialty to be directed, and must meet one of the following requirements:

(1) Be a physician licensed under chapter 458 or chapter 459;

(2) Hold an earned doctoral degree in a chemical, physical, or biological science from an institutionally ~~a regionally~~ accredited institution and maintain national certification requirements equal to those required by the federal Health Care Financing Administration; or

(3) For the subspecialty of oral pathology, be a physician licensed under chapter 458 or chapter 459 or a dentist licensed under chapter 466.

Section 15. Subsection (3) of section 490.003, Florida Statutes, is amended to read:

490.003 Definitions.—As used in this chapter:

(3)(a) "Doctoral degree from an American Psychological Association accredited program" means ~~Effective July 1, 1999, "doctoral-level psychological education" and "doctoral degree in psychology" mean~~ a Psy.D., an Ed.D. in psychology, or a Ph.D. in psychology from a psychology program at an educational

institution that, at the time the applicant was enrolled and graduated:

1.~~(a)~~ Had institutional accreditation from an agency recognized and approved by the United States Department of Education or was recognized as a member in good standing with Universities Canada ~~the Association of Universities and Colleges of Canada~~; and

2.~~(b)~~ Had programmatic accreditation from the American Psychological Association.

(b) "Doctoral degree in psychology" means a Psy.D., an Ed.D. in psychology, or a Ph.D. in psychology from a psychology program at an educational institution that, at the time the applicant was enrolled and graduated, had institutional accreditation from an agency recognized and approved by the United States Department of Education or was recognized as a member in good standing with Universities Canada.

Section 16. Subsection (1) of section 490.005, Florida Statutes, is amended to read:

490.005 Licensure by examination.—

(1) Any person desiring to be licensed as a psychologist shall apply to the department to take the licensure examination. The department shall license each applicant whom ~~who~~ the board certifies has met all of the following requirements:

(a) Completed the application form and remitted a nonrefundable application fee not to exceed $500 and an examination fee set by the board sufficient to cover the actual per applicant cost to the department for development, purchase, and administration of the examination, but not to exceed $500.

(b) Submitted proof satisfactory to the board that the

applicant has received:

1. A doctoral degree from an American Psychological Association accredited program ~~Doctoral-level psychological education~~; or

2. The equivalent of a doctoral degree from an American Psychological Association accredited program ~~doctoral-level psychological education, as defined in s. 490.003(3),~~ from ~~a program at~~ a school or university located outside the United States of America which was officially recognized by the government of the country in which it is located as an institution or program to train students to practice professional psychology. The applicant has the burden of establishing that this requirement has been met.

(c) Had at least 2 years or 4,000 hours of experience in the field of psychology in association with or under the supervision of a licensed psychologist meeting the academic and experience requirements of this chapter or the equivalent as determined by the board. The experience requirement may be met by work performed on or off the premises of the supervising psychologist if the off-premises work is not the independent, private practice rendering of psychological services that does not have a psychologist as a member of the group actually rendering psychological services on the premises.

(d) Passed the examination. However, an applicant who has obtained a passing score, as established by the board by rule, on the psychology licensure examination designated by the board as the national licensure examination need only pass the Florida law and rules portion of the examination.

Section 17. Subsection (1) of section 490.0051, Florida

Statutes, is amended to read:

490.0051 Provisional licensure; requirements.—

(1) The department shall issue a provisional psychology license to each applicant whom ~~who~~ the board certifies has met all of the following criteria:

(a) Completed the application form and remitted a nonrefundable application fee not to exceed $250, as set by board rule.

(b) Earned a doctoral degree from an American Psychological Association accredited program ~~in psychology as defined in s. 490.003(3)~~.

(c) Met any additional requirements established by board rule.

Section 18. Effective upon this act becoming a law, subsections (1), (3), and (4) of section 491.005, Florida Statutes, are amended to read:

491.005 Licensure by examination.—

(1) CLINICAL SOCIAL WORK.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, ~~plus the actual per applicant cost to the department for purchase of the examination from the American Association of State Social Worker's Boards or a similar national organization,~~ the department shall issue a license as a clinical social worker to an applicant whom ~~who~~ the board certifies has met all of the following criteria:

(a) ~~Has~~ Submitted an application and paid the appropriate fee.

(b)1. ~~Has~~ Received a doctoral degree in social work from a graduate school of social work which at the time the applicant

graduated was accredited by an accrediting agency recognized by the United States Department of Education or ~~has~~ received a master's degree in social work from a graduate school of social work which at the time the applicant graduated:

a. Was accredited by the Council on Social Work Education;

b. Was accredited by the Canadian Association for ~~of Schools of~~ Social Work Education; or

c. Has been determined to have been a program equivalent to programs approved by the Council on Social Work Education by the Foreign Equivalency Determination Service of the Council on Social Work Education. An applicant who graduated from a program at a university or college outside of the United States or Canada must present documentation of the equivalency determination from the council in order to qualify.

2. The applicant's graduate program ~~must have~~ emphasized direct clinical patient or client health care services, including, but not limited to, coursework in clinical social work, psychiatric social work, medical social work, social casework, psychotherapy, or group therapy. The applicant's graduate program must have included all of the following coursework:

a. A supervised field placement which was part of the applicant's advanced concentration in direct practice, during which the applicant provided clinical services directly to clients.

b. Completion of 24 semester hours or 32 quarter hours in theory of human behavior and practice methods as courses in clinically oriented services, including a minimum of one course in psychopathology, and no more than one course in research,

taken in a school of social work accredited or approved pursuant to subparagraph 1.

3. If the course title which appears on the applicant's transcript does not clearly identify the content of the coursework, the applicant provided ~~shall be required to provide~~ additional documentation, including, but not limited to, a syllabus or catalog description published for the course.

(c) Completed ~~Has had~~ at least 2 years of clinical social work experience, which took place subsequent to completion of a graduate degree in social work at an institution meeting the accreditation requirements of this section, under the supervision of a licensed clinical social worker or the equivalent who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy clinical experience requirements must register pursuant to s. 491.0045 before commencing practice. If the applicant's graduate program was not a program which emphasized direct clinical patient or client health care services as described in subparagraph (b)2., the supervised experience requirement must take place after the applicant has completed a minimum of 15 semester hours or 22 quarter hours of the coursework required. A doctoral internship may be applied toward the clinical social work experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting.

(d) ~~Has~~ Passed a theory and practice examination designated by board rule ~~provided by the department for this purpose~~.

(e) ~~Has~~ Demonstrated, in a manner designated by board rule ~~of the board~~, knowledge of the laws and rules governing the

practice of clinical social work, marriage and family therapy, and mental health counseling.

(3) MARRIAGE AND FAMILY THERAPY.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, ~~plus the actual cost of the purchase of the examination from the Association of Marital and Family Therapy Regulatory Board, or similar national organization,~~ the department shall issue a license as a marriage and family therapist to an applicant whom ~~who~~ the board certifies has met all of the following criteria:

(a) ~~Has~~ Submitted an application and paid the appropriate fee.

(b) 1. Attained one of the following:

a. A minimum of a master's degree in marriage and family therapy from a program accredited by the Commission on Accreditation for Marriage and Family Therapy Education.

b. A minimum of a master's degree with a major emphasis in marriage and family therapy or a closely related field from a university program accredited by the Council on Accreditation of Counseling and Related Educational Programs and graduate courses approved by the board.

c. ~~Has~~ A minimum of a master's degree with an ~~major~~ emphasis in marriage and family therapy or a closely related field, with a degree conferred before September 1, 2027, from an institutionally accredited college or university ~~from a program accredited by the Commission on Accreditation for Marriage and Family Therapy Education or from a Florida university program accredited by the Council for Accreditation of Counseling and Related Educational Programs~~ and graduate courses approved by

the board ~~of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling~~.

2. If the course title that appears on the applicant's transcript does not clearly identify the content of the coursework, the applicant provided ~~shall provide~~ additional documentation, including, but not limited to, a syllabus or catalog description published for the course. The required master's degree must have been received in an institution of higher education that, at the time the applicant graduated, was fully accredited by an institutional ~~a regional~~ accrediting body recognized by the Council for Higher Education Accreditation or its successor organization ~~Commission on Recognition of Postsecondary Accreditation~~ or was ~~publicly recognized as~~ a member in good standing with Universities Canada ~~the Association of Universities and Colleges of Canada~~, or an institution of higher education located outside the United States and Canada which, at the time the applicant was enrolled and at the time the applicant graduated, maintained a standard of training substantially equivalent to the standards of training of those institutions in the United States which are accredited by an institutional ~~a regional~~ accrediting body recognized by the Council for Higher Education Accreditation or its successor organization ~~Commission on Recognition of Postsecondary Accreditation~~. Such foreign education and training must have been received in an institution or program of higher education officially recognized by the government of the country in which it is located as an institution or program to train students to practice as professional marriage and family therapists or psychotherapists. The applicant has the burden of establishing

that the requirements of this provision have been met, and the board shall require documentation, such as an evaluation by a foreign equivalency determination service, as evidence that the applicant's graduate degree program and education were equivalent to an accredited program in this country. An applicant with a master's degree from a program that did not emphasize marriage and family therapy may complete the coursework requirement in a training institution fully accredited by the Commission on Accreditation for Marriage and Family Therapy Education recognized by the United States Department of Education.

(c) Completed ~~Has had~~ at least 2 years of clinical experience during which 50 percent of the applicant's clients were receiving marriage and family therapy services, which must be at the post-master's level under the supervision of a licensed marriage and family therapist with at least 5 years of experience, or the equivalent, who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy the clinical experience requirements must register pursuant to s. 491.0045 before commencing practice. If a graduate has a master's degree with a major emphasis in marriage and family therapy or a closely related field which did not include all of the coursework required by paragraph (b), credit for the post-master's level clinical experience may not commence until the applicant has completed a minimum of 10 of the courses required by paragraph (b), as determined by the board, and at least 6 semester hours or 9 quarter hours of the course credits must have been completed in the area of marriage and family systems, theories, or techniques. Within the 2 years

of required experience, the applicant shall provide direct individual, group, or family therapy and counseling to cases including those involving unmarried dyads, married couples, separating and divorcing couples, and family groups that include children. A doctoral internship may be applied toward the clinical experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting.

(d) ~~Has~~ Passed a theory and practice examination designated by board rule ~~provided by the department~~.

(e) ~~Has~~ Demonstrated, in a manner designated by board rule, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.

For the purposes of dual licensure, the department shall license as a marriage and family therapist any person who meets the requirements of s. 491.0057. Fees for dual licensure may not exceed those stated in this subsection.

(4) MENTAL HEALTH COUNSELING.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, ~~plus the actual per applicant cost of purchase of the examination from the National Board for Certified Counselors or its successor organization,~~ the department shall issue a license as a mental health counselor to an applicant whom ~~who~~ the board certifies has met all of the following criteria:

(a) ~~Has~~ Submitted an application and paid the appropriate fee.

(b)1. Attained ~~Has~~ a minimum of an earned master's degree

from a mental health counseling program accredited by the Council for the Accreditation of Counseling and Related Educational Programs which consists of at least 60 semester hours or 80 quarter hours of clinical and didactic instruction, including a course in human sexuality and a course in substance abuse. If the master's degree is earned from a program related to the practice of mental health counseling which is not accredited by the Council for the Accreditation of Counseling and Related Educational Programs, then the coursework and practicum, internship, or fieldwork must consist of at least 60 semester hours or 80 quarter hours and meet all of the following requirements:

a. Thirty-three semester hours or 44 quarter hours of graduate coursework, which must include a minimum of 3 semester hours or 4 quarter hours of graduate-level coursework in each of the following 11 content areas: counseling theories and practice; human growth and development; diagnosis and treatment of psychopathology; human sexuality; group theories and practice; individual evaluation and assessment; career and lifestyle assessment; research and program evaluation; social and cultural foundations; substance abuse; and legal, ethical, and professional standards issues in the practice of mental health counseling. Courses in research, thesis or dissertation work, practicums, internships, or fieldwork may not be applied toward this requirement.

b. A minimum of 3 semester hours or 4 quarter hours of graduate-level coursework addressing diagnostic processes, including differential diagnosis and the use of the current diagnostic tools, such as the current edition of the American

Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders. The graduate program must have emphasized the common core curricular experience.

c. The equivalent, as determined by the board, of at least 700 hours of university-sponsored supervised clinical practicum, internship, or field experience that includes at least 280 hours of direct client services, as required in the accrediting standards of the Council for Accreditation of Counseling and Related Educational Programs for mental health counseling programs. This experience may not be used to satisfy the post-master's clinical experience requirement.

2. ~~Has~~ Provided additional documentation if a course title that appears on the applicant's transcript does not clearly identify the content of the coursework. The documentation must include, but is not limited to, a syllabus or catalog description published for the course.

Education and training in mental health counseling must have been received in an institution of higher education that, at the time the applicant graduated, was fully accredited by an institutional ~~a regional~~ accrediting body recognized by the Council for Higher Education Accreditation or its successor organization or was ~~publicly recognized as~~ a member in good standing with Universities Canada ~~the Association of Universities and Colleges of Canada~~, or an institution of higher education located outside the United States and Canada which, at the time the applicant was enrolled and at the time the applicant graduated, maintained a standard of training substantially equivalent to the standards of training of those

institutions in the United States which are accredited by an institutional ~~a regional~~ accrediting body recognized by the Council for Higher Education Accreditation or its successor organization. Such foreign education and training must have been received in an institution or program of higher education officially recognized by the government of the country in which it is located as an institution or program to train students to practice as mental health counselors. The applicant has the burden of establishing that the requirements of this provision have been met, and the board shall require documentation, such as an evaluation by a foreign equivalency determination service, as evidence that the applicant's graduate degree program and education were equivalent to an accredited program in this country. Beginning July 1, 2025, an applicant must have a master's degree from a program that is accredited by the Council for Accreditation of Counseling and Related Educational Programs, the Masters in Psychology and Counseling Accreditation Council, or an equivalent accrediting body which consists of at least 60 semester hours or 80 quarter hours to apply for licensure under this paragraph.

(c) Completed ~~Has had~~ at least 2 years of clinical experience in mental health counseling, which must be at the post-master's level under the supervision of a licensed mental health counselor or the equivalent who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy the clinical experience requirements must register pursuant to s. 491.0045 before commencing practice. If a graduate has a master's degree with a major related to the practice of mental health counseling which

did not include all the coursework required under sub-subparagraphs (b)1.a. and b., credit for the post-master's level clinical experience may not commence until the applicant has completed a minimum of seven of the courses required under sub-subparagraphs (b)1.a. and b., as determined by the board, one of which must be a course in psychopathology or abnormal psychology. A doctoral internship may be applied toward the clinical experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting.

(d) ~~Has~~ Passed a theory and practice examination designated by board rule ~~provided by the department for this purpose~~.

(e) ~~Has~~ Demonstrated, in a manner designated by board rule, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.

Section 19. Subsection (6) and paragraph (c) of subsection (9) of section 766.314, Florida Statutes, are amended to read:

766.314 Assessments; plan of operation.—

(6)(a) The association shall make all assessments required by this section, except initial assessments of physicians licensed ~~on or after October 1, 1988, which assessments will be made~~ by the Department of Health ~~Business and Professional Regulation~~, and except assessments of casualty insurers pursuant to subparagraph (5)(c)1., which assessments will be made by the Office of Insurance Regulation. ~~Beginning October 1, 1989, for any physician licensed between October 1 and December 31 of any year, the Department of Business and Professional Regulation shall make the initial assessment plus the assessment for the~~

~~following calendar year.~~ The Department of Health ~~Business and Professional Regulation~~ shall provide the association, in an electronic format, with a monthly report ~~such frequency as determined to be necessary, a listing, in a computer-readable form,~~ of the names and license numbers ~~addresses~~ of all physicians licensed under chapter 458 or chapter 459.

(b)1. The association may enforce collection of assessments required to be paid pursuant to ss. 766.301-766.316 by suit filed in county court, or in circuit court if the amount due could exceed the jurisdictional limits of county court. The association is ~~shall be~~ entitled to an award of attorney ~~attorney's~~ fees, costs, and interest upon the entry of a judgment against a physician for failure to pay such assessment, with such interest accruing until paid. Notwithstanding ~~the provisions of~~ chapters 47 and 48, the association may file such suit in either Leon County or the county of the residence of the defendant. The association shall notify the Department of Health and the applicable board of any unpaid final judgment against a physician within 7 days after the entry of final judgment.

2. The Department of Health ~~Business and Professional Regulation~~, upon notification by the association that an assessment has not been paid and that there is an unsatisfied judgment against a physician, shall refuse to ~~not~~ renew any license issued to ~~practice for~~ such physician under ~~issued pursuant to~~ chapter 458 or chapter 459 until the association notifies the Department of Health that ~~such time as~~ the judgment is satisfied in full.

(c) The Agency for Health Care Administration shall, upon notification by the association that an assessment has not been

timely paid, enforce collection of such assessments required to be paid by hospitals pursuant to ss. 766.301-766.316. Failure of a hospital to pay such assessment is grounds for disciplinary action pursuant to s. 395.1065 notwithstanding any ~~provision of~~ law to the contrary.

(9)

(c) If ~~In the event~~ the total of all current estimates equals 80 percent of the funds on hand and the funds that will become available to the association within the next 12 months from all sources described in subsections (4) and (5) and paragraph (7)(a), the association may ~~shall~~ not accept any new claims without express authority from the Legislature. Nothing in this section precludes ~~herein shall preclude~~ the association from accepting any claim if the injury occurred 18 months or more before ~~prior to~~ the effective date of this suspension. Within 30 days after ~~of~~ the effective date of this suspension, the association shall notify the Governor, the Speaker of the House of Representatives, the President of the Senate, the Office of Insurance Regulation, the Agency for Health Care Administration, and the Department of Health~~, and the Department of Business and Professional Regulation~~ of this suspension.

Section 20. Except as otherwise expressly provided in this act and except for this section, which shall take effect upon this act becoming a law, this act shall take effect July 1, 2022.

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 768
INTRODUCER:	Health Policy Committee and Senator Rodriguez
SUBJECT:	Department of Health
DATE:	January 26, 2022
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 768 addresses numerous health care-related issues regulated by the Department of Health (DOH). The bill:

- Updates the "Targeted Outreach for Pregnant Women Act of 1998;"
- Amends s. 381.0303, F.S., to specify that for pediatric special needs shelters, the DOH is the lead agency to coordinate local medical and health care providers for the staffing and management of the shelters and is the decision-making authority for determining the medical supervision in each special needs shelter;
- Allows the DOH to collect samples of marijuana and marijuana delivery devices, in general, from a medical marijuana treatment center (MMTC) for specified testing, rather than only samples of edibles;
- Expands MMTC recall requirements to all marijuana products and delivery devices, rather than only edibles;
- Provides an exception from criminal laws for DOH employees to acquire, possess, test, transport, and lawfully dispose of marijuana and marijuana delivery devices;
- Amends statutes regulating several types of health care professions, including allopathic and osteopathic physicians, nurses, midwives, psychologists, orthotists, prosthetists, clinical lab personnel, chiropractors, mental health counselors, clinical social workers, and marriage and family therapists;
- Amends ss. 460.406, 468.803, 483.824, 490.005, F.S., to delete references to the term "regional" and replace it with the term "institutional" to conform with the U.S. Department

of Education accreditation nomenclature for approving health care-related educational institutions; and

- Amends s. 766.314, F.S., authorizing the Florida Birth-Related Neurological Injury Compensation Association (NICA) to collect and enforce physician assessments in circuit court, if necessary, and requires the NICA to notify the DOH and the appropriate board of any unpaid final judgments against a physician within a specific timeframe.

The bill provides an effective date of July 1, 2022, except as otherwise provided.

II. Present Situation:

Targeted Outreach for Pregnant Women

The Targeted Outreach for Pregnant Women Act (TOPWA) was enacted by the Florida Legislature in 1998. The TOPWA program is designed to establish targeted outreach to high-risk pregnant women who may not be receiving proper prenatal care, who suffer from substance abuse problems, or who may be infected with the human immunodeficiency virus (HIV). The goal of the program is to provide these high-risk pregnant women with referrals for information and services.

In 2019, there were 453 HIV-exposed births in Florida. While there were no known perinatal HIV transmissions in 2019, the DOH does not have a definitive status on roughly 25 percent of the 453 HIV-exposed births.

Without proper care for both mother and newborn, each of these births risks vertical transmission. The TOPWA supports outreach programs aimed at preventing vertical HIV transmission and other health issues by linking high-risk pregnant women with services that can help them have healthier pregnancies and deliveries and can aid them in ensuring their newborn gets a healthy start.[1]

Many of the women targeted by TOPWA programs may not otherwise receive prenatal care or know their HIV status. In 2021, there were eight TOPWA programs in Florida.[2] The TOPWA programs, which are funded through General Revenue (GR) dollars and grant funds from the federal Centers for Disease Control and Prevention (CDC), provided services to 7,703 women from January 2016 to July 2020. Women living with HIV made up just under 10 percent of TOPWA program enrollments.[3]

If a pregnant woman tests positive for HIV, medical interventions and prevention, such as the following, can greatly reduce her risk of transmitting the virus to her baby during childbirth:

- Antiretroviral medication to the mother;

[1] Section 381.0045(2), F.S.
[2] Florida Department of Health, Diseases and Conditions, AIDS, Prevention, *TOWPA Map*, available at http://www.floridahealth.gov/diseases-and-conditions/aids/prevention/_documents/topwa/TOPWAProviderMap2021.pdf (last visited Nov. 2, 2021).
[3] Department of Health, *Senate Bill 768 2022 Agency Legislative Bill Analysis* (July 23, 2021) (on file with the Senate Committee on Health Policy).

- Delivery by caesarian section;
- Avoiding breastfeeding; and
- Antiretroviral medication to the newborn.

The DOH has developed a GR-funded program, Baby Rxpress, which provides a six-week course of ARV medication to HIV-exposed newborns at no cost to the mother. In 2019, this program filled 304 prescriptions to 264 HIV-exposed newborns at a cost of $10,801.96, or $40.92 per baby.[4]

Special Needs Shelter Program

Section 381.0303, F.S., was enacted in 2000 to create the Special Needs Shelter Program to provide for the operation and closure of special needs shelters (shelters). The shelters are designed for persons with a physical impairment, mental impairment, cognitive impairment, or sensory disability who, during periods of evacuation or emergency, require sheltering assistance to have a safe and secure place to go during an emergency or disaster. In s. 381.0303(1), F.S., the Legislature designates the DOH, through its county health departments, as the lead agency for coordinating and recruiting health care practitioners to staff the shelters during emergencies or disasters.[5]

In s. 381.0303(2), F.S., the Legislature delineates the responsibilities for the shelters as follows:

- The DOH has the lead responsibility for coordinating local medical and health care providers, the American Red Cross, and other interested parties and in developing a plan for the staffing and medical management of the shelters;
- The DOH's local Children's Medical Services (CMS) offices have responsible for the coordination of local medical and health care providers, the American Red Cross, and other interested parties, and for developing a plan for the staffing and medical management of the shelters;
- The county health departments, in conjunction with the local emergency management agencies, have lead responsibility for the coordination and recruitment of the health care practitioners to staff local shelters;
- Local emergency management agencies have responsibility for the designation and operation of the shelters during an emergency or disaster and the closure of the facilities following the event; and
- The local county health department, local CMS office, and local emergency management agency are jointly responsible for deciding who is responsible for the medical supervision in each shelter.[6]

According to the DOH, this shared lead responsibility between the DOH, through its local county health departments, and CMS, through its local offices was, in large part, due to the large local CMS workforce of health care practitioners with specialized training and experience in the provision of services for children with special needs. Through a series of program and organizational changes at the DOH, toward a more effective operation and cost savings, the CMS

[4] *Id.*
[5] Section 381.0303(1), F.S.
[6] Section 381.0303(2), F.S.

workforce has been reduced by more than 70 percent since 2018. Due to this change in CMS workforce, the DOH advises that CMS is unable to fulfill its responsibilities under s. 381.3030, F.S.[7]

Medical Marijuana

Amendment 2

On November 4, 2016, Amendment 2 was approved by the statewide electorate and established Article X, section 29 of the Florida Constitution. This section of the constitution became effective on January 3, 2017, and created several exemptions from criminal and civil liability for:

- Qualifying patients who medically use marijuana in compliance with the amendment;
- Physicians, solely for issuing physician certifications with reasonable care and in compliance with the amendment; and
- MMTCs and their agents and employees for actions or conduct under the amendment and in compliance with rules promulgated by the DOH.

Implementation

Subsequently, the Legislature passed SB 8-A in Special Session A of 2017.[8] The bill revised the Compassionate Medical Cannabis Act of 2014[9] in s. 381.986, F.S., to implement Article X, section 29 of the State Constitution.

Testing Marijuana and Exemption from Criminal Offenses

Pursuant to s. 381.986(8)(11)d., F.S., the DOH may select a random sample from edibles available for purchase in an MMTC's DOH-approved dispensing facility for testing. The DOH must test the random samples for potency, safety for human consumption, and accuracy of Tetrahydrocannabinol (THC) and Cannabidiol (CBD) labeling.

MMTCs are required to recall all edibles, including all edibles made from the same batch of marijuana, which fail to meet potency requirements, which are unsafe for human consumption, or for which the labeling of the THC and CBD concentration is inaccurate.

Presently, the DOH and its employees are not expressly exempt from criminal prosecution under ss. 893.13, 893.135, and 893.147, F.S., when acquiring, possessing, testing, transporting, and disposing of marijuana and delivery devices under certain circumstances when acting within the scope of their duties.[10]

[7] Department of Health, 2022 *Senate Bill 768 Fiscal Analysis* (July 23, 2021) (on file with the Senate Committee on Health Policy).
[8] Chapter 2017-232, Laws of Fla.
[9] Chapter 2014-157, Laws of Fla.
[10] Department of Health, *Senate Bill 1568 Fiscal Analysis* (Mar. 12, 2021) (on file with the Senate Committee on Health Policy).

Additional Disclosure for Physician Licensure and Renewal

Section 456,039, F.S., requires each physician,[11] chiropractor, and podiatrist seeking initial licensure, or license renewal, in Florida, in addition to normal required licensure information, to submit the following to the DOH:

- Name of each medical school attended, including dates of attendance, graduation, and a description of all graduate medical education completed, except continuing education (CE) requirements;
- Name of each hospital where the applicant has privileges;
- Primary practice address;
- Specialty board certifications, if any;
- Date applicant began practicing medicine;
- Medical school faculty appointments currently held and whether the applicant has had the responsibility for graduate medical education within the past 10 years;
- Any criminal offenses, felony or misdemeanor, of which the applicant has been found guilty, regardless of whether adjudication was withheld, or to which the applicant has pled guilty or nolo contendere, including those committed in another jurisdiction which would constitute a felony or misdemeanor in Florida;
- Any final professional disciplinary action within the previous 10 years in Florida or any other jurisdiction, or by any specialty board, similar national organization, licensed hospital, health maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home;
- Any claim or action for damages in Florida, in another jurisdiction or in a foreign country, for personal injury alleged to have been caused by error, omission, or negligence in the performance of licensee's professional services; and
- Fingerprints.

Any change in the above information must be updated within 45 days after the occurrence of an event or change in status that is required to be reported. The DOH compiles this information and submits it to the practitioner profile of the applicant.[12]

Educational Institution Accreditation

Each profession includes the requirement of completion of a program from a "regionally accredited" institution. The U.S. Department of Education issued a letter of guidance on February 26, 2020, specifying that final regulations published that year omit references to "regional" and "national" accreditation. The letter specifies, "Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded." Provisions implemented in 34 C.F.R. § 602.32(d), relating to the recognition of accrediting agencies, will become effective January 1, 2021.[13]

[11] *See* ss. 458.345 and 459 021, F.S., Registered medical and osteopathic, residents are exempt from the requirement of 456.039, F.S.
[12] Section 456.041, F.S.
[13] U.S. Department of Education, Office of the Under Secretary, *Final Accreditation and State Authorization Regulations,* February 26, 2020, (on file with the Senate Committee on Health Policy).

Nursing

Licensure by Examination

Part I of ch. 464, F.S., the Nurse Practice Act, governs the licensure and regulation of nurses in Florida. Nurses are licensed by the DOH[14] and are regulated by the Board of Nursing (BON).[15] Currently, a person desiring to practice nursing in the state of in Florida must obtain a Florida license by examination, endorsement[16]or have a multistate license.[17]

Applicants for licensure by examination as a registered nurse (RN) or licensed practical nurse (LPN) must, among other requirements:

- Graduate from an approved program or its equivalent as determined by the BON.[18]
- Submit an application to the DOH;
- Pay a fee;
- Submit information for a criminal background check;[19] and
- Pass the National Council Licensure Examination (NCLEX).[20]

Any applicant who fails the NCLEX three consecutive times, regardless of the jurisdiction where the examination is taken, must complete a board-approved remedial course before the applicant will be approved to re-take the NCLEX. After taking the remedial course, the applicant may be approved to retake the examination up to three additional times before the applicant must retake remediation. The applicant must apply for reexamination within 6 months after completion of remediation.[21]

If an applicant who graduates from an approved program does not take the licensure examination within six months after graduation, he or she must enroll in and successfully complete a BON-approved licensure examination preparatory course. The applicant is responsible for all costs associated with the course and may not use state or federal financial aid for such costs. The BON is directed to, by rule, establish guidelines for licensure examination preparatory courses.[22]

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[14] Section 464.008, F.S.

[15] The BON is composed of 13 members appointed by the Governor and confirmed by the Senate who serve four-year terms. All members must be residents of the state. Seven members must be registered nurses who are representative of the diverse areas of practice within the nursing profession. Three members must be licensed practical nurses and three members must be laypersons. At least one member of the board must be 60 years of age or older. *See* Section 464.004, F.S.

[16] Section 464.009, F.S., provides the requirements for licensure by endorsement, and requires an applicant to submit an application and fee, passing a criminal background screening, and 1) Hold a valid license to practice professional or practical nursing in another state or territory of the United States which, when issued, met or exceeded those in Florida at that time; 2) Meet the requirements for licensure in Florida and having successfully completed an examination in another state which is substantially equivalent to the examination in Florida; or 3) Have actively practiced nursing in another state, jurisdiction, or territory of the United States for two of the preceding three years without having his or her license acted against by the licensing authority of any jurisdiction.

[17] Section 464.0095, F.S., A "Multistate license" is a license to practice as a registered nurse (RN) or a licensed practical/vocational nurse (LPN/VN) issued by another Nurse Licensure Compact state's licensing board which authorizes the licensed nurse to practice in all party states under a multistate licensure privilege.

[18] Section 464.008(1)(c), F.S.

[19] Section 464.008(1)(b), F.S.

[20] Section 464.008(2), F.S.

[21] Section 464.008(3), F.S.

[22] Section 464.008 (4), F.S.

Disciplinary Actions

Once an individual is licensed to practice nursing in Florida, he or she has a professional responsibility to practice nursing at a minimum level of competency to ensure the safety of the public. The safe practice of nursing also requires that a nurse not commit any of the hundreds of acts that would constitute grounds for the denial of a license, disciplinary action, or even criminal prosecution, as set out under ss. 456.072(2), 464.0095, and 464.018, F.S.

Section 464.018(1)(c)-(e), F.S., as currently written, uses the modifying phrase, "regardless of adjudication;" but where the phrase is placed in subsections (c) and (d) verses subsection (e) has a significant impact on its application in law.

In s. 464.018(1)(e), F.S., the placement of the phrase, "regardless of adjudication," only applies to licensees "having been found guilty of," offenses listed in s. 435.04, F.S., or an offense of domestic violence under s. 741.20, F.S. "Regardless of adjudication" does not apply to those "entering a plea of guilty or nolo contendere to" listed offenses. This interpretation could result in those licensees entering a plea of nolo contendere or guilty and not being found guilty (i.e. adjudication is withheld), therefore not being subject to professional disciplinary action.

Midwifery

"Midwifery" is the practice of supervising the conduct of a normal labor and childbirth, with the informed consent of the parent; the practice of advising the parents as to the progress of the childbirth; and the practice of rendering prenatal and postpartal care.[23]

Chapter 467, F.S., is the Midwifery Practice Act. Any person who seeks to practice midwifery in Florida must be at least 21 years of age and be:

- Licensed under s. 464.012, F.S., as an Advanced Practice Registered Nurse (APRN) nurse midwife; or
- Licensed as a midwife under ch. 467, F.S.

Section 467.009, F.S., governs midwifery programs and education and training requirements which are a minimum of three years in an approved program. An applicant must have:

- A high school diploma or the equivalent.
- Taken at least three college-level credits such as math and English.

It is unclear under current law whether both a high school diploma and three college level credits are required for admission, or whether one or the other will satisfy the admission requirement.

Section 467.009, F.S., also requires a student midwife, during training, to undertake the care of 50 women in each of the prenatal, intrapartal, and postpartal periods, and observe an additional 25 women in the intrapartal period under the supervision of a preceptor, but the same women need not be seen through all periods. Prenatal, intrapartal, and postpartal periods are not defined, and the statute is unclear as to whether this requires 150 patients prenatal, intrapartal, and postpartal periods, or just 50 patients in any one of the three phases of pregnancy and delivery.

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

The statute is also unclear as to whether the two references to intrapartal care and observation may be the same patient or require different patient contacts.

Section 467.009, F.S., uses the terms, "applicant" and "student midwife" interchangeably, which is inaccurate. These sections frame standards for admission, education, and clinical training in the context of student requirements. Preceptors direct, teach, supervise, and evaluate the learning experiences of the student midwife and may be physicians, licensed midwives, or a certified nurse midwife, who have a minimum of three years professional experience.[24] Persons with previous midwifery education, RNs, and LPNs may have a reduced training period, but in no case less than two years.

Chapter 467.009, F.S., does not include any provisions explicitly allowing a new midwifery program to be provisionally approved nor does it provide guidance to schools regarding the circumstances under which the DOH may rescind the approval of program.

Section 467.011, F.S., licensure by examination, requires the DOH to:
- Administer the licensure examination to test the proficiency of applicants in the core competencies required to practice midwifery as specified in s. 467.009, F.S.;
- Develop, publish, and make available to interested parties at a reasonable cost a bibliography and guide for the examination; and
- Issue a license to practice midwifery to an applicant who has graduated from an approved midwifery program, successfully completed the examination, and paid a licensure fee.

The DOH no longer administers midwifery examinations, and, pursuant to s. 456.017(c), F.S., the DOH has approved the use of a national examination for midwives seeking to become licensed.[25]

In lieu of examination, an applicant may apply for a license by endorsement based on verification that the applicant holds a current valid license to practice midwifery in another jurisdiction that has equivalent or more stringent licensure requirements than those in Florida.[26]

A midwife may accept and provide care only for those women who are expected to have a normal pregnancy, labor, and delivery and must ensure that:
- The patient has signed an informed consent form; and
- If the patient is delivering at home, the home is safe and hygienic.

The statute does not define "normal delivery," "low risk pregnancy," or "high risk pregnancy."

A midwife licensed under ch. 467, F.S., may administer the following:
- Prophylactic ophthalmic medication;
- Oxygen;
- Postpartum oxytocin;

[24] Section 467.003(12), F.S.
[25] Department of Health, *Senate Bill 678 2022 Agency Legislative Bill Analysis -Midwifery* (July 23, 2021) (on file with the Senate Committee on Health Policy).
[26] Section 467.0125, F.S.

- Vitamin K;
- Rho immune globulin (human); and
- Local anesthetic and other medications prescribed by a practitioner.[27]

A midwife's care of mothers and infants throughout the prenatal, intrapartal, and postpartal periods must be in conformity with DOH rules and the health laws of Florida. The midwife must:

- 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;
- Instruct the patient and family regarding the preparation of the environment and ensure availability of equipment and supplies needed for delivery and infant care;
- Instruct the patient in the hygiene of pregnancy and nutrition as it relates to prenatal care;
- Maintain equipment and supplies;
- Determine the progress of labor and, when birth is imminent, be immediately available until delivery is accomplished, and must:
  - Maintain a safe and hygienic environment;
  - Monitor the progress of labor and the status of the fetus;
  - Recognize early signs of distress or complications; and
  - Enact the written emergency plan when indicated;
- Remain with the postpartal mother until the conditions of the mother and the neonate are stabilized; and
- Instill into each eye of the newborn infant a prophylactic in accordance with s. 383.04, F.S.

Section 467.0125, F.S., also includes provisions for licensure by endorsement and temporary certification of a midwife who is qualifying for endorsement to practice in an area of critical need. This statute defines the term "area of critical need" differently from every other profession which has temporary certification that allows practice in an area of critical need. In addition, the current provisions for temporary certification of midwives require revocation if the area in which they practice loses its designation as an area of critical need.

Section 467.205, F.S., provides that any accredited or state-licensed institution of higher learning, public or private, may provide midwifery education and training. The statute sets out the DOH approval requirements for programs desiring to conduct an approved midwifery education program. Under the application and recertification process:

- The applicant must submit evidence of the program's compliance with the requirements in s. 467.009, F.S.
- The DOH must survey the organization applying for approval. If the DOH is satisfied that the program meets the requirements of s. 467.009, F.S., it must approve the program.
- The DOH must certify whether each approved midwifery program complies with the standards developed under s. 467.009, F.S., at least every three years.
  - If the DOH finds that an approved program no longer meets the required standards, it may place the program on probation until such time as the standards are restored.
  - If a program fails to correct these conditions within a specified period of time, the DOH may rescind the approval.

[27] Section 467.015, F.S.

- Any program having its approval rescinded has the right to reapply.
- Provisional approval of a new program may be granted pending the licensure results of the first graduating class.[28]

Practice of Orthotics, Prosthetics, and Pedorthics

The practice of orthotics, prosthetics, and pedorthics is governed by part XIV of ch. 468, F.S., and all three professions evaluate, measure, design, fabricate, assemble, fit, adjust, service, or provide the initial training necessary to accomplish the fitting of an orthosis or pedorthic device.[29]

Section 468.803, F.S., provides minimum qualifications for licensure to practice orthotics, prosthetics, and pedorthics. An applicant must be 18 years of age or older and must:
- Submit an application and fee;
- Submit fingerprint forms and the cost of the state and national criminal background checks;
- Be of good moral character;
- Have completed a one year residency or internship in orthotics or prosthetics approved by the Board of Orthotists and Prosthetists (BOAP); and
- Meet the following degree requirements to take the appropriate BOAP-approved examination:
  - *Orthoptist*: A bachelor of science or higher-level postgraduate degree in orthotics and prosthetics from a regionally accredited college or university, or a bachelor's degree with a certificate in orthotics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the BOAP.
  - *Prosthetist:* A bachelor of science or higher-level postgraduate degree in orthotics and prosthetics from a regionally accredited college or university, or a bachelor's degree with a certificate in prosthetics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the BOAP; and
- Pass the BOAP-approved examination.

Clinical Lab Personnel

Part I of ch. 483, F.S., regulates clinical laboratory personnel. "Clinical laboratory personnel" includes a clinical laboratory director, supervisor, technologist, blood gas analyst, or technician who performs or is responsible for laboratory test procedures, but the term does not include trainees, persons who perform screening for blood banks or plasmapheresis centers, phlebotomists, or persons employed by a clinical laboratory to perform manual pretesting duties or clerical, personnel, or other administrative responsibilities.[30]

Section 483.824(2), F.S., requires that the doctoral degree held by a clinical laboratory director must be from a regionally-accredited institution in a chemical, physical, or biological science.

[28] Section 467.205, F.S.
[29] Section 468.80, F.S.
[30] Section 483.803(4), F.S.

Psychologists

Chapter 490, F.S., regulates the practice of psychology by psychologists. A psychologist is a person licensed by examination under s. 490.005(1), F.S., or endorsement under s. 490.006, F.S.

Section 490.003. F.S., defines a "doctoral-level psychological education" and "doctoral degree in psychology" as of July 1, 1999, to include a Psy.D., an Ed.D. in psychology, or a Ph.D. in psychology from a psychology program at an educational institution that, at the time the applicant was enrolled and graduated:

- Had institutional accreditation from an agency recognized and approved by the U.S. Department of Education or was recognized as a member in good standing with the Association of Universities and Colleges of Canada; and
- Had programmatic accreditation from the American Psychological Association (APA).

Section 490.005, F.S., provides that any person desiring to be licensed by examination as a psychologist must apply to the DOH to take the licensure examination. The DOH will license each applicant who the Board of Psychology (BOP) certifies has:

- Completed an application and submitted a fee;
- Submitted proof satisfactory to the BOP that the applicant has received:
  - Doctoral-level psychological education; or
  - The equivalent of a doctoral-level psychological education from a program at a school or university located outside the U.S.;
- Had at least two years or 4,000 hours of experience in the field of psychology; and
- Passed the licensing examination.

Section 490.0051, F.S., also requires the DOH to issue a provisional psychology license to each applicant who the BOP certifies has:

- Completed the application form and paid the fee;
- Earned a doctoral degree in psychology as defined in s. 490.003(3); and
- Met any additional requirements established by BOP rule.

Provisional licensees must practice under the supervision of a licensed psychologist until the provisional licensee receives a license or a letter from the DOH stating that he or she is licensed as a psychologist. A provisional license expires 24 months after the date it is issued and may not be renewed or reissued.

Mental Health Professionals

Section 491.005, F.S., sets out the educational and examination requirements for a clinical social worker, marriage and family therapist, and mental health counselor to obtain a license by examination in Florida. An individual applying for licensure by examination who has satisfied the clinical experience requirements of s. 491.005, F.S., or an individual applying for licensure by endorsement pursuant to s. 491.006, F.S., intending to provide clinical social work, marriage and family therapy, or mental health counseling services in Florida, while satisfying coursework

or examination requirements for licensure, must obtain a provisional license in the profession for which he or she is seeking licensure prior to beginning practice.[31]

An individual who has not satisfied the postgraduate or post-master's level of experience requirements under s. 491.005, F.S., must register as an intern in the profession for which he or she is seeking licensure before commencing the post-master's experience requirement. An individual who intends to satisfy part of the required graduate-level practicum, internship, or field experience outside the academic arena, must register as an intern in the profession for which he or she is seeking licensure before commencing the practicum, internship, or field experience.[32]

Clinical Social Workers

Section 491.005(1), F.S., relates to licensure by examination for clinical social workers. The DOH must issue a license to an applicant as a clinical social worker if the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling (Board) certifies that the applicant:

- Has submitted an application and appropriate fees;
- Has earned a doctoral degree in social work from a graduate school of social work accredited by an accrediting agency recognized by the U.S. Department of Education, or a master's degree in social work from a graduate school of social work which:
  - Was accredited by the Council on Social Work Education (CSWE);
  - Was accredited by the Canadian Association of Schools of Social Work (CASSW); or
  - Has been determined to be an equivalent program to programs approved by the CSWE by the Foreign Equivalency Determination Service of the CSWE;
  - Completed all of the following coursework:
    - A supervised field placement during which the applicant provided clinical services directly to clients; and
    - Twenty-four semester hours or 32 quarter hours in theory of human behavior and practice methods as courses in clinically oriented services, with a minimum of one course in psychopathology and no more than one course in research;
- Has completed at least two post graduate years of clinical social work experience under the supervision of a licensed clinical social worker or the equivalent supervisor as determined by the Board;[33]
- Has passed a theory and practice examination; and
- Demonstrates, in a manner designated by Board rule, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.

Marriage and Family Therapists

Section 491.005(3), F.S., relates to licensure by examination for marriage and family therapists.

[31] Section 491.0046, F.S.
[32] Section 491.0045, F.S.
[33] Section 491.005(1)(c), F.S. An individual who intends to practice in Florida to satisfy clinical experience requirements must register with the DOH pursuant to s. 491.0045, F.S., before commencing practice.

The DOH must issue a license to an applicant as a marriage and family therapist if the Board certifies that the applicant has:

- Submitted an application and appropriate fee;
- A minimum of a master's degree with major emphasis in marriage and family therapy or a closely related field from a:
  - Program accredited by the Commission on Accreditation for Marriage and Family Therapy Education (CAMFTE); or
  - Florida university program accredited by the Council for Accreditation of Counseling and Related Educational Programs (CACREP);
- Documentation of the completion of graduate courses approved by the Board;[34]
- Completed at least two years of clinical experience during which 50 percent of the applicant's clients were receiving marriage and family therapy services:
  - At the post-master's level; and
  - Under the supervision of a licensed marriage and family therapist with at least five years of experience, or the equivalent, and whom the Board determines is a qualified supervisor;
- Passed a theory and practice examination provided by the DOH;[35]
- Demonstrated, in a manner designated by Board rule, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.[36]

The required master's degree must have been earned at an institution of higher education that, at the time the applicant graduated, was fully accredited by a regional accrediting body recognized by:

- The Commission on Recognition of Postsecondary Accreditation (CORPA);
- A member in good standing with the Association of Universities and Colleges of Canada; or
- An institution of higher education located outside the United States and Canada which, at the time the applicant attended and graduated, maintained a standard of training substantially equivalent to the standards of training of those institutions in the United States which are accredited by a regional accrediting body recognized by the CORPA.[37]

The applicant has the burden of establishing that all above requirements for licensure are met.

An applicant who has a master's degree from a program that did not emphasize marriage and family therapy may complete the coursework requirement in an institution fully accredited by the CAMFTE, and recognized by the U.S. Department of Education.

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[34] Section 491.005(3)(b), F.S. If the course title that appears on the applicant's transcript does not clearly identify the content of the coursework, the applicant must provide additional documentation, including, but not limited to, a syllabus or catalog description published for the course.

[35] *See* s. 491.004(5), F.S., and Fla. Admin. Code R. 64B4-3.003(2)(c) and 3, (2021). The DOH no longer provides the theory and practice examination for Marriage and Family Therapists. The examination used is the one developed by the Examination Advisory Committee of the Association of Marital and Family Therapy Regulatory Board (AMFTRB). The minimum passing score is established by that provider as well.

[36] *See* Fla. Admin. Code R. 64B4-3.0035, (2021).

[37] *Id.* Such foreign education and training must have been received in an institution or program of higher education officially recognized by the government of the country in which it is located as an institution or program to train students to practice as professional marriage and family therapists or psychotherapists.

To satisfy the clinical experience requirements, an individual who intends to practice in Florida must register with the DOH before he or she may commence practice.

A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting.

The DOH must issue a dual license to persons licensed as psychologists, clinical social workers, mental health counselors, and psychiatric advanced practice registered nurses, if the candidate has:

- A valid, active license for at least three years; and
- Passed the examination provided by the DOH for marriage and family therapy.

Mental Health Counselors

Section 491.005(4), F.S., relates to licensure by examination for mental health counselors. Education and training in mental health counseling must have been received in an institution of higher education that, at the time the applicant graduated, was fully accredited by:

- A regional accrediting body recognized by the Council for Higher Education Accreditation (CHEA) or its successor;
- A publicly recognized member in good standing with the Association of Universities and Colleges of Canada; or
- An institution of higher education located outside the United States and Canada which, at the time the applicant was enrolled and at the time the applicant graduated, was officially recognized by the government of the country in which it is located as an institution or program, to train students to practice as mental health counselors that maintained a standard of training substantially equivalent to the standards of training of those institutions in the United States which are accredited by a regional accrediting body recognized by the CHEA or its successor.

The DOH must issue a license to an applicant as a mental health counselor if the Board certifies that the applicant has:

- Submitted an application and appropriate fees;
- Earned a minimum of a master's degree from:
  - A mental health counseling program accredited by the CACREP[38] which includes clinical and didactic instruction, including courses in human sexuality and substance abuse; or
  - A non-CACREP accredited program related to the practice of mental health counseling, but with coursework and practicum, internship, or fieldwork that meet all of the following:
    - Thirty-three semester hours, or 44 quarter hours, which must include a minimum of three semester hours, or four quarter hours, of graduate-level coursework in 11 specified content areas;[39]or

[38] Council for Accreditation of Counseling & Related Educational Programs, *2016 CACREP Standards*, *available at* http://www.cacrep.org/wp-content/uploads/2018/05/2016-Standards-with-Glossary-5.3.2018.pdf (last visited Nov. 20, 2021).
[39] *See* s. 491.005(4)(b)1.a., F.S. The graduate course work must include the following 11 content areas: counseling theories and practice; human growth and development; diagnosis and treatment of psychopathology; human sexuality; group theories

    - A minimum of one graduate level course emphasizing the diagnostic processes, including differential diagnosis and the use of the current diagnostic tools, such as the current edition of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders. the common core curricular experience; or
    - An equivalent program to the two previously described options, as determined by the Board, including at least 700 hours of university-sponsored supervised clinical practicum, internship, or field work, that includes at least 280 hours of direct client services, as required by CACREP accrediting standards for mental health counseling programs. This experience may not be used to satisfy the post-master's clinical experience requirement;
- Had at least two years of clinical experience in mental health counseling, which must be at the post-master's level under the supervision of a licensed mental health counselor or the equivalent who is a Board qualified supervisor;[40]
- Passed a theory and practice examination provided by the DOH;[41] and
- Demonstrated, in a manner designated by Board rule, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.[42]

Beginning July 1, 2025, an applicant for mental health counseling licensure must have a master's degree from a program that is accredited by the CACREP which consists of at least 60 semester hours or 80 quarter hours.

A licensed mental health professional is required to be on the premises when clinical services are provided by a registered intern in a private practice setting. Section 491.005, F. S., contains the same provision for registered clinical social worker interns.

Recent Legislative History of Section 491.005, F.S.

The current program accreditation and licensure requirements in s. 491.005, F.S., for social workers, marriage and family therapists and mental health counselors were enacted during the 2020 legislative session.

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and practice; individual evaluation and assessment; career and lifestyle assessment; research and program evaluation; social and cultural foundations; substance abuse; and legal, ethical, and professional standards issues in the practice of mental health counseling. Courses in research, thesis or dissertation work, practicums, internships, or fieldwork may not be applied toward this requirement.

[40] Section 491.005(4), F.S., An individual who intends to practice in Florida to satisfy the clinical experience requirements must register pursuant to s. 491.0045, F.S., before commencing practice. If a graduate has a master's degree with a major related to the practice of mental health counseling which did not include all the coursework required under sub-subparagraphs (b)1.a. and b., credit for the post-master's level clinical experience may not commence until the applicant has completed a minimum of seven of the courses required under sub-subparagraphs (b)1.a. and b., as determined by the Board, one of which must be a course in psychopathology or abnormal psychology. A doctoral internship may be applied toward the clinical experience requirement.

[41] *See* s. 491.004(5), F.S., and Fla. Admin Code R. 64B4-3.003(2)(b) and 3, (2021). The DOH no longer provides the theory and practice examination for mental health counselors. The examination used is the National Clinical Mental Health Counseling Examination (NCMHCE), clinical simulation examination developed by the National Board for Certified Counselors (NBCC). Applicants for licensure by endorsement may use the National Counselor Examination for Licensure and Certification (NCE) if the exam was taken prior to the year 2000. The minimum passing score is established by the test provider.

[42] Fla. Admin. Code R. 64B4-3.0035, (2021).

As of July 1, 2020 an applicant seeking licensure under current s. 491.005(4), F.S., as a mental health counselor was required to have a master's degree from an a program accredited by the CACREP beginning July 1, 2025. Until July 1, 2025, mental health counseling students in programs related to the practice of mental health counseling that were not accredited by the CACREP could still obtain a license as a mental health counselor by satisfying the additional statutory requirements in s. 491.005(4), F.S., which required coursework and practicum, internship, or fieldwork consisting of at least 60 semester hours or 80 quarter hours and meeting other specific requirements. This window of time also gave those non-CACREP accredited programs time to apply for and obtain CACREP accreditation.

However, for marriage and family therapy licensure candidates, the current s. 491.005(3), F.S., contains no similar window of time for students to obtain licensure, or programs to obtain CAMFTE or CACREP accreditation. On July 1, 2020, students who had satisfied the previous requirements of s. 491.005(3), F.S., for licensure in programs not accredited by the CAMFTE, or who were in a Florida program not accredited by the CACREP, became immediately unable to obtain a license to practice marriage and family therapy without seeking a variance from the Board.

Currently, there are six universities in Florida with a marriage and family program that are not accredited by either COAMFTE or CACREP. They are: Carlos Albizu, Jacksonville University, Palm Beach Atlantic University, St. Thomas University, University of Miami, and University of Phoenix. As a result, students who are presently enrolled in a marriage and family program at one of the specified universities will not meet minimum requirements for Florida licensure upon graduation, although the programs did meet the requirements at the time of the student's enrollment.[43]

Regional Accreditation

The minimum qualifications for licensure specified in s. 491.005(3), F.S., includes the requirement of completion of a graduate program from a "regionally accredited body recognized by the Commission on Recognition of Postsecondary Accreditation." The U.S. Department of Education issued a letter of guidance on February 26, 2020, specifying that final regulations published that year omit references to "regional" and "national" accreditation. The letter specifies, "Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded." Provisions implemented in 34 C.F.R. s. 602.32(d), relating to the recognition of accrediting agencies, will become effective January 1, 2021.[44]

Department Examination

The DOH has discontinued the practice of conducting examinations or purchasing examinations for licensure. Applicants are presently responsible for coordinating the completion of an examination with an approved vendor and submitting passing scores to the applicable board to

[43] Department of Health, *Senate Bill 768 2022 Agency Legislative Bill Analysis - Mental Health Professionals* (July 23, 2021) (on file with the Senate Committee on Health Policy.)
[44] *Id.*

meet minimum qualifications. Current statutory references to the DOH collecting fees for examinations or conducting examinations is not consistent with current practice.[45]

Florida Birth-Related Neurological Injury Compensation Association (NICA)

In 1988 the Florida Legislature created the Florida Birth-Related Neurological Injury Compensation Association (NICA), to provide compensation, long-term medical care, and other services to persons with birth-related neurological injuries.[46] If an infant suffers such an injury, and the physician participates in NICA and delivers obstetrical services in connection with the birth, then an administrative award for a compensable injury is the infant's sole and exclusive remedy for the injury, with exceptions.[47] Although the benefits paid under the Florida Birth-Related Neurological Injury Compensation Plan (the Plan) are limited, the Plan does not require the claimant to prove malpractice and provides a streamlined administrative hearing process to resolve the claim.[48]

A "birth-related neurological injury" is an injury to the brain or spinal cord of a live infant who weighs at least 2,500 grams for a single gestation or, in the case of a multiple gestation, a live infant who weighs at least 2,000 grams at birth caused by oxygen deprivation or by mechanical injury occurring in the course of labor, delivery, or resuscitation in the immediate post-delivery period in a hospital.[49] Such an injury addressed by this statute renders the infant permanently and substantially mentally and physically impaired.[50]

The NICA is an independent association, and was created by the Legislature to manage the Plan. Although it is not a state agency, NICA is subject to regulation and oversight by the Office of Insurance Regulation (OIR) and the Joint Legislative Auditing Committee. Directors on the NICA's board are appointed by the Chief Financial Officer for staggered terms of three years or until their successor is appointed, but there is no limit on the number of terms a director may serve.[51] The five-member board of directors of NICA administers the Plan.[52] The board of directors is composed of:

- One citizen representative;
- One representative of participating physicians;
- One representative of hospitals;
- One representative of casualty insurers; and
- One representative of physicians other than participating physicians.[53]

The duties of the NICA board of directors include:

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[45] *Id.*
[46] Chapter 88-1, ss. 60-75, Laws of Fla., was enacted by the Legislature to stabilize and reduce malpractice insurance premiums for physicians practicing obstetrics. The intent of the Legislature is to provide compensation, on a no-fault basis, for a limited class of high costs catastrophic injuries, specifically birth-related neurological injuries, that result in unusually high costs for custodial care and rehabilitation. Section 766.301, F.S.
[47] Section 766.31(1), F.S.
[48] See *Florida Birth-Related Neurological Injury Compensation Ass'n v. McKaughan*, 668 So.2d 974, 977 (Fla. 1996).
[49] Section 766.302(2), F.S.
[50] *Id.*
[51] Section 766.315, F.S., and ch. 88-1, s. 74, Laws of Fla.
[52] Sections 766.315(1) and (2), F.S.
[53] Section 766.315, F.S., and ch. 88-1, s. 74, Laws of Fla.

- Administering the Plan;
- Administering the funds collected on behalf of the Plan;
- Reviewing and paying claims;
- Directing the investment and reinvestment of any surplus funds over losses and expenses, provided that any investment income generated thereby remains credited to the Plan;
- Reinsuring the risks of the Plan in whole or in part;
- Suing and being sued, appearing and defending, in all actions and proceedings in its name;
- Exercising all powers necessary or convenient to effect any or all of the purposes for which the Plan was created;
- Entering into such contracts as are necessary or proper to administer the Plan;
- Employing or retaining such persons as are necessary to perform the administrative and financial transactions and responsibilities of the Plan;
- Taking such legal action as may be necessary to avoid payment of improper claims; and
- Indemnifying any person acting on behalf of the Plan in an official capacity, provided that such person acted in good faith.[54]

Annually, the NICA must furnish audited financial reports to:
- Any Plan participant upon request;
- The OIR; and
- The Joint Legislative Auditing Committee.[55]

The reports must be prepared in accordance with accepted accounting procedures. The OIR or the Joint Legislative Auditing Committee may conduct an audit of the Plan at any time.[56]

NICA Funding

The initial funding for the Plan is derived from an appropriation of $20 million by the Legislature at the time the Plan was created[57] and annual assessments paid by physicians and hospitals.[58] A participating physician is required to pay a $5,000 fee each year for coverage which runs January 1 through December 31.[59] All licensed Florida physicians pay a mandatory fee of $250, regardless of specialty. Hospitals pay $50 for each live birth during the previous calendar year. Certain exemptions apply to all of these categories, including resident physicians, retired physicians, government physicians, and facilities.[60] In 2019, NICA collected $26,989,960 in hospital and physician assessments. In 2020, NICA collected $27,000,000.[61]

Section 766.314, F.S., requires the OIR to maintain a $20 million reserve in the Insurance Regulatory Trust Fund. If the assessments collected and the appropriation of funds provided by ch. 88-277, s. 41, Laws of Florida, to the Plan from the trust fund are insufficient to maintain the

[54] Section 766.315(4), F.S.
[55] Section 766.315(5)(e), F.S.
[56] *Id*.
[57] Section 766.314(5)(b), F.S.
[58] Section 766.314, F.S.
[59] *Id*.
[60] *Id*.
[61] Turner Consulting, Inc., *Proposed Increase in Parental Award – Section 766.31 (1) (b) (1), Florida Statutes* (Jan. 14, 2020).

Plan on an actuarially sound basis, the OIR is authorized to transfer an additional amount up to $20 million to the NICA from the Insurance Regulatory Trust Fund reserve.[62]

Obsolete Statutory References and Provisions

Currently, s. 766.314, F.S., contains numerous references to the Department of Business and Professional Regulation (DBPR) as the agency housing the Florida Board of Medicine and the Florida Board of Osteopathic Medicine. All medical boards were moved to the DOH in the early 2000s. DOH accepted all of the responsibilities in this statute when the boards moved; however, the statute still indicates that these functions should be performed by the DBPR. In addition, the statute contains obsolete language related to how the initial NICA assessment was collected in 1988. This language is no longer needed.

"Following Year" Assessments

The statute requires the DBPR to collect the initial NICA assessment (fee) from all applicants. The statute also requires that if a license is being issued between October 1 and December 31, the DBPR is to collect the fee for the following year.

Currently, the DOH is not collecting the "following year" fees from individuals licensed during the specified period. Every licensee pays the initial NICA assessment (ranging from $0 to $5,000) at the time of application. The "following year" fees have been collected directly by NICA since the boards were moved to the DOH. NICA requires fees to be paid by January 31 of the calendar year.

Data Sharing with NICA

The statute requires the DBPR to provide a listing in a computer-readable format of the names and addresses of physicians licensed under chs. 458 and 459, F.S., as often "as determined to be necessary."

Currently, the DOH provides NICA with a list of newly licensed physicians each month, including their license numbers, the date they were licensed, and the fees collected. Any additional information that NICA may need can be downloaded from DOH's website. This coincides with the transfer of those fees collected by the DOH to NICA, allowing NICA to reconcile the amount received with the fees listed in the monthly report.

III. Effect of Proposed Changes:

Targeted Outreach for Pregnant Women

The bill amends s. 381.0045, F.S., to:

- Add pregnant women who are suffering from mental health problems to the list of outreach targets;
- Encourage high risk pregnant women to get tested for other sexually transmissible diseases, as well as HIV, per DOH rule;

[62] Section 766.314(5)(b), F.S.

- Provide pregnant women with information on:
  - The need for antiretroviral medications, deleting reference to a single type of antiretroviral (AZT), for themselves and their newborn; and
  - How to access antiretroviral medications after discharge from the hospital;
- Link women to mental health services; and
- Require additional follow up for HIV-exposed newborns to determine final HIV status and ensure continued linkages to care, if needed.

Special Needs Shelters

The bill amends s. 381.0303, F.S., and removes CMS from responsibility for coordinating local medical and health care providers, the American Red Cross, and other interested parties in developing a plan for the staffing and medical management of pediatric special needs shelters. The bill instead specifies that the DOH has the sole lead-agency responsibility in the coordination of local medical and health care providers for the staffing and management of pediatric special needs shelters and is the decision-making authority for determining the medical supervision in each special needs shelter. Under the bill, the DOH will no longer share that duty with CMS.

Medical Marijuana Sampling and Testing

The bill amends s. 381.986, F.S., related to the medical use of marijuana to:
- Allow the DOH to collect samples of marijuana and marijuana delivery devices from a MMTC for specified testing. Currently, the DOH may only collect samples of edibles;
- Expand MMTC recall requirements to all marijuana products and delivery devices, rather than only edibles; and
- Provide an exception from criminal laws for DOH employees to acquire, possess, test, transport, and lawfully dispose of marijuana and marijuana delivery devices.

Additional Disclosure Requirement for Physician Licensure and Renewal

The bill amends s. 456.039, F.S., requiring require each physician seeking licensure, or license renewal, under chs, 458 or 459, F.S., to provide, in addition to the other requirements, proof of payment of the NICA assessment required under s. 766.314, F.S., if applicable.

Chiropractic Licensure

The bill amends s. 460.406, F.S., to deletes references to the term “regional” and replaces it with the term “institutional” to conform with the U.S. Department of Education accreditation nomenclature for approving educational institutions.

Nursing Licensure and Disciplinary Actions

The bill amend s. 464.008, F.S., and deletes the requirement that graduates from an approved nursing program who do not take the licensure examination within six months after graduation, must successfully complete and pay for a board-approved licensure examination preparatory course.

The bill also amends s. 464.018(1)(e), F.S., and moves the placement of the phrase, "regardless of adjudication," after the phrase "[h]aving been found guilty of, or entered a plea of nolo contendere or guilty to", to clarify that "regardless of adjudication" does not apply only to guilty pleas but to any plea to offenses listed in ss. 435.04, F.S., or 741.28, F.S.

Midwifery

The bill amends s. 467.003(12) to clearly define "preceptor" in the midwifery education process. Specifically, the bill provides that a preceptor may not supervise an individual as a midwifery student unless the student has been enrolled in an approved midwifery program.

The bill defines "prelicensure course" to mean a course of study, offered by an accredited midwifery program and approved by the DOH, which an applicant for licensure must complete before a license may be issued, and which provides instruction in the laws and rules of Florida and demonstrates the student's competency to practice midwifery. The bill clarifies language to promote consistency in terminology and that midwifery programs must incorporate all required standards, guidelines, and education objectives.

The bill also clarifies that both a high school diploma or the equivalent and three college-level credits in math and English or demonstration of competency in communication and computation may be required for admission to a midwifery program. The bill amends s. 467.009, F.S., and requires, for the accreditation and approval of midwifery programs, that a program's clinical training must include all of the following:

- Care for 50 women in each of the prenatal, intrapartal, and postpartal periods under the supervision of a preceptor;
- Observation of an additional 25 women in the intrapartal period before qualifying for a license;
- Training in a hospital and alternate birth settings or both; and
- Assessment and differentiation between a high-risk and low-risk pregnancy.

The bill amends s. 467.011, F.S., to require the following for the issuance of a midwifery license:

- Application and fee;
- Graduation from:
  - An accredited and approved midwifery program;
  - A medical or midwifery program offered in another jurisdiction whose graduation requirements were equivalent to or exceeded those required in Florida;
  - Completion of a prelicensure course offered by an accredited and approved midwifery program; and
  - A passing score on the examination specified by the DOH.

The bill amends s. 467.0125, F.S, to repeal the abbreviated oral examination to determine the applicant's competency without a written examination for temporary certificates and clarifies the criteria for obtaining a license by endorsement and temporary certificate to practice in areas of critical need. The bill does not specifically define "areas of critical need" for temporary certificates but requires the applicant to:

- Specify that he or she will only practice in one or more of the following areas:

  - A county health department;
  - A correctional facility;
  - A U.S. Department of Veterans' Affairs clinic;
  - A community health center funded by s. 329, s. 330, or s. 340 of the United States Public Health Service Act;
  - Any other agency or institution that is approved by the state Surgeon General that provides health care to meet the needs of an underserved populations in this state; or
  - Areas of critical need determined by the state Surgeon General, which areas include, but are not be limited to, health professional shortage areas designated by the U.S. Department of Health and Human Services.
- Practice only under the supervision of a physician, an APRN certified nurse midwife or a midwife licensed under ch. 467, F.S., who has a minimum of three years professional experience; and
- Voluntarily relinquish the temporary certificate, or report a new practice area of critical need to the DOH, if his or her current practice area ceases to be an area of critical need.

The bill amends s. 467.205, F.S., to update the DOH's approval process of midwifery programs to allow such programs to be provisionally approved for five years. This conforms to the five-year period provisional licensure period the Florida Department of Education's Commission for Independent Education uses when seeking accreditation status. For private institutions, the bill adds to the CHEA, an accrediting agency approved by the U.S. Department of Education, as an institutional accrediting agency for direct-entry midwifery education programs and its licensing or provisional licensing by the Commission for Independent Education. The DOH will be able to give provisional approval to a new program that has meet all requirements except for showing its students have an 80-percent passage rate on the national exam. Programs provisionally approved will have five years to demonstrate the required exam approval rate after they are preliminary approved. This time period should allow completion the three-year education program for at least one cohort of students and for those students to take the exam before the DOH tries to determine the passing rate.[63]

The bill requires the DOH to certify every three years whether each approved midwifery program is compliant and has maintained compliance with the requirements of s. 467.009, F.S., or has lost its accreditation status. The DOH must provide its finding to the program in writing and may place the program on probationary status for a specified period of time, not to exceed three years. If a program on probationary status does not come into compliance or regain its accreditation status within the specified time, the DOH may rescind the program's approval.

Practice of Orthotics, Prosthetics, and Pedorthics

The bill amends part XIV of ch. 468, F.S., to reflect current procedures for applicants to obtain a criminal history check and the method of transmission to the DOH for review. The DOH no longer collects fingerprint forms or fees from applicants to process the initial criminal history check for licensure. Applicants are required to complete fingerprinting electronically through independent vendors and provide an originating agency identifier number specific to the

[63] Department of Health, *Senate Bill 768 2022 Agency Legislative Bill Analysis - Midwifery* (July 23, 2021) (on file with the Senate Committee on Health Policy).

profession for the results to be submitted to the DOH. If a criminal history is indicated, the BOAP will review the application for consideration of licensure.[64]

The bill also amends the educational requirements for orthotists and prosthetists. The orthoptist and prosthetists acceptable bachelor of science or higher-level postgraduate degree in orthotics and prosthetics from an accredited college or university must now also specifically be recognized by the Commission on Accreditation of Allied Health Education Programs.

The bill deletes references to the term "regionally accredited" and replaces it with the term "institutionally accredited" or simply references the programmatic accrediting body to conform with the U.S. Department of Education accreditation nomenclature for approving educational institutions.[65]

Clinical Lab Personnel

The bill amends s. 483.824(2), F.S., to delete the reference to the term "regionally" and replace it with "institutionally" in regard to the accredited institution at which a clinical laboratory director is required to have earned a doctoral degree in a chemical, physical, or biological science.

Psychologists

The bill amends ss. 490.003, 490.005, and 490.0051, F.S., to clarify definitions and the educational requirements for psychologists applying for licensure by examination or provisional licensure.

The bill defines a "doctoral degree from an APA accredited program" as a Psy.D., an Ed.D. in psychology, or a Ph.D. in psychology from a psychology program at an educational institution that, at the time the applicant was enrolled and graduated had both an institutional accreditation from an agency recognized and approved by the U.S. Department of Education or was as recognized as a member in good standing with the Association of Universities and Colleges of Canada, and had programmatic accreditation from the APA.

The bill further defines "doctoral degree in psychology" as a Psy.D., an Ed.D. in psychology, or a Ph.D. in psychology from a psychology program at an educational institution that, at the time the applicant was enrolled and graduated, had institutional accreditation from an agency recognized and approved by the U.S. Department of Education or was recognized as a member in good standing with the Association of Universities and Colleges of Canada.

The bill requires psychologists applying for licensure to have obtained a doctoral degree from:
- An APA accredited program; or
- The equivalent of a degree from APA-accredited program from a school or university located outside the United States which was officially recognized by the government of the country

[64] Department of Health, *Senate Bill 768 Fiscal Analysis - Practice of Orthotics, Prosthetics, and Pedorthics* (July 23, 2021) (on file with the Senate Committee on Health Policy).
[65] Department of Health, *Senate Bill 768 2022 Agency Legislative Bill Analysis - Practice of Orthotics, Prosthetics, and Pedorthics* (July 23, 2021) (on file with the Senate Committee on Health Policy).

in which it is located as an institution or program to train students to practice professional psychology.

Provisional licensure applicants must have earned a degree from an APA accredited program. Lack of a degree from an APA-accredited program would be grounds for denial of licensure under the bill.

Mental Health Professionals

The bill amends s. 491.005, F.S., effective upon the bill becoming law, to create three pathways to licensure for applicants for a marriage and family therapy license to meet the minimum educational requirements by one of the following methods:

- A minimum of a master's degree in marriage and family therapy from a college or university that is accredited by the CAMFTE;
- A minimum of a master's degree with an emphasis in marriage and family therapy from a college or university that is accredited by the CACREP and graduate courses approved by the board; or
- A minimum of a master's degree with an emphasis in marriage and family therapy or a closely related field, with a degree conferred date before September 1, 2027, from an institutionally accredited college or university.

The bill updates the education requirements for marriage and family therapists, including current law's obsolete reference to accreditation by CORPA, which was dissolved in 1997. The bill replaces the CORPA with the CHEA or its successors.

The bill deletes references to the term "regional" in s. 491.005(3), F.S., and replaces it with the term "institutional" to conform with the U.S. Department of Education accreditation nomenclature for approving educational institutions and deletes obsolete statutory references to the DOH collecting fees for examinations or conducting examinations.

Florida Birth-Related Neurological Injury Compensation Association (NICA)

The bill amends s. 766.314, F.S., deleting references to the DBPR and revising the frequency and content of certain reports which the DOH must submit to the NICA. The bill eliminates unnecessary and obsolete language regarding the initial fees collected in 1988.

The bill deletes obsolete language and updates provisions to conform to current law. The bill authorizes the NICA to enforce the collection of physician assessments in circuit court under certain circumstances and requires the NICA to notify the DOH and the appropriate regulatory board of any unpaid final judgments against a physician within seven days of the issuance of a final judgment.

The bill updates the provisions regarding data sharing with the NICA to reflect current DOH practice and requires DOH to continue providing NICA with an electronic monthly report of physicians licensed in the previous month, including their license numbers, the date they were licensed, and the fees collected.

The bill provides an effective date of July 1, 2022, except as otherwise provided.

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 DOH indicates it will experience a non-recurring workload increase associated with updating online applications and websites; limited costs associated with rule making; limited costs associated with updating licensure databases and the License and Enforcement System; and minimal costs associated with testing from MMTCs. According to the DOH, current resources are adequate to absorb these costs.[66]

VI. Technical Deficiencies:

None.

[66] Department of Health, *Senate Bill 768 2022 Agency Legislative Bill Analysis- Practice of Orthotics, Prosthetics, and Pedorthics* (July 23, 2021) (on file with the Senate Committee on Health Policy)

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.0045, 381.0303, 381.986, 456.039, 460.406, 464.008, 464.018, 467.003, 467.009, 467.011, 467.0125, 467.205, 468.803, 483.824, 490.003, 490.005, 490.0051, 491.005, and 766.314.

IX. Additional Information:

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

CS by Health Policy on January 26, 2022:
The CS:

- Removes the underlying bill's provisions relating to emergency medical services;
- Requires allopathic and osteopathic physicians who apply to the DOH for Florida licensure to provide proof of payment of any NICA assessments, as applicable;
- Requires NICA to inform the DOH and the applicable regulatory board of an unpaid final judgment against a physician within seven days of the final judgment;
- Removes authority granted by the underlying bill for counseling interns to provide services via telehealth under certain conditions; and
- Makes technical corrections to the underlying bill's provisions relating to practitioner education requirements for numerous practitioner types.

B. Amendments:

None.

By Senator Rodriguez

39-00626C-22 2022768__

A bill to be entitled

An act relating to the Department of Health; amending s. 381.0045, F.S.; revising the purpose of the department's targeted outreach program for certain pregnant women; requiring the department to encourage high-risk pregnant women of unknown status to be tested for sexually transmissible diseases; requiring the department to provide specified information to pregnant women who have human immunodeficiency virus (HIV); requiring the department to link women with mental health services when available; requiring the department to educate pregnant women who have HIV on certain information; requiring the department to provide, for a specified purpose, continued oversight of newborns exposed to HIV; amending s. 381.0303, F.S.; removing the Children's Medical Services office from parties required to coordinate in the development of local emergency management plans for special needs shelters; amending s. 381.986, F.S.; authorizing the department to select samples of marijuana from medical marijuana treatment center facilities for certain testing; authorizing the department to select samples of marijuana delivery devices from medical marijuana treatment centers to determine whether the device is safe for use; requiring medical marijuana treatment centers to recall marijuana and marijuana delivery devices, instead of just edibles, under certain circumstances; exempting the department and its employees from criminal provisions if they acquire,

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possess, test, transport, or lawfully dispose of marijuana and marijuana delivery devices under certain circumstances; amending s. 401.23, F.S.; revising definitions; amending s. 401.25, F.S.; conforming a provision to changes made by the act; amending s. 401.27, F.S.; revising certification and recertification requirements for emergency medical technicians and paramedics; amending s. 401.2701, F.S.; revising requirements for emergency medical services training programs; authorizing certain site visits to be conducted either in person or through electronic means; authorizing programs to substitute certain simulated, remote videoconferencing options for in-person training and related requirements; specifying requirements for requests for department approval of such options; providing for the renewal of program certification; providing for initial and ongoing department site visits of programs; revising program application procedures; amending s. 401.272, F.S.; revising functions paramedics and emergency medical technicians may perform in nonemergency environments; authorizing paramedics to administer public health countermeasures in nonemergency environments under certain circumstances; conforming provisions to changes made by the act; amending s. 401.30, F.S.; revising recordkeeping requirements for emergency medical services providers; authorizing records to be in either written or electronic formats; revising the list of individuals and entities that may

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

receive limited disclosure of certain otherwise confidential and exempt records; requiring the release of such records to be in compliance with specified provisions; amending s. 401.34, F.S.; deleting provisions and fees related to an obsolete examination; amending s. 401.425, F.S.; authorizing emergency medical review committees to review the performances of emergency medical technicians, paramedics, and emergency medical services providers to make recommendations for improvement; amending s. 401.435, F.S.; relabeling "first responder agencies" as "emergency medical responder agencies"; revising minimum standards for emergency medical first responder training; amending s. 460.406, F.S.; revising provisions related to chiropractic physician licensing; amending s. 464.008, F.S.; deleting a requirement that certain nursing program graduates complete a specified preparatory course; amending s. 464.018, F.S.; revising grounds for disciplinary action against licensed nurses; amending s. 467.003, F.S.; revising and defining terms; amending s. 467.009, F.S.; revising provisions related to approved midwifery programs; amending s. 467.011, F.S.; revising requirements for licensure of midwives; amending s. 467.0125, F.S.; revising requirements for licensure by endorsement of midwives; revising requirements for temporary certificates to practice midwifery in this state; amending s. 467.205, F.S.; revising provisions relating to approval, continued

monitoring, probationary status, provisional approval, and approval rescission of midwifery programs; amending s. 468.803, F.S.; revising provisions related to orthotist and prosthetist registration, examination, and licensing; amending s. 483.824, F.S.; revising educational requirements for clinical laboratory directors; amending s. 490.003, F.S.; defining the terms "doctoral degree from an American Psychological Association accredited program" and "doctoral degree in psychology"; amending ss. 490.005 and 490.0051, F.S.; revising education requirements for psychologist licensure and provisional licensure, respectively; amending s. 491.005, F.S.; revising requirements for licensure of clinical social workers, marriage and family therapists, and mental health counselors; requiring that a licensed mental health professional be accessible through certain means when a registered intern provides clinical services through telehealth; amending s. 766.314, F.S.; deleting obsolete language and updating provisions to conform to current law; revising the frequency with which the department must submit certain reports to the Florida Birth-Related Neurological Injury Compensation Association; revising the content of such reports; providing an effective date.

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

Section 1. Subsections (2) and (3) of section 381.0045,

Florida Statutes, are amended to read:

381.0045 Targeted outreach for pregnant women.—

(2) It is the purpose of this section to establish a targeted outreach program for high-risk pregnant women who may not seek proper prenatal care, who suffer from substance abuse or mental health problems, or who have acquired ~~are infected with~~ human immunodeficiency virus (HIV), and to provide these women with links to much-needed ~~much needed~~ services and information.

(3) The department shall:

(a) Conduct outreach programs through contracts with, grants to, or other working relationships with persons or entities where the target population is likely to be found.

(b) Provide outreach that is peer-based, culturally sensitive, and performed in a nonjudgmental manner.

(c) Encourage high-risk pregnant women of unknown status to be tested for HIV and other sexually transmissible diseases as specified by department rule.

(d) Educate women not receiving prenatal care as to the benefits of such care.

(e) Provide ~~HIV-infected~~ pregnant women who have HIV with information on the need for antiretroviral medication for their newborn, their medication options, and how they can access the medication after their discharge from the hospital ~~so they can make an informed decision about the use of Zidovudine (AZT)~~.

(f) Link women with substance abuse treatment and mental health services, when available, and act as a liaison with Healthy Start coalitions, children's medical services, Ryan White-funded providers, and other services of the Department of

Health.

(g) Educate pregnant women who have HIV on the importance of engaging in and continuing HIV care.

(h) Provide continued oversight of any newborn exposed to HIV to determine the newborn's final HIV status and ensure continued linkage to care if the newborn is diagnosed with HIV ~~to HIV-exposed newborns~~.

Section 2. Paragraphs (a) and (c) of subsection (2) of section 381.0303, Florida Statutes, are amended to read:

381.0303 Special needs shelters.—

(2) SPECIAL NEEDS SHELTER PLAN; STAFFING; STATE AGENCY ASSISTANCE.—If funds have been appropriated to support disaster coordinator positions in county health departments:

(a) The department shall assume lead responsibility for the coordination of local medical and health care providers, the American Red Cross, and other interested parties in developing a plan for the staffing and medical management of special needs shelters and~~. The local Children's Medical Services offices shall assume lead responsibility for the coordination of local medical and health care providers, the American Red Cross, and other interested parties in developing a plan for the staffing and medical management of~~ pediatric special needs shelters. Plans must conform to the local comprehensive emergency management plan.

(c) The appropriate county health department~~, Children's Medical Services office,~~ and local emergency management agency shall jointly decide who has responsibility for medical supervision in each special needs shelter.

Section 3. Present paragraphs (e) through (h) of subsection

(14) of section 381.986, Florida Statutes, are redesignated as paragraphs (f) through (i), respectively, a new paragraph (e) is added to that subsection, and paragraph (e) of subsection (8) of that section is amended, to read:

381.986 Medical use of marijuana.—

(8) MEDICAL MARIJUANA TREATMENT CENTERS.—

(e) A licensed medical marijuana treatment center shall cultivate, process, transport, and dispense marijuana for medical use. A licensed medical marijuana treatment center may not contract for services directly related to the cultivation, processing, and dispensing of marijuana or marijuana delivery devices, except that a medical marijuana treatment center licensed pursuant to subparagraph (a)1. may contract with a single entity for the cultivation, processing, transporting, and dispensing of marijuana and marijuana delivery devices. A licensed medical marijuana treatment center must, at all times, maintain compliance with the criteria demonstrated and representations made in the initial application and the criteria established in this subsection. Upon request, the department may grant a medical marijuana treatment center a variance from the representations made in the initial application. Consideration of such a request shall be based upon the individual facts and circumstances surrounding the request. A variance may not be granted unless the requesting medical marijuana treatment center can demonstrate to the department that it has a proposed alternative to the specific representation made in its application which fulfills the same or a similar purpose as the specific representation in a way that the department can reasonably determine will not be a lower standard than the

specific representation in the application. A variance may not be granted from the requirements in subparagraph 2. and subparagraphs (b)1. and 2.

1. A licensed medical marijuana treatment center may transfer ownership to an individual or entity who meets the requirements of this section. A publicly traded corporation or publicly traded company that meets the requirements of this section is not precluded from ownership of a medical marijuana treatment center. To accommodate a change in ownership:

a. The licensed medical marijuana treatment center shall notify the department in writing at least 60 days before the anticipated date of the change of ownership.

b. The individual or entity applying for initial licensure due to a change of ownership must submit an application that must be received by the department at least 60 days before the date of change of ownership.

c. Upon receipt of an application for a license, the department shall examine the application and, within 30 days after receipt, notify the applicant in writing of any apparent errors or omissions and request any additional information required.

d. Requested information omitted from an application for licensure must be filed with the department within 21 days after the department's request for omitted information or the application shall be deemed incomplete and shall be withdrawn from further consideration and the fees shall be forfeited.

e. Within 30 days after the receipt of a complete application, the department shall approve or deny the application.

2. A medical marijuana treatment center, and any individual or entity who directly or indirectly owns, controls, or holds with power to vote 5 percent or more of the voting shares of a medical marijuana treatment center, may not acquire direct or indirect ownership or control of any voting shares or other form of ownership of any other medical marijuana treatment center.

3. A medical marijuana treatment center may not enter into any form of profit-sharing arrangement with the property owner or lessor of any of its facilities where cultivation, processing, storing, or dispensing of marijuana and marijuana delivery devices occurs.

4. All employees of a medical marijuana treatment center must be 21 years of age or older and have passed a background screening pursuant to subsection (9).

5. Each medical marijuana treatment center must adopt and enforce policies and procedures to ensure employees and volunteers receive training on the legal requirements to dispense marijuana to qualified patients.

6. When growing marijuana, a medical marijuana treatment center:

a. May use pesticides determined by the department, after consultation with the Department of Agriculture and Consumer Services, to be safely applied to plants intended for human consumption, but may not use pesticides designated as restricted-use pesticides pursuant to s. 487.042.

b. Must grow marijuana within an enclosed structure and in a room separate from any other plant.

c. Must inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural

interests of the state in accordance with chapter 581 and any rules adopted thereunder.

d. Must perform fumigation or treatment of plants, or remove and destroy infested or infected plants, in accordance with chapter 581 and any rules adopted thereunder.

7. Each medical marijuana treatment center must produce and make available for purchase at least one low-THC cannabis product.

8. A medical marijuana treatment center that produces edibles must hold a permit to operate as a food establishment pursuant to chapter 500, the Florida Food Safety Act, and must comply with all the requirements for food establishments pursuant to chapter 500 and any rules adopted thereunder. Edibles may not contain more than 200 milligrams of tetrahydrocannabinol, and a single serving portion of an edible may not exceed 10 milligrams of tetrahydrocannabinol. Edibles may have a potency variance of no greater than 15 percent. Edibles may not be attractive to children; be manufactured in the shape of humans, cartoons, or animals; be manufactured in a form that bears any reasonable resemblance to products available for consumption as commercially available candy; or contain any color additives. To discourage consumption of edibles by children, the department shall determine by rule any shapes, forms, and ingredients allowed and prohibited for edibles. Medical marijuana treatment centers may not begin processing or dispensing edibles until after the effective date of the rule. The department shall also adopt sanitation rules providing the standards and requirements for the storage, display, or dispensing of edibles.

9. Within 12 months after licensure, a medical marijuana treatment center must demonstrate to the department that all of its processing facilities have passed a Food Safety Good Manufacturing Practices, such as Global Food Safety Initiative or equivalent, inspection by a nationally accredited certifying body. A medical marijuana treatment center must immediately stop processing at any facility which fails to pass this inspection until it demonstrates to the department that such facility has met this requirement.

10. A medical marijuana treatment center that produces prerolled marijuana cigarettes may not use wrapping paper made with tobacco or hemp.

11. When processing marijuana, a medical marijuana treatment center must:

a. Process the marijuana within an enclosed structure and in a room separate from other plants or products.

b. Comply with department rules when processing marijuana with hydrocarbon solvents or other solvents or gases exhibiting potential toxicity to humans. The department shall determine by rule the requirements for medical marijuana treatment centers to use such solvents or gases exhibiting potential toxicity to humans.

c. Comply with federal and state laws and regulations and department rules for solid and liquid wastes. The department shall determine by rule procedures for the storage, handling, transportation, management, and disposal of solid and liquid waste generated during marijuana production and processing. The Department of Environmental Protection shall assist the department in developing such rules.

d. Test the processed marijuana using a medical marijuana testing laboratory before it is dispensed. Results must be verified and signed by two medical marijuana treatment center employees. Before dispensing, the medical marijuana treatment center must determine that the test results indicate that low-THC cannabis meets the definition of low-THC cannabis, the concentration of tetrahydrocannabinol meets the potency requirements of this section, the labeling of the concentration of tetrahydrocannabinol and cannabidiol is accurate, and all marijuana is safe for human consumption and free from contaminants that are unsafe for human consumption. The department shall determine by rule which contaminants must be tested for and the maximum levels of each contaminant which are safe for human consumption. The Department of Agriculture and Consumer Services shall assist the department in developing the testing requirements for contaminants that are unsafe for human consumption in edibles. The department shall also determine by rule the procedures for the treatment of marijuana that fails to meet the testing requirements of this section, s. 381.988, or department rule. The department may select samples of marijuana ~~a random sample~~ from ~~edibles available for purchase in~~ a medical marijuana treatment center ~~dispensing~~ facility which shall be tested by the department to determine whether ~~that~~ the marijuana ~~edible~~ meets the potency requirements of this section, is safe for human consumption, and is accurately labeled with ~~the labeling of~~ the tetrahydrocannabinol and cannabidiol concentration or to verify the result of marijuana testing conducted by a marijuana testing laboratory. The department may also select samples of marijuana delivery devices from a medical

marijuana treatment center to determine whether the marijuana delivery device is safe for use by qualified patients ~~is accurate~~. A medical marijuana treatment center may not require payment from the department for the sample. A medical marijuana treatment center must recall marijuana ~~edibles~~, including all marijuana and marijuana products ~~edibles~~ made from the same batch of marijuana, that fails ~~which fail~~ to meet the potency requirements of this section, that is ~~which are~~ unsafe for human consumption, or for which the labeling of the tetrahydrocannabinol and cannabidiol concentration is inaccurate. A medical marijuana treatment center must also recall all marijuana delivery devices determined to be unsafe for use by qualified patients. The medical marijuana treatment center must retain records of all testing and samples of each homogenous batch of marijuana for at least 9 months. The medical marijuana treatment center must contract with a marijuana testing laboratory to perform audits on the medical marijuana treatment center's standard operating procedures, testing records, and samples and provide the results to the department to confirm that the marijuana or low-THC cannabis meets the requirements of this section and that the marijuana or low-THC cannabis is safe for human consumption. A medical marijuana treatment center shall reserve two processed samples from each batch and retain such samples for at least 9 months for the purpose of such audits. A medical marijuana treatment center may use a laboratory that has not been certified by the department under s. 381.988 until such time as at least one laboratory holds the required certification, but in no event later than July 1, 2018.

e. Package the marijuana in compliance with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.

f. Package the marijuana in a receptacle that has a firmly affixed and legible label stating the following information:

(I) The marijuana or low-THC cannabis meets the requirements of sub-subparagraph d.

(II) The name of the medical marijuana treatment center from which the marijuana originates.

(III) The batch number and harvest number from which the marijuana originates and the date dispensed.

(IV) The name of the physician who issued the physician certification.

(V) The name of the patient.

(VI) The product name, if applicable, and dosage form, including concentration of tetrahydrocannabinol and cannabidiol. The product name may not contain wording commonly associated with products marketed by or to children.

(VII) The recommended dose.

(VIII) A warning that it is illegal to transfer medical marijuana to another person.

(IX) A marijuana universal symbol developed by the department.

12. The medical marijuana treatment center shall include in each package a patient package insert with information on the specific product dispensed related to:

a. Clinical pharmacology.

b. Indications and use.

c. Dosage and administration.

d. Dosage forms and strengths.

e. Contraindications.

f. Warnings and precautions.

g. Adverse reactions.

13. In addition to the packaging and labeling requirements specified in subparagraphs 11. and 12., marijuana in a form for smoking must be packaged in a sealed receptacle with a legible and prominent warning to keep away from children and a warning that states marijuana smoke contains carcinogens and may negatively affect health. Such receptacles for marijuana in a form for smoking must be plain, opaque, and white without depictions of the product or images other than the medical marijuana treatment center's department-approved logo and the marijuana universal symbol.

14. The department shall adopt rules to regulate the types, appearance, and labeling of marijuana delivery devices dispensed from a medical marijuana treatment center. The rules must require marijuana delivery devices to have an appearance consistent with medical use.

15. Each edible shall be individually sealed in plain, opaque wrapping marked only with the marijuana universal symbol. Where practical, each edible shall be marked with the marijuana universal symbol. In addition to the packaging and labeling requirements in subparagraphs 11. and 12., edible receptacles must be plain, opaque, and white without depictions of the product or images other than the medical marijuana treatment center's department-approved logo and the marijuana universal symbol. The receptacle must also include a list of all the edible's ingredients, storage instructions, an expiration date,

a legible and prominent warning to keep away from children and pets, and a warning that the edible has not been produced or inspected pursuant to federal food safety laws.

16. When dispensing marijuana or a marijuana delivery device, a medical marijuana treatment center:

a. May dispense any active, valid order for low-THC cannabis, medical cannabis and cannabis delivery devices issued pursuant to former s. 381.986, Florida Statutes 2016, which was entered into the medical marijuana use registry before July 1, 2017.

b. May not dispense more than a 70-day supply of marijuana within any 70-day period to a qualified patient or caregiver. May not dispense more than one 35-day supply of marijuana in a form for smoking within any 35-day period to a qualified patient or caregiver. A 35-day supply of marijuana in a form for smoking may not exceed 2.5 ounces unless an exception to this amount is approved by the department pursuant to paragraph (4)(f).

c. Must have the medical marijuana treatment center's employee who dispenses the marijuana or a marijuana delivery device enter into the medical marijuana use registry his or her name or unique employee identifier.

d. Must verify that the qualified patient and the caregiver, if applicable, each have an active registration in the medical marijuana use registry and an active and valid medical marijuana use registry identification card, the amount and type of marijuana dispensed matches the physician certification in the medical marijuana use registry for that qualified patient, and the physician certification has not already been filled.

e. May not dispense marijuana to a qualified patient who is younger than 18 years of age. If the qualified patient is younger than 18 years of age, marijuana may only be dispensed to the qualified patient's caregiver.

f. May not dispense or sell any other type of cannabis, alcohol, or illicit drug-related product, including pipes or wrapping papers made with tobacco or hemp, other than a marijuana delivery device required for the medical use of marijuana and which is specified in a physician certification.

g. Must, upon dispensing the marijuana or marijuana delivery device, record in the registry the date, time, quantity, and form of marijuana dispensed; the type of marijuana delivery device dispensed; and the name and medical marijuana use registry identification number of the qualified patient or caregiver to whom the marijuana delivery device was dispensed.

h. Must ensure that patient records are not visible to anyone other than the qualified patient, his or her caregiver, and authorized medical marijuana treatment center employees.

(14) EXCEPTIONS TO OTHER LAWS.—

(e) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other law, but subject to the requirements of this section, the department, including an employee of the department acting within the scope of his or her employment, may acquire, possess, test, transport, and lawfully dispose of marijuana and marijuana delivery devices as provided in this section, in s. 381.988, and by department rule.

Section 4. Section 401.23, Florida Statutes, is amended to read:

401.23 Definitions.—As used in this part, the term:

(1) "Advanced life support" means assessment or treatment by a person certified ~~qualified~~ under this part to perform ~~through~~ the ~~use of~~ techniques ~~such as endotracheal intubation, the administration of drugs or intravenous fluids, telemetry, cardiac monitoring, cardiac defibrillation, and other techniques~~ described for the paramedic level in ~~the EMT-Paramedic National Standard Curriculum or~~ the United States Department of Transportation's National EMS Education Standards and approved by~~, pursuant to rules of the~~ department rule.

(2) "Advanced life support service" means any emergency medical services provider that offers or provides ~~transport or nontransport service which uses~~ advanced life support ~~techniques~~.

(3) "Air ambulance" means any fixed-wing or rotary-wing aircraft used for, or intended to be used by an emergency medical services provider to provide, advanced life support services and transportation of individuals receiving such services ~~for, air transportation of sick or injured persons requiring or likely to require medical attention during transport~~.

(4) "Air ambulance service" means any emergency medical services provider that offers or provides advanced life support from or onboard an air ambulance ~~publicly or privately owned service, licensed in accordance with the provisions of this part, which operates air ambulances to transport persons requiring or likely to require medical attention during transport~~.

(5) "Ambulance" or "emergency medical services vehicle" means any ~~privately or publicly owned~~ land or water vehicle or

air ambulance ~~that is designed, constructed, reconstructed, maintained, equipped, or operated for, and is~~ used by ~~for,~~ or intended to be used by an emergency medical services provider to provide basic or advanced life support services ~~for, land or water transportation of sick or injured persons requiring or likely to require medical attention during transport~~.

(6) "Ambulance driver" means any person who meets the requirements of s. 401.281.

(7) "Basic life support" means the assessment or treatment by a person certified ~~qualified~~ under this part to perform ~~through the use of~~ techniques described in the United States Department of Transportation's ~~EMT-Basic National Standard Curriculum or the~~ National EMS Education Standards ~~of the United States Department of Transportation~~ and approved by ~~the~~ department rule. The term includes the administration of oxygen and other techniques that have been approved and are performed under conditions specified by rules of the department.

(8) "Basic life support service" means any emergency medical services provider that offers or provides ~~service which uses~~ only basic life support ~~techniques~~.

(9) "Certification" means any authorization issued under ~~pursuant to~~ this part to a person to provide basic life support ~~act~~ as an emergency medical technician or to provide basic and advanced life support as a paramedic.

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

(11) "Emergency medical technician" means a person ~~who is~~ certified by the department under this part to provide ~~perform~~ basic life support under medical direction in any of the following settings: ~~pursuant to this part~~

(a) Local communities.

(b) Hospitals as defined in s. 395.002.

(c) Urgent care centers as defined in s. 395.002.

(d) Any other location specified by department rule.

(12) "Interfacility transfer" means the transportation by ambulance of a patient between two facilities licensed under chapter 393, chapter 395, chapter 400, or chapter 429 or other facilities as specified by department rule~~, pursuant to this part~~.

(13) "Licensee" means any basic life support service, advanced life support service, or air ambulance service licensed under ~~pursuant to~~ this part.

(14) "Medical direction" means oral instruction ~~direct supervision~~ by a physician in person or through two-way voice communication or, when such voice communication is unavailable, through ~~established~~ standing orders, pursuant to rules of the department.

(15) "Medical director" means a physician who is employed or contracted by a licensee and who provides medical direction ~~supervision~~, including ~~appropriate~~ quality assurance but not including administrative and managerial functions, for daily operations and training under ~~pursuant to~~ this part.

(16) "Mutual aid agreement" means a written agreement between two or more entities whereby the signing parties agree to lend aid to one another under conditions specified in the agreement and as authorized ~~sanctioned~~ by the governing body of each affected county.

(17) "Paramedic" means a person ~~who is~~ certified by the department under this part to provide ~~perform~~ basic and advanced

life support under medical direction in any of the following settings:

(a) Local communities.

(b) Hospitals as defined in s. 395.002.

(c) Urgent care centers as defined in s. 395.002.

(d) Any other location specified by department rule ~~pursuant to this part~~.

(18) "Permit" means any authorization issued under ~~pursuant to~~ this part for a vehicle to be operated as a basic life support or advanced life support transport vehicle or an advanced life support nontransport vehicle providing basic or advanced life support.

(19) "Physician" means a person ~~practitioner who is~~ licensed to practice medicine under ~~the provisions of~~ chapter 458 or osteopathic medicine under chapter 459. For the purpose of providing "medical direction" as defined in subsection (14) for the treatment of patients immediately before ~~prior to~~ or during transportation to a United States Department of Veterans Affairs medical facility, "physician" also means a person appointed to a physician position ~~practitioner employed~~ by the Secretary of the United States Department of Veterans Affairs.

(20) "Registered nurse" means a person ~~practitioner who is~~ licensed to practice professional nursing under ~~pursuant to~~ part I of chapter 464.

(21) "Service location" means any permanent location in or from which a licensee solicits, accepts, or conducts business under this part.

(22) "Volunteer ambulance service" means a faith-based, not-for-profit charitable corporation registered under chapter

617 which is licensed under this part as a basic life support service or an advanced life support service; which is not a parent, subsidiary, or affiliate of, or related to, any for-profit entity; and which uses only unpaid volunteers to provide basic life support services or advanced life support services free of charge, is not operating for pecuniary profit or financial gain, and does not distribute to or inure to the benefit of its directors, volunteers, members, or officers any part of its assets or income.

Section 5. Paragraph (d) of subsection (2) of section 401.25, Florida Statutes, is amended to read:

401.25 Licensure as a basic life support or an advanced life support service.—

(2) The department shall issue a license for operation to any applicant who complies with the following requirements:

(d) The applicant has obtained a certificate of public convenience and necessity from each county in which the applicant will operate. In issuing the certificate of public convenience and necessity, the governing body of each county shall consider the recommendations of municipalities within its jurisdiction. An applicant that is an active emergency medical ~~first~~ responder agency is exempt from this requirement if it:

1. Is a faith-based, not-for-profit charitable corporation registered under chapter 617 which has been responding to medical emergencies in this state for at least 10 consecutive years.

2. Is not a parent, subsidiary, or affiliate of, or related to, any for-profit entity.

3. Provides basic life support services or advanced life

support services solely through at least 50 unpaid licensed emergency medical technician or paramedic volunteers.

4. Is not operating for pecuniary profit or financial gain.

5. Does not distribute to or inure to the benefit of its directors, members, or officers any part of its assets or income.

6. Does not receive any government funding. However, the volunteer ambulance service may receive funding from specialty license plate proceeds.

7. Has never had a license denied, revoked, or suspended.

8. Provides services free of charge.

9. As part of its application for licensure, provides to the department a management plan that includes a training program, dispatch protocols, a complaint management system, an accident or injury handling system, a quality assurance program, and proof of adequate insurance coverage to meet state or county insurance requirements, whichever requirements are greater.

10. Provides a disclaimer on all written materials that the volunteer ambulance service is not associated with the state's 911 system.

The exemption under this paragraph may be granted to no more than four counties. This exemption notwithstanding, an applicant is not exempted from and must comply with all other requirements for licensure. An applicant must also take all reasonable efforts to enter into a memorandum of understanding with the emergency medical services licensee within whose jurisdiction the applicant will provide services in order to facilitate communications and coordinate emergency services for situations

beyond the scope of the applicant's capacity and for situations of advanced life support that are deemed priority 1 or priority 2 emergencies.

Section 6. Subsections (3), (4), and (5) of section 401.27, Florida Statutes, are amended to read:

401.27 Personnel; standards and certification.—

(3) Any person who desires to be certified or recertified as an emergency medical technician or paramedic must apply to the department ~~under oath~~ on forms provided by the department which shall contain such information as the department reasonably requires, which may include affirmative evidence of ability to comply with applicable laws and rules. 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.

(4) An applicant for certification or recertification as an emergency medical technician or paramedic must:

(a) Have completed an appropriate training program as follows:

1. For an emergency medical technician, an emergency medical technician training program approved by the department as equivalent to the most recent ~~EMT-Basic National Standard Curriculum or the~~ National EMS Education Standards of the United States Department of Transportation;

2. For a paramedic, a paramedic training program approved by the department as equivalent to the most recent ~~EMT-Paramedic National Standard Curriculum or the~~ National EMS Education Standards of the United States Department of Transportation;

(b) Confirm ~~Certify under oath~~ that he or she is not addicted to alcohol or any controlled substance;

(c) Confirm ~~Certify under oath~~ that he or she is free from any physical or mental defect or disease that might impair the applicant's ability to perform his or her duties;

(d) Within 2 years after program completion have passed an examination developed or required by the department;

(e)1. For an emergency medical technician, hold a current American Heart Association cardiopulmonary resuscitation course card or an American Red Cross cardiopulmonary resuscitation course card or its equivalent as defined by department rule;

2. For a paramedic, hold a certificate of successful course completion in advanced cardiac life support from the American Heart Association or its equivalent as defined by department rule;

(f) Submit to the department the application ~~the certification~~ fee ~~and the nonrefundable examination fee~~ prescribed in s. 401.34, and submit to the examination provider the nonrefundable ~~which~~ examination fee ~~will be~~ required for each examination administered to an applicant; and

(g) Submit a completed application to the department, which application documents compliance with paragraphs (a), (b), (c), (e), (f), and this paragraph, and, if applicable, paragraph (d). ~~The application must be submitted so as to be received by the department at least 30 calendar days before the next regularly scheduled examination for which the applicant desires to be scheduled.~~

~~(5) The certification examination must be offered monthly. The department shall issue an examination admission notice to~~

~~the applicant advising him or her of the time and place of the examination for which he or she is scheduled. Individuals achieving a passing score on the certification examination may be issued a temporary certificate with their examination grade report. The department must issue an original certification within 45 days after the examination. Examination questions and answers are not subject to discovery but may be introduced into evidence and considered only in camera in any administrative proceeding under chapter 120. If an administrative hearing is held, the department shall provide challenged examination questions and answers to the administrative law judge. The department shall establish by rule the procedure by which an applicant, and the applicant's attorney, may review examination questions and answers in accordance with s. 119.071(1)(a).~~

Section 7. Section 401.2701, Florida Statutes, is amended to read:

401.2701 Emergency medical services training programs.—

(1) Any private or public institution in Florida desiring to conduct an approved program for the education of emergency medical technicians and paramedics must ~~shall~~:

(a) Submit a completed application on a form adopted ~~provided~~ by ~~the~~ department rule, which must include:

1. Evidence that the institution is in compliance with all applicable requirements of the Department of Education.

2. Evidence of an affiliation agreement with a hospital that has an emergency department staffed by at least one physician and one registered nurse.

3. Evidence of an affiliation agreement with a current emergency medical services provider that is licensed in this

state. Such agreement shall include, at a minimum, a commitment by the provider to conduct the field experience portion of the education program. Evidence of an affiliation agreement is not required if the applicant is licensed by the department as an advanced life support service.

4. Documentation verifying faculty, including:

a. A medical director who is a licensed physician meeting the applicable requirements for emergency medical services medical directors as outlined in this chapter and rules of the department. The medical director shall have the duty and responsibility of certifying that graduates have successfully completed all phases of the education program and are proficient in basic or advanced life support techniques, as applicable.

b. A program director responsible for the operation, organization, periodic review, administration, development, and approval of the program.

5. Documentation verifying that the curriculum:

a. Meets the most recent ~~Emergency Medical Technician-Basic National Standard Curriculum or the~~ National EMS Education Standards approved by the department ~~for emergency medical technician programs and Emergency Medical Technician-Paramedic National Standard Curriculum or the National EMS Education Standards approved by the department for paramedic programs~~.

b. Includes 2 hours of instruction on the trauma scorecard methodologies for assessment of adult trauma patients and pediatric trauma patients as specified by the department by rule.

6. Evidence of sufficient medical and educational equipment to meet emergency medical services training program needs.

(b) Receive a scheduled in-person or department-approved remote audio-visual site visit from the department to the applicant's institution~~. Such site visit shall be conducted~~ within 30 days after the department's notification to the institution that the application was accepted for onsite review. During the site visit, the department must determine the applicant's compliance with the following criteria:

1. Emergency medical technician programs must be a minimum of 300 ~~110~~ hours, with at least 20 hours of supervised clinical supervision, including 10 hours in a hospital emergency department.

2. Paramedic programs must be available only to Florida-certified emergency medical technicians or ~~an~~ emergency medical technicians, active duty and reserve military-trained emergency medical technicians, and emergency medical technician applicants ~~applicant~~ who will obtain Florida certification before ~~prior to~~ completion of phase one of the paramedic program. Paramedic programs must be a minimum of 1,100 ~~700~~ hours of didactic and skills practice components, with the skills laboratory student-to-instructor ratio not exceeding six to one. Paramedic programs must provide a field internship experience aboard an advanced life support permitted ambulance. However, a portion of the field internship experience may be satisfied aboard an advanced life support permitted vehicle other than an ambulance or by supervised, remote live videoconferencing together with simulated direct patient contact in a simulated advanced life support ambulance as provided ~~determined~~ by ~~rule of the~~ department rule.

(2) A program may request department approval to substitute

simulation and remote, live videoconferencing for supervised in-person clinical instruction and direct patient-contact skills laboratory requirements. Requests must be made in writing and include the following:

(a) The written approval of the training program medical director.

(b) Documentation that all hospitals or emergency medical services providers with whom the program has an existing affiliation agreement have suspended in-person access for purposes of supervised clinical instruction and direct patient-contact field internships.

(c) The time period during which in-person access has been suspended.

(d) Documentation of the design, development, and implementation of simulation and videoconferencing training.

(e) Documentation of the inclusion of simulation and videoconferencing within the curriculum, the efficacy of simulation and videoconferencing, and student evaluations of simulation, debriefing, and videoconferencing.

(3) After completion of the site visit, the department shall prepare a report that must ~~which shall~~ be provided to the institution. Upon completion of the report, an ~~the~~ application from a program that meets the criteria in paragraph (1)(b) is ~~shall be~~ deemed complete, and ~~the provisions of~~ s. 120.60 applies. An application from a program that does not meet the criteria in paragraph (1)(b) is deemed incomplete, and subsection (5) applies ~~shall apply~~.

(4)~~(3)~~ If the program is approved, the department must issue the institution a 2-year certificate of approval as an

emergency medical technician training program or a paramedic training program. The department shall renew the certificate of approval upon receipt of a written statement from the program attesting that the training program continues to meet the requirements of the Department of Education and remains accredited by a national organization recognized by the department. The department shall perform a site visit for all initial nonaccredited programs. The department may periodically and randomly perform in-person and remote telecommunication inspection site visits to ensure compliance with this part and department rules.

(5) If an ~~the~~ application is deemed incomplete ~~denied~~, the department must notify the applicant of any errors, omissions, and ~~areas of strength,~~ areas needing improvement~~,~~ and any suggested means of improving ~~improvement of~~ the program. The applicant must respond within 5 days after receiving the department's notice either with a notice of intent to provide a plan of correction or a request for the department to proceed with a final determination on the application without a plan of correction. A ~~denial notification shall be provided to the applicant so as to allow the applicant 5 days prior to the expiration of the application processing time in s. 120.60 to advise the department in writing of its intent to submit a plan of correction. Such intent notification shall provide the time for application processing in s. 120.60. The~~ plan of correction must be received by ~~submitted to~~ the department within 30 days after the date of the applicant's notice of intent and must specify the date by which the applicant intends to complete the application ~~of the notice~~. The department shall notify ~~advise~~

the applicant of its approval or denial of the plan of correction within 30 days after ~~of~~ receipt. The denial of the plan of correction or denial of the application may be reviewed as provided in chapter 120.

(6)~~(4)~~ Approved emergency medical services training programs must maintain records and reports that must be made available to the department, upon written request. Such records must include student applications, records of attendance, records of participation in hospital clinic and field training, medical records, course objectives and outlines, class schedules, learning objectives, lesson plans, number of applicants, number of students accepted, admission requirements, description of qualifications, duties and responsibilities of faculty, and correspondence.

(7)~~(5)~~ Each approved program must notify the department within 30 days after any change in the professional or employment status of faculty. Each approved program must require its students to pass a comprehensive final written and practical examination evaluating the skills described in the current United States Department of Transportation EMT-Basic or EMT-Paramedic National Standard Curriculum or the National EMS Education Standards and approved by the department. Each approved program must issue a certificate of completion to program graduates within 14 days after completion.

Section 8. Section 401.272, Florida Statutes, is amended to read:

401.272 Emergency medical services community health care.—

(1) The purpose of this section is to encourage more effective use ~~utilization~~ of the skills of emergency medical

technicians and paramedics by enabling them to perform, in partnership with local county health departments, specific additional health care tasks that are consistent with the public health and welfare.

(2) Notwithstanding any other ~~provision of~~ law to the contrary:

(a) Paramedics or emergency medical technicians may perform health promotion and wellness activities ~~and blood pressure screenings~~ in a nonemergency environment, within the scope of their training, and under medical direction ~~the direction of a medical director~~. As used in this paragraph, the term "health promotion and wellness" means the provision of public health programs pertaining to the prevention of illness and injury.

(b) Paramedics may administer immunizations and other public health countermeasures in a nonemergency environment, within the scope of their training, and under medical ~~the~~ direction ~~of a medical director~~. There must be a written agreement between the paramedic's medical director and the department or the county health department located in each county in which the paramedic administers immunizations or other public health countermeasures. This agreement must establish the protocols, policies, and procedures under which the paramedic must operate.

(3) Each medical director under whose direction a paramedic administers immunizations or other public health countermeasures must verify and document that the paramedic has received sufficient training and experience to administer the immunizations or other public health countermeasures, as applicable. The verification must be documented on forms

developed by the department, and the completed forms must be maintained at the service location of the licensee and made available to the department upon request.

(4) The department may adopt and enforce all rules necessary to enforce the provisions relating to a paramedic's administration of immunizations and other public health countermeasures and the performance of health promotion and wellness activities ~~and blood pressure screenings~~ by a paramedic or emergency medical technician in a nonemergency environment.

Section 9. Subsections (1), (2), and (4) of section 401.30, Florida Statutes, are amended to read:

401.30 Records.—

(1) Each licensee must maintain accurate records of emergency calls on written or electronic forms that contain such information as is required by the department. The written or electronic ~~These~~ records must be available for inspection by the department at any reasonable time, and paper or electronic copies thereof must be furnished to the department upon request. The department shall prescribe by rule the ~~give each licensee notice of what~~ information such forms must contain.

(2) Each licensee must provide the receiving facility ~~hospital~~ with a copy of an individual patient care record for each patient ~~who is~~ transported to the receiving facility ~~hospital~~. The information contained in the patient care record and the method and timeframe for providing the record shall be prescribed by department rule ~~of the department~~.

(4) Records of emergency calls which contain patient examination or treatment information are confidential and exempt from the provisions of s. 119.07(1) and may not be disclosed

without the consent of the person to whom they pertain, but appropriate limited disclosure may be made without such consent:

(a) To the person's guardian as defined in s. 744.102, to the person's designated surrogate as defined in s. 765.101, to the person's personal representative or trustee as those terms are defined in s. 731.201 ~~to the next of kin~~ if the person is deceased, or to a minor's principal as defined in s. 765.101 ~~parent if the person is a minor~~;

(b) To facility ~~hospital~~ personnel for use in conjunction with the treatment of the patient;

(c) To the department;

(d) To the emergency medical services provider ~~service~~ medical director;

(e) For use in a critical incident stress debriefing. Any such discussions during a critical incident stress debriefing shall be considered privileged communication under s. 90.503;

(f) In any civil or criminal action, unless otherwise prohibited by law, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice by the party seeking such records, to the patient or his or her legal representative; or

(g) To a local trauma agency or a regional trauma agency, or a panel or committee assembled by such an agency to assist the agency in performing quality assurance activities in accordance with a plan approved under s. 395.401. Records obtained under this paragraph are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

Notwithstanding any other law to the contrary, the release of

patient care records or data from patient care records must be in accordance with s. 401.425 and chapter 405. This subsection does not prohibit the department or a licensee from providing information to any law enforcement agency or any other regulatory agency responsible for the regulation or supervision of emergency medical services and personnel.

Section 10. Subsections (4) through (7) of section 401.34, Florida Statutes, are amended to read:

401.34 Fees.—

(4)(a) If a certificate, license, or permit issued under this part is lost or destroyed, the person or entity to whom the certificate, license, or permit was issued may, upon payment of a fee to be set by the department not to exceed $10, obtain a ~~duplicate, or~~ substitute thereof.

(b) Upon surrender of the original emergency medical technician or paramedic certificate and receipt of a replacement fee to be set by the department not to exceed $10, the department shall issue a replacement certificate to make a change in name.

~~(5) The department may provide same-day grading of the examination for an applicant for emergency medical technician or paramedic certification.~~

~~(6) The department may offer walk-in eligibility determination and examination to applicants for emergency medical technician or paramedic certification who pay to the department a nonrefundable fee to be set by the department not to exceed $65. The fee is in addition to the certification fee and examination fee. The department must establish locations and times for eligibility determination and examination.~~

~~(7) The cost of emergency medical technician or paramedic certification examination review may not exceed $50.~~

Section 11. Subsection (5) of section 401.425, Florida Statutes, is amended, and subsection (8) is added to that section, to read:

401.425 Emergency medical services quality assurance; immunity from liability.—

(5) The records or reports obtained or produced by a committee providing quality assurance or quality improvement activities as described in subsections (1)-(4) are exempt from ~~the provisions of~~ s. 119.07(1) and s. 24(a), Art. I of the State Constitution, and committee proceedings and meetings regarding quality assurance or quality improvement activities are exempt from ~~the provisions of~~ s. 286.011 and s. 24(b), Art. I of the State Constitution. The investigations, proceedings, and records of a committee providing quality assurance activities as described in subsections (1)-(4) are ~~shall~~ not ~~be~~ subject to discovery or introduction into evidence in any civil action or disciplinary proceeding by the department or employing agency arising out of matters that ~~which~~ are the subject of evaluation and review by the committee, and a ~~no~~ person who was in attendance at a meeting of such committee may not ~~shall~~ be permitted or required to testify in any such civil action or disciplinary proceeding as to any evidence or other matters produced or presented during the proceedings of such committee or as to any findings, recommendations, evaluations, opinions, or other actions of such committee or any members thereof. However, information, documents, or records provided to the committee from sources external to the committee are not immune

from discovery or use in any such civil action or disciplinary proceeding merely because they were presented during proceedings of such committee, nor may ~~should~~ any person who testifies before a committee or who is a member of such committee be prevented from testifying as to matters within the person's knowledge, but, such witness may ~~shall~~ not be asked about his or her testimony before a committee or information obtained from or opinions formed by him or her as a result of participating in activities conducted by a committee.

(8) An emergency medical review committee may review the performance of an emergency medical technician, a paramedic, or an emergency medical services provider and make recommendations for performance improvement.

Section 12. Section 401.435, Florida Statutes, is amended to read:

401.435 Emergency medical ~~First~~ responder agencies and training.—

(1) The department must adopt by rule the United States Department of Transportation National EMS Education Standards for the Emergency Medical Responder level ~~Services: First Responder Training Course~~ as the minimum standard for emergency medical ~~first~~ responder training. In addition, the department must adopt rules establishing minimum emergency medical ~~first~~ responder instructor qualifications. For purposes of this section, an emergency medical ~~a first~~ responder includes any individual who receives training to render initial care to an ill or injured person, other than an individual trained and certified pursuant to s. 943.1395(1), but who does not have the primary responsibility of treating and transporting ill or

injured persons.

(2) Each emergency medical ~~first~~ responder agency must take all reasonable efforts to enter into a memorandum of understanding with the emergency medical services licensee within whose territory the agency operates in order to coordinate emergency services at an emergency scene. The department must provide a model memorandum of understanding for this purpose. The memorandum of understanding must ~~should~~ include dispatch protocols, the roles and responsibilities of emergency medical ~~first~~ responder personnel at an emergency scene, and the documentation required for patient care rendered. For purposes of this section, the term "emergency medical ~~first~~ responder agency" includes a law enforcement agency, a fire service agency not licensed under this part, a lifeguard agency, and a volunteer organization that renders, as part of its routine functions, on-scene patient care before emergency medical technicians or paramedics arrive.

Section 13. Subsection (1) of section 460.406, Florida Statutes, is amended to read:

460.406 Licensure by examination.—

(1) Any person desiring to be licensed as a chiropractic physician must apply to the department to take the licensure examination. There shall be an application fee set by the board not to exceed $100 which shall be nonrefundable. There shall also be an examination fee not to exceed $500 plus the actual per applicant cost to the department for purchase of portions of the examination from the National Board of Chiropractic Examiners or a similar national organization, which may be refundable if the applicant is found ineligible to take the

examination. The department shall examine each applicant whom ~~who~~ the board certifies has met all of the following criteria:

(a) Completed the application form and remitted the appropriate fee.

(b) Submitted proof satisfactory to the department that he or she is not less than 18 years of age.

(c) Submitted proof satisfactory to the department that he or she is a graduate of a chiropractic college which is accredited by or has status with the Council on Chiropractic Education or its predecessor agency. However, any applicant who is a graduate of a chiropractic college that was initially accredited by the Council on Chiropractic Education in 1995, who graduated from such college within the 4 years immediately preceding such accreditation, and who is otherwise qualified is ~~shall be~~ eligible to take the examination. An ~~No~~ application for a license to practice chiropractic medicine may not ~~shall~~ be denied solely because the applicant is a graduate of a chiropractic college that subscribes to one philosophy of chiropractic medicine as distinguished from another.

(d)1. For an applicant who has matriculated in a chiropractic college before ~~prior to~~ July 2, 1990, completed at least 2 years of residence college work, consisting of a minimum of one-half the work acceptable for a bachelor's degree granted on the basis of a 4-year period of study, in a college or university accredited by an institutional accrediting agency recognized and approved by the United States Department of Education. However, before ~~prior to~~ being certified by the board to sit for the examination, each applicant who has matriculated in a chiropractic college after July 1, 1990, must ~~shall~~ have

been granted a bachelor's degree, based upon 4 academic years of study, by a college or university accredited by an institutional ~~a regional~~ accrediting agency that ~~which~~ is a member of the Commission on Recognition of Postsecondary Accreditation.

2. Effective July 1, 2000, completed, before ~~prior to~~ matriculation in a chiropractic college, at least 3 years of residence college work, consisting of a minimum of 90 semester hours leading to a bachelor's degree in a liberal arts college or university accredited by an institutional accrediting agency recognized and approved by the United States Department of Education. However, before ~~prior to~~ being certified by the board to sit for the examination, each applicant who has matriculated in a chiropractic college after July 1, 2000, must ~~shall~~ have been granted a bachelor's degree from an institution holding accreditation for that degree from an institutional ~~a regional~~ accrediting agency that ~~which~~ is recognized by the United States Department of Education. The applicant's chiropractic degree must consist of credits earned in the chiropractic program and may not include academic credit for courses from the bachelor's degree.

(e) Successfully completed the National Board of Chiropractic Examiners certification examination in parts I, II, III, and IV, and the physiotherapy examination of the National Board of Chiropractic Examiners, with a score approved by the board.

(f) Submitted to the department a set of fingerprints on a form and under procedures specified by the department, along with payment in an amount equal to the costs incurred by the Department of Health for the criminal background check of the

applicant.

The board may require an applicant who graduated from an institution accredited by the Council on Chiropractic Education more than 10 years before the date of application to the board to take the National Board of Chiropractic Examiners Special Purposes Examination for Chiropractic, or its equivalent, as determined by the board. The board shall establish by rule a passing score.

Section 14. Subsection (4) of section 464.008, Florida Statutes, is amended to read:

464.008 Licensure by examination.—

~~(4) If an applicant who graduates from an approved program does not take the licensure examination within 6 months after graduation, he or she must enroll in and successfully complete a board-approved licensure examination preparatory course. The applicant is responsible for all costs associated with the course and may not use state or federal financial aid for such costs. The board shall by rule establish guidelines for licensure examination preparatory courses.~~

Section 15. Paragraph (e) of subsection (1) of section 464.018, Florida Statutes, is amended 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:

(e) Having been found guilty of~~, regardless of adjudication,~~ or entered a plea of nolo contendere or guilty to, regardless of adjudication, any offense prohibited under s.

435.04 or similar statute of another jurisdiction; or having committed an act which constitutes domestic violence as defined in s. 741.28.

Section 16. Present subsections (13) and (14) of section 467.003, Florida Statutes, are redesignated as subsections (14) and (15), respectively, a new subsection (13) is added to that section, and subsections (1) and (12) of that section are amended, to read:

467.003 Definitions.—As used in this chapter, unless the context otherwise requires:

(1) "Approved midwifery program" means ~~a midwifery school or~~ a midwifery training program ~~which is~~ approved by the department pursuant to s. 467.205.

(12) "Preceptor" means a physician licensed under chapter 458 or chapter 459, a ~~licensed~~ midwife licensed under this chapter, or a certified nurse midwife licensed under chapter 464~~,~~ who has a minimum of 3 years' professional experience~~,~~ and who directs, teaches, supervises, and evaluates the learning experiences of a ~~the~~ student midwife as part of an approved midwifery program.

(13) "Prelicensure course" means a course of study, offered by an approved midwifery program and approved by the department, which an applicant for licensure must complete before a license may be issued and which provides instruction in the laws and rules of this state and demonstrates the student's competency to practice midwifery under this chapter.

Section 17. Section 467.009, Florida Statutes, is amended to read:

467.009 Approved midwifery programs; education and training

requirements.—

(1) The department shall adopt standards for approved midwifery programs which must include, but need not be limited to, standards for all of the following:

(a) ~~. The standards shall encompass~~ Clinical and classroom instruction in all aspects of prenatal, intrapartal, and postpartal care, including all of the following:

1. Obstetrics.~~;~~

2. Neonatal pediatrics.~~;~~

3. Basic sciences.~~;~~

4. Female reproductive anatomy and physiology.~~;~~

5. Behavioral sciences.~~;~~

6. Childbirth education.~~;~~

7. Community care.~~;~~

8. Epidemiology.~~;~~

9. Genetics.~~;~~

10. Embryology.~~;~~

11. Neonatology.~~;~~

12. Applied pharmacology.~~;~~

13. The medical and legal aspects of midwifery.~~;~~

14. Gynecology and women's health.~~;~~

15. Family planning.~~;~~

16. Nutrition during pregnancy and lactation.~~;~~

17. Breastfeeding.~~; and~~

18. Basic nursing skills~~; and any other instruction determined by the department and council to be necessary~~.

(b) ~~The standards shall incorporate the~~ Core competencies, incorporating those established by the American College of Nurse Midwives and the Midwives Alliance of North America, including

knowledge, skills, and professional behavior in all of the following areas:

1. Primary management, collaborative management, referral, and medical consultation.~~;~~

2. Antepartal, intrapartal, postpartal, and neonatal care.~~;~~

3. Family planning and gynecological care.~~;~~

4. Common complications.~~; and~~

5. Professional responsibilities.

(c) Noncurricular ~~The standards shall include noncurriculum~~ matters under this section, including, but not limited to, staffing and teacher qualifications.

(2) An approved midwifery program must offer ~~shall include~~ a course of study ~~and clinical training~~ for a minimum of 3 years which incorporates all of the standards, curriculum guidelines, and educational objectives provided in this section and the rules adopted hereunder.

(3) An approved midwifery program may reduce ~~If the applicant is a registered nurse or a licensed practical nurse or has previous nursing or midwifery education,~~ the required period of training ~~may be reduced~~ to the extent of the student's ~~applicant's~~ qualifications as a registered nurse or licensed practical nurse or based on prior completion of equivalent nursing or midwifery education, as determined ~~under rules adopted~~ by ~~the~~ department rule~~. In no case shall the training be reduced to a period of less than 2 years~~.

(4)~~(3)~~ An approved midwifery program may accept students who ~~To be accepted into an approved midwifery program, an applicant shall~~ have both:

(a) A high school diploma or its equivalent.

(b) Taken three college-level credits each of math and English or demonstrated competencies in communication and computation.

(5) ~~(4)~~ As part of its course of study, an approved midwifery program must require clinical training that includes all of the following:

(a) ~~A student midwife, during training, shall undertake, under the supervision of a preceptor,~~ The care of 50 women in each of the prenatal, intrapartal, and postpartal periods under the supervision of a preceptor.~~, but~~ The same women need not be seen through all three periods.

(b) ~~(5)~~ Observation of ~~The student midwife shall observe~~ an additional 25 women in the intrapartal period ~~before qualifying for a license~~.

(6) Clinical ~~The~~ training required under this section must include all of the following:

(a) ~~shall include~~ Training in ~~either~~ hospitals or alternative birth settings, or both.

(b) A requirement that students demonstrate competency in the assessment of and differentiation~~, with particular emphasis on learning the ability to differentiate~~ between low-risk pregnancies and high-risk pregnancies.

(7) A hospital or birthing center receiving public funds shall be required to provide student midwives access to observe labor, delivery, and postpartal procedures, provided the woman in labor has given informed consent. The Department of Health shall assist in facilitating access to hospital training for approved midwifery programs.

(8) ~~(7)~~ The Department of Education shall adopt curricular

frameworks for midwifery programs offered by ~~conducted within~~ public educational institutions under ~~pursuant to~~ this section.

~~(8) Nonpublic educational institutions that conduct approved midwifery programs shall be accredited by a member of the Commission on Recognition of Postsecondary Accreditation and shall be licensed by the Commission for Independent Education.~~

Section 18. Section 467.011, Florida Statutes, is amended to read:

467.011 Licensed midwives; qualifications; examination ~~Licensure by examination.~~

~~(1) The department shall administer an examination to test the proficiency of applicants in the core competencies required to practice midwifery as specified in s. 467.009.~~

~~(2) The department shall develop, publish, and make available to interested parties at a reasonable cost a bibliography and guide for the examination.~~

~~(3)~~ The department shall issue a license to practice midwifery to an applicant who meets all of the following criteria:

(1) Demonstrates that he or she has graduated from one of the following:

(a) An approved midwifery program.

(b) A medical or midwifery program offered in another state, jurisdiction, territory, or country whose graduation requirements were equivalent to or exceeded those required by s. 467.009 and the rules adopted thereunder at the time of graduation.

(2) Demonstrates that he or she has ~~and~~ successfully completed a prelicensure course offered by an approved midwifery

program. Students graduating from an approved midwifery program may meet this requirement by showing that the content requirements for the prelicensure course were covered as part of their course of study.

(3) Submits an application for licensure on a form approved by the department and pays the appropriate fee.

(4) Demonstrates that he or she has received a passing score on an ~~the~~ examination specified by the department~~, upon payment of the required licensure fee~~.

Section 19. Section 467.0125, Florida Statutes, is amended to read:

467.0125 Licensed midwives; qualifications; ~~Licensure by~~ endorsement; temporary certificates.—

(1) The department shall issue a license by endorsement to practice midwifery to an applicant who, upon applying to the department, demonstrates to the department that she or he meets all of the following criteria:

(a)~~1. Holds a valid certificate or diploma from a foreign institution of medicine or midwifery or from a midwifery program offered in another state, bearing the seal of the institution or otherwise authenticated, which renders the individual eligible to practice midwifery in the country or state in which it was issued, provided the requirements therefor are deemed by the department to be substantially equivalent to, or to exceed, those established under this chapter and rules adopted under this chapter, and submits therewith a certified translation of the foreign certificate or diploma; or~~

~~2.~~ Holds an active, unencumbered ~~a valid certificate or~~ license to practice midwifery in another state, jurisdiction, or

territory ~~issued by that state~~, provided the licensing requirements of that state, jurisdiction, or territory at the time the license was issued were ~~therefor are deemed by the department to be~~ substantially equivalent to~~,~~ or exceeded ~~to exceed,~~ those established under this chapter and the rules adopted hereunder ~~under this chapter~~.

(b) Has successfully completed a ~~4-month~~ prelicensure course conducted by an approved midwifery program ~~and has submitted documentation to the department of successful completion~~.

(c) Submits an application for licensure on a form approved by the department and pays the appropriate fee ~~Has successfully passed the licensed midwifery examination~~.

(2) The department may issue a temporary certificate to practice in areas of critical need to an applicant ~~any midwife~~ who is qualifying for a midwifery license ~~licensure by endorsement~~ under subsection (1) and who meets all of the following criteria~~, with the following restrictions~~:

(a) Submits an application for a temporary certificate on a form approved by the department and pays the appropriate fee, which may not exceed $50 and is in addition to the fee required for licensure by endorsement under subsection (1).

(b) Specifies on the application that he or she will ~~The Department of Health shall determine the areas of critical need, and the midwife so certified shall~~ practice only in one or more of the following locations:

1. A county health department.

2. A correctional facility.

3. A United States Department of Veterans Affairs clinic.

4. A community health center funded by s. 329, s. 330, or s. 340 of the Public Health Service Act.

5. Any other agency or institution that is approved by the State Surgeon General and provides health care to meet the needs of an underserved population in this state.

(c) Will practice only ~~those specific areas,~~ under the supervision ~~auspices~~ of a physician licensed under ~~pursuant to~~ chapter 458 or chapter 459, a certified nurse midwife licensed under ~~pursuant to~~ part I of chapter 464, or a midwife licensed under this chapter~~,~~ who has a minimum of 3 years' professional experience.

(3) The department may issue a temporary certificate under this section with the following restrictions:

(a) A requirement that a temporary certificateholder practice only in areas of critical need. The State Surgeon General shall determine the areas of critical need, which ~~Such areas shall~~ include, but are not ~~be~~ limited to, health professional shortage areas designated by the United States Department of Health and Human Services.

(b) A requirement that if a temporary certificateholder's practice area ceases to be an area of critical need, within 30 days after such change the certificateholder must either:

1. Report a new practice area of critical need to the department; or

2. Voluntarily relinquish the temporary certificate.

(4) The department shall review a temporary certificateholder's practice at least annually to determine whether the certificateholder is meeting the requirements of subsections (2) and (3) and the rules adopted thereunder. If the

department determines that a certificateholder is not meeting these requirements, the department must revoke the temporary certificate.

(5) A temporary certificate issued under this section is ~~shall be~~ valid ~~only as long as an area~~ for ~~which it is issued remains an area of critical need, but no longer than~~ 2 years~~,~~ and is ~~shall~~ not ~~be~~ renewable.

~~(c) The department may administer an abbreviated oral examination to determine the midwife's competency, but no written regular examination shall be necessary.~~

~~(d) The department shall not issue a temporary certificate to any midwife who is under investigation in another state for an act which would constitute a violation of this chapter until such time as the investigation is complete, at which time the provisions of this section shall apply.~~

~~(e) The department shall review the practice under a temporary certificate at least annually to ascertain that the minimum requirements of the midwifery rules promulgated under this chapter are being met. If it is determined that the minimum requirements are not being met, the department shall immediately revoke the temporary certificate.~~

~~(f) The fee for a temporary certificate shall not exceed $50 and shall be in addition to the fee required for licensure.~~

Section 20. Section 467.205, Florida Statutes, is amended to read:

467.205 Approval of midwifery programs.—

(1) The department must approve an accredited or state-licensed public or private institution seeking to provide midwifery education and training as an approved midwifery

program in this state if the institution meets all of the following criteria:

(a) Submits an application for approval on a form approved by the department.

(b) Demonstrates to the department's satisfaction that the proposed midwifery program complies with s. 467.009 and the rules adopted thereunder.

(c) For a private institution, demonstrates its accreditation by a member of the Council for Higher Education Accreditation or an accrediting agency approved by the United States Department of Education and its licensing or provisional licensing by the Commission for Independent Education ~~An organization desiring to conduct an approved program for the education of midwives shall apply to the department and submit such evidence as may be required to show that it complies with s. 467.009 and with the rules of the department. Any accredited or state-licensed institution of higher learning, public or private, may provide midwifery education and training.~~

~~(2) The department shall adopt rules regarding educational objectives, faculty qualifications, curriculum guidelines, administrative procedures, and other training requirements as are necessary to ensure that approved programs graduate midwives competent to practice under this chapter.~~

~~(3) The department shall survey each organization applying for approval. If the department is satisfied that the program meets the requirements of s. 467.009 and rules adopted pursuant to that section, it shall approve the program~~.

(2) ~~(4)~~ The department shall, at least once every 3 years, certify whether each approved midwifery program is currently

compliant, and has maintained compliance, ~~complies~~ with the requirements of ~~standards developed under~~ s. 467.009 and the rules adopted thereunder.

(3) ~~(5)~~ If the department finds that an approved midwifery program is not in compliance with the requirements of s. 467.009 or the rules adopted thereunder, or has lost its accreditation status, the department must provide its finding to the program in writing and ~~no longer meets the required standards, it~~ may place the program on probationary status for a specified period of time, which may not exceed 3 years ~~until such time as the standards are restored~~.

(4) If a program on probationary status does not come into compliance with the requirements of s. 467.009 or the rules adopted thereunder, or regain its accreditation status, as applicable, within the period specified by the department ~~fails to correct these conditions within a specified period of time~~, the department may rescind the program's approval.

(5) A ~~Any~~ program that has ~~having~~ its approval rescinded has ~~shall have~~ the right to reapply for approval.

(6) The department may grant provisional approval of a new program seeking accreditation status, for a period not to exceed 5 years, provided that all other requirements of this section are met.

(7) The department may rescind provisional approval of a program that fails to meet the requirements of s. 467.009, this section, or the rules adopted thereunder, in accordance with procedures provided in subsections (3) and (4) ~~may be granted pending the licensure results of the first graduating class~~.

Section 21. Subsections (2), (3), and (4) and paragraphs

(a) and (b) of subsection (5) of section 468.803, Florida Statutes, are amended to read:

468.803 License, registration, and examination requirements.—

(2) An applicant for registration, examination, or licensure must apply to the department on a form prescribed by the board for consideration of board approval. Each initial applicant shall submit ~~a set of~~ fingerprints to the department in accordance with ~~on a form and under~~ procedures specified by the department~~, along with payment in an amount equal to the costs incurred by the department~~ for state and national criminal history checks of the applicant. ~~The department shall submit the fingerprints provided by an applicant to the Department of Law Enforcement for a statewide criminal history check, and the Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check of the applicant.~~ The board shall screen the results to determine if an applicant meets licensure requirements. The board shall consider for examination, registration, or licensure each applicant whom ~~who~~ the board verifies:

(a) Has submitted the completed application and completed the fingerprinting requirements ~~fingerprint forms~~ and has paid the applicable application fee, not to exceed $500~~, and the cost of the state and national criminal history checks~~. The application fee is ~~and cost of the criminal history checks shall be~~ nonrefundable;

(b) Is of good moral character;

(c) Is 18 years of age or older; and

(d) Has completed the appropriate educational preparation.

(3) A person seeking to attain the orthotics or prosthetics experience required for licensure in this state must be approved by the board and registered as a resident by the department. Although a registration may be held in both disciplines, for independent registrations the board may not approve a second registration until at least 1 year after the issuance of the first registration. Notwithstanding subsection (2), a person who has been approved by the board and registered by the department in one discipline may apply for registration in the second discipline without an additional state or national criminal history check during the period in which the first registration is valid. Each independent registration or dual registration is valid for 2 years after the date of issuance unless otherwise revoked by the department upon recommendation of the board. The board shall set a registration fee not to exceed $500 to be paid by the applicant. A registration may be renewed once by the department upon recommendation of the board for a period no longer than 1 year, as such renewal is defined by ~~the~~ board ~~by~~ rule. The renewal fee may not exceed one-half the current registration fee. To be considered by the board for approval of registration as a resident, the applicant must have one of the following:

(a) A Bachelor of Science or higher-level postgraduate degree in orthotics and prosthetics from an ~~a regionally~~ accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs.

(b) A minimum of a bachelor's degree from an institutionally ~~a regionally~~ accredited college or university

and a certificate in orthotics or prosthetics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board.

(c) A minimum of a bachelor's degree from an institutionally ~~a regionally~~ accredited college or university and a dual certificate in both orthotics and prosthetics from programs recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board.

(4) The department may develop and administer a state examination for an orthotist or a prosthetist license, or the board may approve the existing examination of a national standards organization. The examination must be predicated on a minimum of a baccalaureate-level education and formalized specialized training in the appropriate field. Each examination must demonstrate a minimum level of competence in basic scientific knowledge, written problem solving, and practical clinical patient management. The board shall require an examination fee not to exceed the actual cost to the board in developing, administering, and approving the examination, which fee must be paid by the applicant. To be considered by the board for examination, the applicant must have:

(a) For an examination in orthotics:

1. A Bachelor of Science or higher-level postgraduate degree in orthotics and prosthetics from an institutionally ~~a regionally~~ accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs or, at a minimum, a bachelor's degree from an institutionally ~~a~~

~~regionally~~ accredited college or university and a certificate in orthotics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board; and

2. An approved orthotics internship of 1 year of qualified experience, as determined by the board, or an orthotic residency or dual residency program recognized by the board.

(b) For an examination in prosthetics:

1. A Bachelor of Science or higher-level postgraduate degree in orthotics and prosthetics from an institutionally ~~a regionally~~ accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs or, at a minimum, a bachelor's degree from an institutionally ~~a regionally~~ accredited college or university and a certificate in prosthetics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board; and

2. An approved prosthetics internship of 1 year of qualified experience, as determined by the board, or a prosthetic residency or dual residency program recognized by the board.

(5) In addition to the requirements in subsection (2), to be licensed as:

(a) An orthotist, the applicant must pay a license fee not to exceed $500 and must have:

1. A Bachelor of Science or higher-level postgraduate degree in orthotics and prosthetics from an institutionally ~~a regionally~~ accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs,

or a bachelor's degree from an institutionally accredited college or university and ~~with~~ a certificate in orthotics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board;

2. An approved ~~appropriate~~ internship of 1 year of qualified experience, as determined by the board, or a residency program recognized by the board;

3. Completed the mandatory courses; and

4. Passed the state orthotics examination or the board-approved orthotics examination.

(b) A prosthetist, the applicant must pay a license fee not to exceed $500 and must have:

1. A Bachelor of Science or higher-level postgraduate degree in orthotics and prosthetics from an institutionally ~~a regionally~~ accredited college or university recognized by the Commission on Accreditation of Allied Health Education Programs, or a bachelor's degree from an institutionally accredited college or university and ~~with~~ a certificate in prosthetics from a program recognized by the Commission on Accreditation of Allied Health Education Programs, or its equivalent, as determined by the board;

2. An internship of 1 year of qualified experience, as determined by the board, or a residency program recognized by the board;

3. Completed the mandatory courses; and

4. Passed the state prosthetics examination or the board-approved prosthetics examination.

Section 22. Section 483.824, Florida Statutes, is amended

to read:

483.824 Qualifications of clinical laboratory director.—A clinical laboratory director must have 4 years of clinical laboratory experience with 2 years of experience in the specialty to be directed or be nationally board certified in the specialty to be directed, and must meet one of the following requirements:

(1) Be a physician licensed under chapter 458 or chapter 459;

(2) Hold an earned doctoral degree in a chemical, physical, or biological science from an ~~a regionally~~ accredited institution and maintain national certification requirements equal to those required by the federal Health Care Financing Administration; or

(3) For the subspecialty of oral pathology, be a physician licensed under chapter 458 or chapter 459 or a dentist licensed under chapter 466.

Section 23. Subsection (3) of section 490.003, Florida Statutes, is amended to read:

490.003 Definitions.—As used in this chapter:

(3)(a) "Doctoral degree from an American Psychological Association accredited program" means ~~Effective July 1, 1999, "doctoral-level psychological education" and "doctoral degree in psychology" mean~~ a Psy.D., an Ed.D. in psychology, or a Ph.D. in psychology from a psychology program at an educational institution that, at the time the applicant was enrolled and graduated:

1.~~(a)~~ Had institutional accreditation from an agency recognized and approved by the United States Department of

Education or was recognized as a member in good standing with the Association of Universities and Colleges of Canada; and

2.~~(b)~~ Had programmatic accreditation from the American Psychological Association.

(b) "Doctoral degree in psychology" means a Psy.D., an Ed.D. in psychology, or a Ph.D. in psychology from a psychology program at an educational institution that, at the time the applicant was enrolled and graduated, had institutional accreditation from an agency recognized and approved by the United States Department of Education or was recognized as a member in good standing with the Association of Universities and Colleges of Canada.

Section 24. Subsection (1) of section 490.005, Florida Statutes, is amended to read:

490.005 Licensure by examination.—

(1) Any person desiring to be licensed as a psychologist shall apply to the department to take the licensure examination. The department shall license each applicant whom ~~who~~ the board certifies has met all of the following requirements:

(a) Completed the application form and remitted a nonrefundable application fee not to exceed $500 and an examination fee set by the board sufficient to cover the actual per applicant cost to the department for development, purchase, and administration of the examination, but not to exceed $500.

(b) Submitted proof satisfactory to the board that the applicant has received:

1. A doctoral degree from an American Psychological Association accredited program ~~Doctoral-level psychological education~~; or

2. The equivalent of a doctoral degree from an American Psychological Association accredited program ~~doctoral-level psychological education, as defined in s. 490.003(3),~~ from ~~a program at~~ a school or university located outside the United States of America which was officially recognized by the government of the country in which it is located as an institution or program to train students to practice professional psychology. The applicant has the burden of establishing that this requirement has been met.

(c) Had at least 2 years or 4,000 hours of experience in the field of psychology in association with or under the supervision of a licensed psychologist meeting the academic and experience requirements of this chapter or the equivalent as determined by the board. The experience requirement may be met by work performed on or off the premises of the supervising psychologist if the off-premises work is not the independent, private practice rendering of psychological services that does not have a psychologist as a member of the group actually rendering psychological services on the premises.

(d) Passed the examination. However, an applicant who has obtained a passing score, as established by the board by rule, on the psychology licensure examination designated by the board as the national licensure examination need only pass the Florida law and rules portion of the examination.

Section 25. Subsection (1) of section 490.0051, Florida Statutes, is amended to read:

490.0051 Provisional licensure; requirements.—

(1) The department shall issue a provisional psychology license to each applicant who the board certifies has:

(a) Completed the application form and remitted a nonrefundable application fee not to exceed $250, as set by board rule.

(b) Earned a doctoral degree from an American Psychological Association accredited program ~~in psychology as defined in s. 490.003(3)~~.

(c) Met any additional requirements established by board rule.

Section 26. Subsections (1), (3), and (4) of section 491.005, Florida Statutes, are amended to read:

491.005 Licensure by examination.—

(1) CLINICAL SOCIAL WORK.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, ~~plus the actual per applicant cost to the department for purchase of the examination from the American Association of State Social Worker's Boards or a similar national organization,~~ the department shall issue a license as a clinical social worker to an applicant whom ~~who~~ the board certifies has met all of the following criteria:

(a) ~~Has~~ Submitted an application and paid the appropriate fee.

(b)1. ~~Has~~ Received a doctoral degree in social work from a graduate school of social work which at the time the applicant graduated was accredited by an accrediting agency recognized by the United States Department of Education or ~~has~~ received a master's degree in social work from a graduate school of social work which at the time the applicant graduated:

a. Was accredited by the Council on Social Work Education;

b. Was accredited by the Canadian Association of Schools of

Social Work; or

c. Has been determined to have been a program equivalent to programs approved by the Council on Social Work Education by the Foreign Equivalency Determination Service of the Council on Social Work Education. An applicant who graduated from a program at a university or college outside of the United States or Canada must present documentation of the equivalency determination from the council in order to qualify.

2. The applicant's graduate program must have emphasized direct clinical patient or client health care services, including, but not limited to, coursework in clinical social work, psychiatric social work, medical social work, social casework, psychotherapy, or group therapy. The applicant's graduate program must have included all of the following coursework:

a. A supervised field placement which was part of the applicant's advanced concentration in direct practice, during which the applicant provided clinical services directly to clients.

b. Completion of 24 semester hours or 32 quarter hours in theory of human behavior and practice methods as courses in clinically oriented services, including a minimum of one course in psychopathology, and no more than one course in research, taken in a school of social work accredited or approved pursuant to subparagraph 1.

3. If the course title which appears on the applicant's transcript does not clearly identify the content of the coursework, the applicant shall be required to provide additional documentation, including, but not limited to, a

syllabus or catalog description published for the course.

(c) ~~Has~~ Had at least 2 years of clinical social work experience, which took place subsequent to completion of a graduate degree in social work at an institution meeting the accreditation requirements of this section, under the supervision of a licensed clinical social worker or the equivalent who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy clinical experience requirements must register pursuant to s. 491.0045 before commencing practice. If the applicant's graduate program was not a program which emphasized direct clinical patient or client health care services as described in subparagraph (b)2., the supervised experience requirement must take place after the applicant has completed a minimum of 15 semester hours or 22 quarter hours of the coursework required. A doctoral internship may be applied toward the clinical social work experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting. When a registered intern provides clinical services through telehealth, a licensed mental health professional must be accessible by telephone or electronic means.

(d) ~~Has~~ Passed a theory and practice examination designated by board rule ~~provided by the department for this purpose~~.

(e) ~~Has~~ Demonstrated, in a manner designated by rule of the board, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.

(3) MARRIAGE AND FAMILY THERAPY.—Upon verification of

documentation and payment of a fee not to exceed $200, as set by board rule, plus the actual cost of the purchase of the examination from the Association of Marital and Family Therapy Regulatory Board, or similar national organization, the department shall issue a license as a marriage and family therapist to an applicant whom ~~who~~ the board certifies has met all of the following criteria:

(a) ~~Has~~ Submitted an application and paid the appropriate fee.

(b)1. Obtained one of the following:

a. ~~Has~~ A minimum of a master's degree with major emphasis in marriage and family therapy or a closely related field from a program accredited by the Commission on Accreditation for Marriage and Family Therapy Education or from a Florida university program accredited by the Council for Accreditation of Counseling and Related Educational Programs.

b. A minimum of a master's degree with an emphasis in marriage and family therapy with a degree conferred date before July 1, 2027, from an institutionally accredited college or university that is not yet accredited by the Commission on Accreditation for Marriage and Family Therapy Education or the Council for Accreditation of Counseling and Related Educational Programs.

2. Completed ~~and~~ graduate courses approved by the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling.

If the course title that appears on the applicant's transcript does not clearly identify the content of the coursework, the

applicant shall provide additional documentation, including, but not limited to, a syllabus or catalog description published for the course. The required master's degree must have been received in an institution of higher education that, at the time the applicant graduated, was fully accredited by an institutional ~~a regional~~ accrediting body recognized by the Commission on Recognition of Postsecondary Accreditation or publicly recognized as a member in good standing with the Association of Universities and Colleges of Canada, or an institution of higher education located outside the United States and Canada which, at the time the applicant was enrolled and at the time the applicant graduated, maintained a standard of training substantially equivalent to the standards of training of those institutions in the United States which are accredited by an institutional ~~a regional~~ accrediting body recognized by the Commission on Recognition of Postsecondary Accreditation. Such foreign education and training must have been received in an institution or program of higher education officially recognized by the government of the country in which it is located as an institution or program to train students to practice as professional marriage and family therapists or psychotherapists. The applicant has the burden of establishing that the requirements of this provision have been met, and the board shall require documentation, such as an evaluation by a foreign equivalency determination service, as evidence that the applicant's graduate degree program and education were equivalent to an accredited program in this country. An applicant with a master's degree from a program that did not emphasize marriage and family therapy may complete the

coursework requirement in a training institution fully accredited by the Commission on Accreditation for Marriage and Family Therapy Education recognized by the United States Department of Education.

(c) ~~Has~~ Had at least 2 years of clinical experience during which 50 percent of the applicant's clients were receiving marriage and family therapy services, which must have been ~~be~~ at the post-master's level under the supervision of a licensed marriage and family therapist with at least 5 years of experience, or the equivalent, who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy the clinical experience requirements must register pursuant to s. 491.0045 before commencing practice. If a graduate has a master's degree with a major emphasis in marriage and family therapy or a closely related field which did not include all of the coursework required by paragraph (b), credit for the post-master's level clinical experience may not commence until the applicant has completed a minimum of 10 of the courses required by paragraph (b), as determined by the board, and at least 6 semester hours or 9 quarter hours of the course credits must have been completed in the area of marriage and family systems, theories, or techniques. Within the 2 years of required experience, the applicant must ~~shall~~ provide direct individual, group, or family therapy and counseling to cases including those involving unmarried dyads, married couples, separating and divorcing couples, and family groups that include children. A doctoral internship may be applied toward the clinical experience requirement. A licensed mental health professional must be on the premises when clinical services are

provided by a registered intern in a private practice setting. When a registered intern provides clinical services through telehealth, a licensed mental health professional must be accessible by telephone or other electronic means.

(d) ~~Has~~ Passed a theory and practice examination designated by board rule ~~provided by the department~~.

(e) ~~Has~~ Demonstrated, in a manner designated by board rule, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.

For the purposes of dual licensure, the department shall license as a marriage and family therapist any person who meets the requirements of s. 491.0057. Fees for dual licensure may not exceed those stated in this subsection.

(4) MENTAL HEALTH COUNSELING.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, ~~plus the actual per applicant cost of purchase of the examination from the National Board for Certified Counselors or its successor organization,~~ the department shall issue a license as a mental health counselor to an applicant whom ~~who~~ the board certifies has met all of the following criteria:

(a) ~~Has~~ Submitted an application and paid the appropriate fee.

(b)1. Obtained ~~Has~~ a minimum of an earned master's degree from a mental health counseling program accredited by the Council for the Accreditation of Counseling and Related Educational Programs which consists of at least 60 semester hours or 80 quarter hours of clinical and didactic instruction,

including a course in human sexuality and a course in substance abuse. If the master's degree is earned from a program related to the practice of mental health counseling which is not accredited by the Council for the Accreditation of Counseling and Related Educational Programs, then the coursework and practicum, internship, or fieldwork must consist of at least 60 semester hours or 80 quarter hours and meet all of the following requirements:

a. Thirty-three semester hours or 44 quarter hours of graduate coursework, which must include a minimum of 3 semester hours or 4 quarter hours of graduate-level coursework in each of the following 11 content areas: counseling theories and practice; human growth and development; diagnosis and treatment of psychopathology; human sexuality; group theories and practice; individual evaluation and assessment; career and lifestyle assessment; research and program evaluation; social and cultural foundations; substance abuse; and legal, ethical, and professional standards issues in the practice of mental health counseling. Courses in research, thesis or dissertation work, practicums, internships, or fieldwork may not be applied toward this requirement.

b. A minimum of 3 semester hours or 4 quarter hours of graduate-level coursework addressing diagnostic processes, including differential diagnosis and the use of the current diagnostic tools, such as the current edition of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders. The graduate program must have emphasized the common core curricular experience.

c. The equivalent, as determined by the board, of at least

700 hours of university-sponsored supervised clinical practicum, internship, or field experience that includes at least 280 hours of direct client services, as required in the accrediting standards of the Council for Accreditation of Counseling and Related Educational Programs for mental health counseling programs. This experience may not be used to satisfy the post-master's clinical experience requirement.

2. ~~Has~~ Provided additional documentation if a course title that appears on the applicant's transcript does not clearly identify the content of the coursework. The documentation must include, but is not limited to, a syllabus or catalog description published for the course.

Education and training in mental health counseling must have been received in an institution of higher education that, at the time the applicant graduated, was fully accredited by an institutional ~~a regional~~ accrediting body recognized by the Council for Higher Education Accreditation or its successor organization or publicly recognized as a member in good standing with the Association of Universities and Colleges of Canada, or an institution of higher education located outside the United States and Canada which, at the time the applicant was enrolled and at the time the applicant graduated, maintained a standard of training substantially equivalent to the standards of training of those institutions in the United States which are accredited by an institutional ~~a regional~~ accrediting body recognized by the Council for Higher Education Accreditation or its successor organization. Such foreign education and training must have been received in an institution or program of higher

education officially recognized by the government of the country in which it is located as an institution or program to train students to practice as mental health counselors. The applicant has the burden of establishing that the requirements of this provision have been met, and the board shall require documentation, such as an evaluation by a foreign equivalency determination service, as evidence that the applicant's graduate degree program and education were equivalent to an accredited program in this country. Beginning July 1, 2025, an applicant must have a master's degree from a program that is accredited by the Council for Accreditation of Counseling and Related Educational Programs which consists of at least 60 semester hours or 80 quarter hours to apply for licensure under this paragraph.

(c) ~~Has~~ Had at least 2 years of clinical experience in mental health counseling, which must be at the post-master's level under the supervision of a licensed mental health counselor or the equivalent who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy the clinical experience requirements must register pursuant to s. 491.0045 before commencing practice. If a graduate has a master's degree with a major related to the practice of mental health counseling which did not include all the coursework required under sub-subparagraphs (b)1.a. and b., credit for the post-master's level clinical experience may not commence until the applicant has completed a minimum of seven of the courses required under sub-subparagraphs (b)1.a. and b., as determined by the board, one of which must be a course in psychopathology or abnormal psychology. A doctoral internship

may be applied toward the clinical experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting. When a registered intern provides clinical services through telehealth, a licensed mental health professional must be accessible by telephone or other electronic means.

(d) ~~Has~~ Passed a theory and practice examination designated by department rule ~~provided by the department for this purpose~~.

(e) ~~Has~~ Demonstrated, in a manner designated by board rule, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.

Section 27. Subsection (6) and paragraph (c) of subsection (9) of section 766.314, Florida Statutes, are amended to read:

766.314 Assessments; plan of operation.—

(6)(a) The association shall make all assessments required by this section, except initial assessments of physicians licensed ~~on or after October 1, 1988, which assessments will be made~~ by the Department of Health ~~Business and Professional Regulation~~, and except assessments of casualty insurers pursuant to subparagraph (5)(c)1., which assessments will be made by the Office of Insurance Regulation. ~~Beginning October 1, 1989, for any physician licensed between October 1 and December 31 of any year, the Department of Business and Professional Regulation shall make the initial assessment plus the assessment for the following calendar year.~~ The Department of Health ~~Business and Professional Regulation~~ shall provide the association, in an electronic format, with a monthly report ~~such frequency as~~

~~determined to be necessary, a listing, in a computer-readable form,~~ of the names and license numbers ~~addresses~~ of all physicians licensed under chapter 458 or chapter 459.

(b)1. The association may enforce collection of assessments required to be paid pursuant to ss. 766.301-766.316 by suit filed in county court. The association is ~~shall be~~ entitled to an award of attorney's fees, costs, and interest upon the entry of a judgment against a physician for failure to pay such assessment, with such interest accruing until paid. Notwithstanding ~~the provisions of~~ chapters 47 and 48, the association may file such suit in either Leon County or the county of the residence of the defendant.

2. The Department of Health ~~Business and Professional Regulation~~, upon notification by the association that an assessment has not been paid and that there is an unsatisfied judgment against a physician, shall refuse to ~~not~~ renew any license issued to ~~practice for~~ such physician under ~~issued pursuant to~~ chapter 458 or chapter 459 until the association notifies the Department of Health that ~~such time as~~ the judgment is satisfied in full.

(c) The Agency for Health Care Administration shall, upon notification by the association that an assessment has not been timely paid, enforce collection of such assessments required to be paid by hospitals pursuant to ss. 766.301-766.316. Failure of a hospital to pay such assessment is grounds for disciplinary action pursuant to s. 395.1065 notwithstanding any ~~provision of~~ law to the contrary.

(9)

(c) If ~~In the event~~ the total of all current estimates

equals 80 percent of the funds on hand and the funds that will become available to the association within the next 12 months from all sources described in subsections (4) and (5) and paragraph (7)(a), the association may ~~shall~~ not accept any new claims without express authority from the Legislature. Nothing in this section precludes ~~herein shall preclude~~ the association from accepting any claim if the injury occurred 18 months or more before ~~prior to~~ the effective date of this suspension. Within 30 days after ~~of~~ the effective date of this suspension, the association shall notify the Governor, the Speaker of the House of Representatives, the President of the Senate, the Office of Insurance Regulation, the Agency for Health Care Administration, and the Department of Health~~, and the Department of Business and Professional Regulation~~ of this suspension.

Section 28. This act shall take effect July 1, 2022.

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

The Florida Senate

Committee Agenda Request

To: Senator Manny Diaz, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: November 30, 2021

I respectfully request that **Senate Bill #768**, relating to Department of Health, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Ana Maria Rodriguez
Florida Senate, District 39

File signed original with committee office

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

1/26/2022
Meeting Date

Health Policy
Committee

768
Bill Number or Topic

Amendment Barcode (if applicable)

Name Melissa Villar

Phone (850) 354-8424

Address 1695 Inclair Rd
Street

Email normltallahassee@gmail.com

Tallahassee FL 32312
City State Zip

Speaking: ☐ For ☐ Against ☑ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

2022 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Florida Department of Health

BILL INFORMATION	
BILL NUMBER:	Click or tap here to enter text.
BILL TITLE:	Department of Health
BILL SPONSOR:	Click or tap here to enter text.
EFFECTIVE DATE:	Click or tap here to enter text.

COMMITTEES OF REFERENCE
1)
2)
3)
4)
5)

CURRENT COMMITTEE

SIMILAR BILLS	
BILL NUMBER:	
SPONSOR:	

PREVIOUS LEGISLATION	
BILL NUMBER:	1565/1568
SPONSOR:	Drake/Rodriguez (A)
YEAR:	2020
LAST ACTION:	

IDENTICAL BILLS	
BILL NUMBER:	
SPONSOR:	

Is this bill part of an agency package?
Yes

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	July 23, 2021
LEAD AGENCY ANALYST:	Andrea Gary, Amber Pepe, Anthony Spivey, Janet Hartman, Kama Monroe, Lola Pouncey, Joe Baker Jr., Allen Hall
ADDITIONAL ANALYST(S):	
LEGAL ANALYST:	Louise St. Laurent

FISCAL ANALYST:	

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

This bill addresses numerous health care-related issues regulated by the Department of Health (DOH).

Section 1: Targeted Outreach for Pregnant Women

Updates Section 381.0045, F.S., also known as the "Targeted Outreach for Pregnant Women Act of 1998" (TOPWA), to reflect the larger variety of antiretroviral medication options now available. The bill also addresses the need for mental health care services among the high-risk population targeted by TOPWA and requires additional follow-up for HIV-exposed newborns.

Section 2: Special Needs Shelters

Section 381.0303, Florida Statutes, designates the Department of Health (department) as the lead agency for the coordination of the recruitment of health care practitioners to staff special needs shelters and to provide resources. This bill updates the statute to reflect that the department, rather than Children's Medical Services(CMS) specifically, is the lead for the coordination of local medical and health care providers in developing a plan for the staffing and medical management of pediatric special needs shelters. Additionally, it assigns to the Department the decision-making for determining who has responsibility for the medical supervision in each special needs shelter.

Section 3: Medical Marijuana Sampling and Testing

The bill provides the Department with authority to test all marijuana and marijuana delivery devices to ensure they meet legal and safety requirements, and to verify testing results of Certified Marijuana Testing Laboratories (CMTLs). Language referring to laboratory audits of medical marijuana treatment centers (MMTCs) is removed, as the CMTL requirements are covered by section 381.988, Florida Statutes, and CMTL rules, which require CMTLs to conduct sampling in accordance with approved protocols and standard operating procedures. Also, this amendment carves out an exception to criminal penalties for Department employees acting within scope of employment to acquire, possess, test, transport, dispose of marijuana and marijuana delivery devices.

Section 4-12: Emergency Medical Services

Florida's 300 EMS agencies respond to over 4 million requests for services every year.[1] There are 75,000 licensed EMS providers in the state of Florida. These requests are primarily responded to by non-profit, governmental agencies such as fire departments, county-based services, and non-profit hospital-based agencies. The amendments included in this bill will modernize our statutory language, allow for the greater use of technology for education and certifications, enable the establishment of more technical paramedic schools, and increase the utilization of emergency medical technicians and paramedics in our healthcare system

Section 13: Chiropractic Medicine

The United States Department of Education recently revised accreditation references to omit the use of the terms "regional" and "national" as it relates to accreditation. The bill removes all references to "regional" accreditation within section 460.406, Florida Statutes (F.S.), replacing the reference with "institutional" accreditation.

Section 14: Nursing Exam

In 464.008, F.S., there is currently a reference to an obsolete exam.

Section 15: Nursing

Clarifies the Department of Health's ability to prosecute licensees under chapter 464, Florida Statutes (F.S.), who had adjudication withheld in their court cases after having entered a plea of nolo contendre or guilty to an offense listed under sections 435.04 and 741.20, F.S.

Section 16-20: Midwifery

Clarifies licensing requirements for midwifery applicants applying by examination and endorsement, removes provisions for examinations no longer offered by the Department of Health (Department), removes duplicative or obsolete language and duplicative rulemaking authority. It also clarifies language regarding preceptorships, approval of midwifery programs, and minimum standards.

Section 21: Practice of Orthotics, Prosthetics, and Pedorthics

The United States Department of Education recently revised accreditation references to omit the use of the terms "regional" and "national" as it relates to accreditation. The bill removes all references to "regional" accreditation within section 468.803, Florida Statutes (F.S.), and replaces the term with the appropriate accreditation references. The bill also updates language related to criminal history checks for applicants for licensure.

Section 22: Clinical Laboratory Personnel

The United States Department of Education recently revised accreditation references to omit the use of the terms "regional" and "national" as it relates to accreditation. The bill removes all references to "regional" accreditation within section 483.824, Florida Statutes (F.S.), replacing the reference with "institutional" accreditation.

Section 23-25: Psychology

Removes a requirement of having graduated from a program accredited by the American Psychological Association (APA) for individuals applying for licensure by the method of "endorsement of 10 years licensed psychology experience."

Section 26: Mental Health Professionals

Mental health professionals provide vital therapeutic services to clients in Florida. To ensure continued safe practice in Florida, minimum qualifications for licensure are necessary with specifications for a period of transition. Registered mental health interns provide essential mental health services to clients in Florida as they prepare for full licensure. As mental health services by telehealth methods expand, alternative considerations for on-site licensed mental health provider accessibility during clinical sessions provided by registered interns is necessary.

Section 27: Neurological Injury Compensation Association (NICA)

Updates the agencies named in the statutes to reflect current governmental structure, since the Boards of Medicine and Osteopathic Medicine are part of the Department of Health (DOH), not the Department of Business and Professional Regulation (DBPR). Additionally, this bill conforms the statute to current practice, updating the section to eliminate outdated language referring to initial assessments (fees) made in 1988, reflecting the current practice for collecting fees, and updating data sharing requirements to align with current practice.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

Section 1: Targeted Outreach for Pregnant Women

In 2019, there were 453 HIV-exposed births in Florida. Without proper care for both mother and newborn, each of these births represents an opportunity for vertical transmission of HIV to occur. TOPWA supports targeted outreach programs that aim to prevent vertical HIV transmission and other health issues by linking high-risk pregnant women with services that can help them have healthier pregnancies and deliveries and can aid them in ensuring their newborn gets a healthy start.

TOPWA programs aim to provide outreach and linkage services to pregnant women who may not seek proper prenatal care, who suffer from substance-use disorders, or who are living with HIV or are at increased risk for HIV acquisition. Many of the women targeted by TOPWA programs would not otherwise receive prenatal care and/or know their HIV status. In 2019, there were seven funded TOPWA programs in Florida. TOPWA programs, which are co-funded through General Revenue (GR) dollars and Centers for Disease Control and Prevention (CDC) HIV Prevention grant funds, provided services to 7,703 women from January 2016 to July 2020. Black women

represented 48 percent of enrollees, Hispanic women represented 39 percent, and white women represented 10 percent. Women living with HIV made up just under 10 percent of TOPWA enrollments.

If a pregnant woman tests positive for HIV, medical interventions, like antiretroviral (ARV) medication and delivery by caesarian section, can greatly reduce her risk of transmitting the virus to her baby during childbirth. And prevention methods, like avoiding breastfeeding, can reduce her risk of transmitting the virus to her child post childbirth. Providing ARV medication to the newborn also decreases the chances of seroconversion in the event of an HIV-exposed birth. The department has developed a GR-funded program, Baby Rxpress, that provides a six-week course of ARV medication to HIV-exposed newborns at no cost to the mother. In 2019, this program filled 304 prescriptions to 264 HIV-exposed newborns at a cost of $10,801.96, or $40.92 per baby

TOPWA programs aim to engage women into care who very likely do not already have knowledge of or access to these interventions. Without these types of interventions, a mother's chances of transmitting HIV to her newborn can be up to 45 percent. With these interventions, the chances of transmission are less than 2 percent.

There were no known perinatal HIV transmissions in 2019; however, the department does not have a definitive status on roughly 25 percent of the 453 HIV-exposed births.

Section 2: Special Needs Shelters

Special needs shelters ensure persons with special needs have a safe and secure location during an emergency or disaster. In 2000, Section 381.0303, Florida Statutes, was created to establish a system to recruit health care practitioners to staff special needs shelters in times of emergencies or disasters, and names the department as the lead agency for these responsibilities. As part of the Department's responsibilities, CMS was identified in the statute as the lead for the coordination of local medical and health care providers to develop a plan for the staffing and medical management of pediatric special needs shelters and to participate in local decision-making regarding the medical supervision of special needs shelters. This was in large part due to the previously considerable CMS workforce of local health care practitioners with specialized training and experience in the provision of services for children with special needs. Through a series of program and organizational changes toward more effective operation and costs, the CMS workforce has been reduced by more than 70% since 2018. Due to this change in workforce, CMS can no longer support the charges of the statute.

Section 3: Medical Marijuana Sampling and Testing

Currently, there is authorization for department employees to only sample edibles for sampling and testing to ensure product meets legal requirements. All medical marijuana should be subject to sampling and testing, and not just edibles.

Section 4-12: Emergency Medical Services

Many changes have occurred in the EMS industry since the original formation of the Raymond H. Alexander, M.D., Emergency Medical Services Transportation Services Act. EMS agencies have become an integral part of public safety, public health, and health care systems throughout the state. During the recent pandemic, the Florida EMS system was forced to adapt in many ways, which accelerated many plans envisioned for the future. Much of those focused on the use of technology, including the use of virtual meeting platforms. These successes demonstrated to our community that technology could work effectively. This bill incorporates the lessons learned from the utilization of this technology. This bill enables the Bureau of Emergency Medical Oversight to conduct schools inspections utilizing virtual platforms. Additionally, it allows emergency medical technicians and paramedic students to receive clinical education upon department approval virtually in situations where the absence of live clinical sites hinders their education. This bill also revises the processes in which emergency medical technicians or paramedics apply for their licenses through electronic submission. This will speed the process and efficiency. This bill also expands the use of emergency medical technicians and paramedics in multiple health care settings. The pandemic has reinforced the use of these providers in non-traditional settings as an effective force multiplier. This bill updates definitions, removes obsolete examination language, and replaces it with a more efficient process.

Section 13: Chiropractic Medicine

Institutional accrediting agencies accredit institutions of higher education. The United States Department of Education issued a letter of guidance on February 26, 2020, specifying that final regulations published this year omit references to "regional" and "national" accreditation. The letter specifies, "[b]ecause the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded." Provisions implemented in 34 C.F.R. § 602.32(d), relating to the recognition of accrediting agencies, will become effective January 1, 2021.

Section 460.406(1)(d)1, F.S., requires an applicant matriculating in a chiropractic college after July 1, 1990, must hold a Bachelor's Degree awarded by a college or university accredited by a regional accrediting agency recognized and approved by the United States Department of Education.

Section 460.406(1)(d)2, F.S., requires an applicant effective July 1, 2000, complete prior to matriculating in a chiropractic college, a Bachelor's Degree from a college or university accredited by a regional accrediting agency recognized and approved by the United States Department of Education.

Section 14: Nursing Exam

In 464.008, F.S., there is currently a reference to an obsolete exam.

Section 15: Nursing

As the statute is currently written, it could be argued that the regardless of adjudication clause only applies to licensees who were found guilty to an offense prohibited by section 435.04, F.S., or an offense which constitutes domestic violence under section 741.20, F.S.

Section 16-20: Midwifery

Chapter 467, Florida Statutes (F.S.), is the Midwifery Practice Act. Although changes have been made by reviser's bills and conforming changes have been made to statutory references, this chapter has not been substantially revised since 2001.

Section 467.009, F.S., governing midwifery programs and education and training requirements and Section 467.205, F.S., governing the approval of midwifery programs, use the terms applicant and student midwife interchangeably. These sections also frame standards for admission, education, and clinical training in the context of student requirements, which causes confusion. As an example, a student must have a high school diploma or the equivalent to enroll in a program, but the statutes do not clearly state that a high school diploma is a requirement for licensure.

The use of the undefined term "midwifery student" has led to unlicensed persons attempting to work with clients and complete clinical requirements without enrolling in or being educated by an approved midwifery program, and midwives attempting to serve as preceptors who are not affiliated with an approved midwifery program in any way. In general, health care practitioners do not start seeing clients in a clinical setting until they have completed prerequisite portions of a course of study and are near the end of their educational program.

In addition, chapter 467 does not include any provisions explicitly allowing a new midwifery program to be provisionally approved nor do they provide clear guidance to schools regarding the circumstances under which the Department may rescind the approval of their program.

Generally, applicants for licensure as a medical practitioner have two methods by which they can apply for a license: examination or endorsement. An applicant by examination typically provides their educational credentials and proof of a passing score on a designated licensing examination. In lieu of these items, an applicant by endorsement is licensed based on verification that they hold a current valid license to practice in another jurisdiction that has equivalent or more stringent licensure requirements to those in Florida.

In many states a midwife may practice based on educational credentials rather than a license. When these practitioners apply for licensure in Florida they are confused by our laws and rules which state that they should apply by endorsement since they were legally permitted to practice in the state or jurisdiction they came from, but must still provide their transcripts and passing exam scores for licensure as if they were applying by examination. The use to the term "endorsement" is a misnomer in this situation since they have no license or licensing agency to endorse from.

In addition, sections 467.011 and 467.0125, F.S., which contain the requirements for licensure by examination and endorsement, contain language which is obsolete. Pursuant to section 456.017(c), F.S., the Department has approved by rule the use of a national examination for midwives seeking to become licensed; the Department no longer administers midwifery examinations.

Section 467.0125, F.S., also includes provisions for the temporary certification of a midwife who is qualifying for endorsement to practice in an area of critical need. This statute defines the term "area of critical need" differently from every other profession which has temporary certification that allows practice in an area of critical need. In addition, the current provisions for temporary certification of a midwife require discipline in the form of revocation, when the area in which they were practicing loses its designation as an area of critical need.

Section 21: Practice of Orthotics, Prosthetics, and Pedorthics

Section 468.803 (2), F.S., specifies requirements for applicants to be screened for state and national criminal history. Applicants complete fingerprinting requirements electronically through independent vendors and provide an ORI number specific to the profession for the results to be submitted to the department. The department no longer collects forms or fees from applicants to process the initial criminal history check for licensure. If a criminal history is indicated, the Board of Orthotists and Prosthetists (Board) reviews the application for consideration of licensure.

Section 468.803, F.S., provides minimum qualifications for licensure to practice orthotics, prosthetics, and pedorthics. Each profession includes the requirement of completion of a program from a "regionally accredited" institution. The United States Department of Education issued a letter of guidance on February 26, 2020, specifying that final regulations published this year omit references to "regional" and "national" accreditation. The letter specifies, "Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded." Provisions implemented in 34 C.F.R. § 602.32(d), relating to the recognition of accrediting agencies, became effective January 1, 2021.

Section 22: Clinical Laboratory Personnel

Institutional accrediting agencies accredit institutions of higher education. The United States Department of Education issued a letter of guidance on February 26, 2020, specifying that final regulations published this year omit references to "regional" and "national" accreditation. The letter specifies, "[b]ecause the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded." Provisions implemented in 34 C.F.R. § 602.32(d), relating to the recognition of accrediting agencies, became effective January 1, 2021.

Section 483.824(2), F.S., requires the doctoral degree held by a clinical laboratory director be from a regionally accredited institution in a chemical, physical, or biological science.

Section 23-25: Psychology

The psychologist licensure application method, endorsement of 10 years licensed psychology experience, requires an applicant to have graduated with a doctoral degree in psychology from an educational institution that held institutional accreditation from an agency approved by the United States Department of Education and programmatic accreditation from the APA. The lack of APA accreditation, under this application method, is grounds for licensure denial.

Section 26: Mental Health Professionals

Marriage and Family Therapy – Minimum Educational Requirements

During the 2020 Legislative Session, section 491.005, Florida Statutes, was amended to revise the minimum requirements for licensure as a marriage and family therapist to include graduation from a program accredited by the Commission on Accreditation for Marriage and Family Therapy Education (COAMFTE) or from a Florida university program accredited by the Council for Accreditation of Counseling and Related Educational Programs (CACREP). The minimum requirement for licensure revision was effective on July 1, 2020.

Currently, there are six universities in Florida with a marriage and family program that is not accredited by either COAMFTE or CACREP, specifically: Carlos Albizu, Jacksonville University, Palm Beach Atlantic University, St. Thomas University, University of Miami, and the University of Phoenix. As a result, students who are presently

enrolled in a marriage and family program at one of these universities will not meet the minimum requirements for Florida licensure upon graduation. However, these programs did meet the requirements at the time of enrollment.

The minimum qualifications for licensure include completion of a "Florida university program accredited by CACREP." As Fsuch, applicants who have completed educational requirements in other states from a CACREP accredited program do not meet licensure requirements. Although there are existing licensing provisions to encourage endorsement applicants with experience in other states, this education requirement presently restricts the portability of health care licensure for marriage and family therapists.

Registered Interns – Licensed Professional on Premises

As documented in the Florida Department of Health, Division of Medical Quality Assurance, Annual Report and Long-Range Plan, Fiscal Year 2019/2020, there are 13,444 registered mental health interns in Florida. To qualify as a registered intern, the applicant must have completed a master's or doctoral degree in a clinical counseling field and a practicum including face-to-face psychotherapy (clinical-level therapy sessions) under the direct supervision of a licensed practitioner.

Registered interns routinely provide independent counseling and psychotherapy, including the use of methods to evaluate, assess, diagnose, and treat emotional and mental dysfunctions or disorders, behavioral disorders, interpersonal relationships, and addictions. Psychotherapy and counseling may be provided in a variety of settings. Registered interns provide services at facilities including, but not limited to:

- Crisis Centers – e.g., suicide prevention programs, shelters for abuse victims, child endangerment response
- In-patient and out-patient behavioral health centers
- Private practice settings
- Hospitals
- Hospice
- Rehabilitation centers

Registered interns currently practice telehealth as part of the scope of their practice as a mechanism for the delivery of health care services. The practice of telehealth is authorized in section 456.47(1)(b), Florida Statutes, for any individual who provides health care and related services using telehealth and who is licensed or certified under chapter 491, Florida Statutes. A registration is included in the definition of a "license" in section 456.001(5), Florida Statutes, which states a license "means any permit, registration, certificate, or license, including a provisional license, issued by the department."

Registered interns are required to complete 1,500 face-to-face psychotherapy hours before applying for full licensure. The face-to-face psychotherapy hours must be completed within five years. Registered interns are a qualified force multiplier to increase the number of educated and prepared mental health practitioners to manage growing mental health concerns and currently provide these services in various face-to-face settings.

In accordance with s. 491.005, Florida Statutes, registered interns are required to have a licensed professional on the premises during counseling sessions. The licensed professional is not required to be in the counseling room observing the session, but on the premises to provide oversight, guidance, and evaluation. This provision ensures that registered interns have a licensed professional readily available, if necessary, during a therapeutic session and to restrict registered interns from operating an independent practice without direct oversight available. Registered interns may provide clinical services to clients by telehealth methods if the licensed professional is on the same premises.

Regional Accreditation

The minimum qualifications for licensure specified in s. 491.005(3), Florida Statutes, includes the requirement of completion of a graduate program from a "regionally accredited body recognized by the Commission on Recognition of Postsecondary Accreditation." The United States Department of Education issued a letter of guidance on February 26, 2020, specifying that final regulations published this year omit references to "regional" and "national" accreditation. The letter specifies, "Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded." Provisions implemented in 34 C.F.R. § 602.32(d), relating to the recognition of accrediting agencies, became effective January 1, 2021.

Department Examination

The Department of Health discontinued the practice of conducting examinations or purchasing examinations for licensure. Applicants are presently responsible for coordinating the completion of an examination with an approved vendor and submitting passing scores to the board to meet minimum qualifications. Current statutory

references to the department collecting fees for examinations or conducting examinations is not consistent with current practice.

Section 27: Neurological Injury Compensation Association (NICA)

Updating agency names and removing obsolete provisions
Currently, section 766.314, Florida Statutes, contains numerous references to the DBPR as the agency housing the Florida Board of Medicine and the Florida Board of Osteopathic Medicine. All medical boards were moved to the DOH in the early 2000s. DOH accepted all of the responsibilities in this statute when the Boards moved; however, the statute still indicates that these functions should be performed by the DBPR. In addition, the statute contains obsolete language related to how the initial assessment was collected in 1988. This language is no longer needed.

"Following Year" Assessments
The statute requires the DBPR to collect the initial Florida Birth-Related Neurological Injury Compensation Association (NICA) assessment (fee) from all applicants. The statute also requires that if a license is being issued between October 1 and December 31, DBPR shall also collect the fee for the following year.

Currently, DOH is not collecting the 'following year' fees from individuals licensed during the specified period. Every licensee pays the initial NICA assessment (ranging from $0 to $5,000) at the time of application. Based on our records, the 'following year' fees have been collected directly by NICA since the Boards were moved to DOH. NICA requires fees to be paid by January 31 of the calendar year.

Data Sharing with NICA
The statute requires DBPR to provide a listing in a computer-readable format of the names and addresses of physicians licensed under chapters 458 and 459, as often "as determined to be necessary."

Currently, DOH provides NICA with a list of newly licensed physicians each month, including their license numbers, the date they were licensed, and the fees collected. Any additional information that NICA may need can be downloaded from DOH's website. This coincides with the transfer of those fees collected by DOH to NICA, allowing NICA to reconcile the amount received with the fees listed in the monthly report.

2. EFFECT OF THE BILL:

Section 1: Targeted Outreach for Pregnant Women

Amends ss. 381.0045(2), F.S., to add pregnant women who are suffering from mental health problems to the list of outreach targets.

Amends paragraph (c) of ss. 381.0045(3), F.S., to refer to the Florida Administrative Code regarding testing recommendations for HIV and other sexually transmissible diseases.

In paragraph (e) of ss. 381.0045(3), F.S., replaces the reference to a single type of antiretroviral with more general information on antiretroviral medications, thus allowing for additional options.

Amends paragraph (f) of ss. 381.0045(3), F.S., to include mental health services as a linkage option.

Amends paragraph (g) of ss. 381.0045(3), F.S., to require additional follow up for HIV-exposed newborns to ensure final HIV status is known and necessary linkages to care are made.

Section 2: Special Needs Shelters

The changes outlined in the bill would align certain responsibilities to the department, rather than a specific portion of the department.

Section 3: Medical Marijuana Sampling and Testing

Allows department employees to sample and test medical marijuana and medical marijuana delivery devices to ensure their safety and accuracy of the labeling.

Section 4-12: Emergency Medical Services

Section 4 amends 401.23, F.S.;

(1) revises the definition of advanced life support to be consistent with new national standards as established by the US Department of Transportation for the types of advanced medical techniques that may be performed;
(2) clarifies language that defines advanced life support services to include entities that offer to provide the service;
(3) clarifies language that establishes that the air ambulance must be an emergency medical services provider in order to provide advanced life support;
(4) clarifies that the air ambulance service is provided by a licensed emergency medical services provider;
(5) revises vehicle language to vehicles designed for advanced and basic care;
(7) revises basic life support definition to be consistent with new national standards as established by the US Department of transportation for the types of basic medical techniques that may be performed;
(8) clarifies language that defines basic life support services to include entities that offer to provide the service;
(9) clarifies the language referring to the provision of emergency medical services as the practice as opposed to the act;
(11) currently, licensed emergency medical technicians are effectively being utilized in many non-traditional areas of healthcare; this clarification enables the department by rule to approve additional locations if needed;
(12) allows the department to establish rules for supplemental destinations for interfacility transfers;
(13) clarifies definition of licensee;
(14) clarifies definition of medical direction;
(15) clarifies definition of a medical director;
(16) clarifies language to be consistent with mutual aid agreement practices;
(17) currently, licensed paramedics are effectively being utilized in many non-traditional areas of healthcare; this clarification allows this practice enables the department by rule to approve additional locations if needed;
(18) clarifies language under this part from pursuant;
(19) this provision clarifies the definition of physicians to include osteopathic physicians, and veterans affairs appointed physicians;
(20)clarifies language in nurse definition.

Section 5 amends 401.25(2)(d), F.S.;

Changes the language to emergency medical responder, which is the nationally recognized designation for this type of responder

Section 6 amends 401.27, F.S.;

(3) removes the under oath requirement of the certification and recertification process; this change will enable the process to be completed online, which will be more efficient for the provider and the department. The applicant will electronically sign to indicate their agreement to terms of licensure;
(4)(a)(1)updates language to the current EMS standards of the United States Department of Transportation for emergency medical technicians;
(4)(a)(2) updates language to the current EMS standards of the United States Department of Transportation for paramedics;
(4)(a)(2)(b) removes the under oath requirement for the confirmation that they are not addicted to alcohol, this change will enable the process to be completed online, which will be more efficient for the provider and the department. The applicant will electronically sign to indicate their confirmation to terms of licensure;
(4)(a)(2)(c) removes the under oath requirement for the confirmation that they are not physically impaired or with mental defect or disease; this change will enable the process to be completed online, which will be more efficient for the provider and the department. The applicant will electronically sign to indicate their confirmation to terms of licensure;
(4)(a)(2)(f) changes language that has the licensure candidates submit testing fees to the department's designated examination provider;
(4)(a)(2)(g) removes obsolete language in the examination process.

Section 7 amends 401.2701, F.S.;

(1) updates language from shall to must and provided to adopted by;

(1)(a)(3) allows department-approved training programs that are also licensed advanced life support providers to provide clinical education without an affiliation agreement;
(1)(a)(5)(a) updates language to the current EMS standards of the United States Department of Transportation for emergency medical technicians;
(1)(a)(6)(b) allows for virtual inspection of emergency medical services education programs;
(1)(a)(6)(b)(1) changes the minimum hours for emergency medical technician education programs from 110 hours to 300 hours which brings it into compliance with the Florida Department of Education hours and national guidelines requirement for emergency medical technician education that are already being performed;
(1)(a)(6)(b)(2) broadens the language to include active duty and reserve military-trained emergency medical technicians to meet admission requirements for paramedic education; changes the minimum hours for paramedic education programs from 700 hours to 1,100 hours which makes consistent with national standards for paramedic education that are already being performed; provides that a portion of field internship may be satisfied by supervised, remote live videoconferencing together with simulated direct patient contact in a simulated advanced life support ambulance;
(2) Makes provisions where a training program may request department approval to substitute simulation and remote, live videoconferencing for supervised in-person clinical instruction and direct patient-contact skills laboratory requirements;
(3) clarifies application language to be consistent with Chapter 120.60, F.S.;
(4) makes provisions that the department shall renew the training program certificate of approval upon receipt of a written statement from the program attesting that the training program continues to meet the requirements of the Department of Education and remains accredited by a national organization recognized by the department;
(5) clarifies application language to be consistent with Chapter 120.60, F.S.;

Section 8 amends. 401.272, F.S.;
(2)(a) clarifies that health promotion and wellness activities in nonemergency environments be performed under medical direction;
(2)(b) adds that paramedics may administer “public health counter measures” in a nonemergency environment under medical direction;
(3) adds that a medical director must verify and document training for paramedics that administer public health countermeasures;
(4) adds the term public health countermeasures to the department’s rule authority for this subsection.

Section 9 amends. 401.30, F.S.;
(1) updates language to allow a licensee to maintain written or electronic records;
(2) updates language from a hospital to “receiving facility”
(4)(a) revising the list of individuals and entities that may receive limited disclosure of certain otherwise confidential and exempt records;
(4)(g) requiring the release of such records to be in compliance with specified provisions of research and quality improvement statutes.

Section 10 amends. 401.34, F.S.;
(4), (5), (6), and (7) deleting provisions and fees related to an obsolete examination.

Section 11 amends. 401.425, F.S.;
(5) clarifies that reports as well as records obtained or produced by an emergency medical review committee providing quality improvement are exempt from provisions of Chapter 119 F.S.;
(8) clarifies that an emergency medical review committees may review the performances of emergency medical technicians, paramedics, and emergency medical services providers to make recommendations for performance improvement.

Section 12 amends. 401.435, F.S.;
(1) and (2) updates the term “first responder agencies” to “emergency medical responder agencies” to be consistent with national terminology.

Section 13: Chiropractic Medicine

The bill deletes references to the term “regional” and replaces it with the term “institutional” to conform with the United States Department of Education accreditation nomenclature for approving educational institutions.

Section 14: Nursing Exam

Amends 464.008, F.S. to remove a reference to an obsolete exam.

Section 15: Nursing

By moving the regardless of adjudication clause behind the “entered a plea of nolo contendre or guilty” language it will now encompass all convictions and pleas to offenses included under chapter 464, F.S.

Section 16-20: Midwifery

Section 1 of the bill amends definitions contained in section 467.003, F.S. It revises the definition of “preceptor” to clearly define their role in the midwifery education process. Specifically, it explicitly states that a preceptor may not supervise an individual as a midwifery student unless the student has been enrolled in an approved midwifery program. This should clarify that an individual cannot begin their clinical practice before enrolling in an approved midwifery program and will explicitly conform midwifery training with the requirements of other medical professions, with students having to complete the majority of their classroom training before working with patients in a clinical setting.

The bill adds a definition of “prelicensure course” to explain the requirements for such a course. This section also changes the term “approved program” to “approved midwifery program” in order to create consistency in the use of terms throughout the chapter.

Section 2 revises the provisions in section 467.009, F.S., governing midwifery schools. The changes made to this section have been proposed to improve the clarity of these provisions and promote consistency in terminology. In addition, language was added to provide that if another national organization comes into existence, their core competency standards can be used to by the Council in setting Florida’s standards, as well as those of the American College of Nurse Midwives and the Midwives Alliance of North America.

Sections 3 and 4 of the bill amend sections 467.011 and 457.0125, F.S., making endorsement and examination licensing requirements equivalent to the requirements in other medical practice acts by disallowing endorsement without a license or certification in another state, territory or jurisdiction and opening a pathway to licensing by examination for applicants who completed education which is equivalent to or exceeds that which is required for licensing in Florida in a state, territory, or jurisdiction that does not license midwives. While these revisions do not change what is actually required to qualify for a midwifery license, they clarify licensure requirements to allowing applicants to better understand those requirements.

The revisions to section 467.0125, F.S., also change the definition of “area of critical need” to match the definition used by other medical professions. In addition, the language would allow a midwife certified to practice in an area of critical need to report a new area of critical need or relinquish the certificate within a specified timeframe following a change in an areas designated status, rather than being immediately subject to disciplinary action, while retaining the Department’s ability to revoke a certificate for non-compliance by the midwife so certified.

Section 5 of the bill revises section 467.205, F.S., which governs the approval of midwifery programs. This language would allow midwifery programs to be provisionally approved for five years. This conforms with the five-year period that they can be provisionally licensed by the Department of Education’s Commission for Independent Education which seeking accreditation status. The Department will be able to give provisional approval to a new program who has meet all requirements except for showing their students have an 80% passage rate on the national exam. Programs provisionally approved will have five years to demonstrate the required exam approval rate after they are preliminary approved. This time period should allow completion the 3-year education program for at least one cohort of students, and for those students to take the exam before the Department tries to determine the passing rate.

These changes may also lead to a reduction in attempts by unlicensed persons to complete clinical requirements outside the context of an approved midwifery program, and midwives attempting to serve as preceptors outside the context of clinical practice under the auspices of an approved program. The language also clarifies the circumstances when the Department may rescind the approval of a midwifery program.

Section 21: Practice of Orthotics, Prosthetics, and Pedorthics

The bill updates the procedures to current practice for applicants to obtain a criminal history check and the method of transmission to the department for review by the Board.

The bill deletes references to the term “regionally accredited” and replaces it with the term “institutionally accredited” or simply references the programmatic accrediting body to conform with the United States Department of Education accreditation nomenclature for approving educational institutions. Institutional accrediting agencies accredit institutions of higher education, and programmatic accrediting agencies accredit specific educational programs that prepare students for entry into a profession, occupation, or vocation.

Section 22: Clinical Laboratory Personnel

The effect of this bill will remove the requirement of having an earned doctoral degree issued from a regionally accredited institution. The United States Department of Education introduced a policy change that removes the distinction between a regional or national accrediting agency and now holds the accrediting standards the same to each, thus only recognizing the entity as an institutional or programmatic accrediting agency.

Section 23-25: Psychology

The bill amends subsections 490.003(3), 490.005(1)(b)(1) and (2), and 490.0051(1)(b), Florida Statutes (F.S.). Outdated language related to an effective date of “July 1, 1999” is removed and the term “doctoral-level psychological education” is eliminated.

The term “doctoral degree in psychology” as it relates to the examination application method, is renamed “American Psychological Association accredited doctoral degree in psychology.” The term “doctoral degree in psychology” as it relates to the application method endorsement of 10 years licensed psychology experience is redefined to no longer require APA accreditation. The effect of these changes is to allow different educational credentials for different application methods.

By redefining the term, “doctoral degree in psychology,” as referenced in section 490.006, F.S., applicants applying by the application method endorsement of 10 years licensed psychology experience, who did not graduate from an APA accredited program, can be licensed. Graduation from an APA accredited program is critical for first time licensees; however, applicants who have practiced for 10 or more years in another state or jurisdiction have demonstrated minimum level of competency.

Elimination of the APA accreditation requirement, under endorsement of 10 years licensed psychology experience, will offer expanded opportunities for licensure for those who do not qualify under the examination application method.

These changes to chapter 490, F.S., will streamline and expedite licensure by endorsement while maintaining the needed accreditation and educational standards for licensure by examination.

Section 26: Mental Health Professionals

Marriage and Family Therapy – Minimum Educational Requirements

The bill authorizes programs not yet accredited by COAMFTE or CACREP a period of five years to become accredited. This period of transition will allow students who have partially completed a program that met the minimum licensing requirements at the time of enrollment to graduate from the program while the university completes the necessary steps to achieve accreditation. The process of attaining CACREP accreditation is estimated as a 12–18-month process but can take up to two years to complete. This provision will provide the affected universities with a time frame for initiating and completing the accreditation process or to ensure adequate noticing to students that the program will not meet state licensing requirements.

Registered Interns – Licensed Professional on Premises

The bill adds additional language to s. 491.005, Florida Statutes, to include a provision for a licensed mental health professional to be available by phone or other electronic methods when clinical services are being provided by a registered intern by telehealth methods. This provision would authorize the registered intern working in private practice to provide services by telehealth methods as an alternative to in-person sessions. This language expands access for Floridians to mental health services performed by qualified registered interns.

Regional Accreditation

The bill deletes references to the term “regional” in s. 491.005(3), Florida Statues, and replaces it with the term “institutional” to conform with the United States Department of Education accreditation nomenclature for approving educational institutions.

Department Examination
The bill eliminates current statutory references to the department collecting fees for examinations or conducting examinations. This modification would have no effect and would ensure the statute and current practice are consistent.

Section 27: Neurological Injury Compensation Association (NICA)

Updating agency names and removing obsolete provisions
This bill updates the statute by changing all references from DBPR to DOH. It also eliminates unnecessary and obsolete language regarding the initial fees collected in 1988.

Following Year Assessments
The bill amends the statute to align with current practice.

Data Sharing with NICA
The bill updates the provisions regarding data sharing with NICA to reflect current practice. Under the bill, DOH will continue to provide NICA with an electronic monthly report of physicians licensed in the previous month, including their license numbers, the date they were licensed, and the fees collected.

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:	**Section 1: Targeted Outreach for Pregnant Women** Documents referenced in the existing Rule, 64-3.015, F.A.C., will require revision to align with the changes proposed in this bill. **Section 2: Special Needs Shelters** The bill maintains the Department’s rulemaking authority. Currently, the department, in coordination with the Division of Emergency Management, has the authority to adopt rules necessary to implement this section. Documents referenced in the existing Rule, 64-3.015, F.A.C., will require revision to align with the changes proposed in this bill. **Section 4-12: Emergency Medical Services** The bill allows the department to adopt and enforce rules necessary to enforce the provisions relating to a paramedic’s administration of immunizations, public health countermeasures and medical countermeasures. **Section 16-20: Midwifery** The bill removes duplicative rulemaking authority related to midwifery programs and approval but retains rulemaking authority for rules related to licensing requirements and midwifery program standards and approval. **Section 27: Neurological Injury Compensation Association (NICA)** Removing the provision of collecting the 'following year' fee on behalf of NICA clarifies an established business process. NICA is able to collect the assessment directly without waiting for funds to pass

	through Florida Department of Financial Services, Division of Treasury and MQA.
Is the change consistent with the agency's core mission?	Y☒ N☐
Rule(s) impacted (provide references to F.A.C., etc.):	**Section 2: Special Needs Shelters** 64-3.015, F.A.C. **Section 4-12: Emergency Medical Services** 64J-1, Florida Administrative Code **Section 16-20: Midwifery** Rules 64B24-2.001, 64B20-2.002, 64B20-2.003, and 64B20-2.004, F.A.C. Rules 64B24-4.001, 64B24-4.002, 64B4-4.003, 64B4-4.005, 64B4-4.006, 64B4-4.007, 64B4-4.008, 64B4-4.010, F.A.C. **Section 23-25: Psychology** Sufficient authority is already provided in chapter 490, F.S., to make the needed rule changes the bill would require. Rule 64B19-11.012. F.A.C., Application Forms

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

Proponents and summary of position:	**Section 13: Chiropractic Medicine** Board of Chiropractic Medicine **Section 22: Clinical Laboratory Personnel** Board of Clinical Laboratory Personnel **Section 23-25: Psychology** Board of Psychology **Section 26: Mental Health Professionals** The Board office has been contacted by educational entities and affected applicants seeking a transition period for implementation of the educational requirements for licensure for marriage & family therapists. Public comment has been received from licensees and crisis therapy organizations indicating support so that telehealth considerations continue to be an option when a licensed person cannot be physically on the premises but can successfully intervene by phone or electronic methods. **Section 27: Neurological Injury Compensation Association (NICA)** NICA currently collects the 'following year' fees as part of their business process; this change would not negatively impact their operations.

	The monthly report of new physicians is sufficient for NICA's operations and the clarifying language provides clear guidance on what is required.
Opponents and summary of position:	Unknown

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y☐ N☒

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

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

Board:	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:	N/A

Expenditures:	**Section 3: Medical Marijuana Sampling and Testing** Minimal cost for testing of the samples but current resources are adequate to absorb. . **Section 4-12: Emergency Medical Services** Minimal cost for rule making but current resources are adequate to absorb. **Section 23-25: Psychology** Limited costs will be associated with rule development and minor changes to the licensure database, License and Enforcement Database System (LEIDS). Current resources are 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:	**Section 3: Medical Marijuana Sampling and Testing** Minimal cost of the samples provided to department.
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.	**Section 21: Practice of Orthotics, Prosthetics, and Pedorthics** DOH/MQA will experience a non-recurring workload associated with updating the online application and websites. **Section 23-25: Psychology** Yes, LEIDS must be updated. The Versa Online (on-line application) system will need to be modified.

	Section 26: Mental Health Professionals The License and Enforcement Database System and Online Service Portal would need to be updated to support the changes. Additionally, the DOH/MQA will experience a non-recurring workload associated with website changes.

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

None.

LEGAL - GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	**Section 2: Special Needs Shelters** There are no legal issues or concerns identified for the Department of Health other than amending the special needs shelter guidelines rule (64-3.015, F.A.C.) to remove any reference to CMS. **Section 3: Medical Marijuana Sampling and Testing** The proposed bill may require rulemaking to define the way the Department will collect and test samples. **Section 4-27:** No legal issues identified during review.

2021 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Florida Department of Health

BILL INFORMATION	
BILL NUMBER:	1568
BILL TITLE:	Department of Health
BILL SPONSOR:	Rodriguez (A)
EFFECTIVE DATE:	July 1, 2021

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

CURRENT COMMITTEE

SIMILAR BILLS	
BILL NUMBER:	1565
SPONSOR:	Drake

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

IDENTICAL BILLS	
BILL NUMBER:	
SPONSOR:	

Is this bill part of an agency package?
Yes

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	March 12, 2021
LEAD AGENCY ANALYST:	Allen Hall
ADDITIONAL ANALYST(S):	
LEGAL ANALYST:	Louise St. Laurent
FISCAL ANALYST:	Jonathan Sackett

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

Senate Bill 1568 relates to the Department of Health (Department) and amends multiple sections of Florida Statutes and impacts multiple divisions or offices within the Department.

The Office of Medical Marijuana Use is impacted as the bill amends section 381.986, F.S. Specifically, Section 6 of the bill amends s. 381.986, F.S., by permitting the Department to select samples of marijuana from a medical marijuana treatment center's (MMTC) Department-approved facility to confirm tetrahydrocannabinol (THC) and cannabidiol (CBD) potency or to verify the result of marijuana testing conducted by a marijuana testing laboratory. The bill also permits the Department to select samples of marijuana delivery devices (devices) from a dispensing facility to determine whether the devices are safe for use by qualified patients.

Additionally, this section of the bill requires an MMTC to recall all marijuana and marijuana products that fail to meet the potency requirements of this section, that are unsafe for human consumption, or for which the labeling of the THC and CBD concentration is inaccurate.

The bill also exempts the Department, including its employees, from certain criminal provisions when acquiring, possessing, testing, transporting, and disposing of marijuana and devices under certain circumstances.

The bill impacts the division of Medical Quality Assurance as it amends numerous practice acts to streamline regulation and increase efficiency. It eliminates obsolete language and updates licensure and accreditation requirements.

This bill impacts the Division of Disease Control and Health Protection as it updates Section 381.0045, F.S., also known as the "Targeted Outreach for Pregnant Women Act of 1998" (TOPWA), to reflect the larger variety of antiretroviral medication options now available. The bill also addresses the need for mental health care services among the high-risk population targeted by TOPWA and requires additional follow-up for HIV-exposed newborns.

The bill further impacts the Bureau of Environmental Health in Sections 2-6 as it corrects "unintended consequences" caused by rewording of statutes associated with the transfer of the Onsite Sewage Program to DEP. These amendments will clarify authority that remains with DOH and that which goes with DEP once the transfer occurs.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

Pursuant to section 381.986(8)(11)d., F.S., the Department may select a random sample from edibles available for purchase in an MMTC's Department-approved dispensing facility for testing. The Department shall test the random sample for potency, safety for human consumption, accuracy of THC and CBD labeling.

MMTCs are required to recall all edibles, including all edibles made from the same batch of marijuana, which fail to meet potency requirements, which are unsafe for human consumption, or for which the labeling of the THC and CBD concentration is inaccurate.

Presently, the Department, including its employees, are not expressly exempt from criminal prosecution under ss. 893.13, .135, .147, F.S., when acquiring, possessing, testing, transporting, and disposing of marijuana and delivery devices under certain circumstances when acting within the scope of its duties.

Subsection 460.406(1), Florida Statutes, provides a list of requirements an applicant for licensure as a chiropractor must meet before being eligible to take the licensure examination. The list is comprised of the following requirements:

(a) Completed the application form and remitted the appropriate fee.

(b) Submitted proof satisfactory to the department that he or she is not less than 18 years of age.
(c) Submitted proof satisfactory to the department that he or she is a graduate of a chiropractic college which is accredited by or has status with the Council on Chiropractic Education or its predecessor agency. However, any applicant who is a graduate of a chiropractic college that was initially accredited by the Council on Chiropractic Education in 1995, who graduated from such college within the 4 years immediately preceding such accreditation, and who is otherwise qualified shall be eligible to take the examination. No application for a license to practice chiropractic medicine shall be denied solely because the applicant is a graduate of a chiropractic college that subscribes to one philosophy of chiropractic medicine as distinguished from another.
(d) 1. For an applicant who has matriculated in a chiropractic college prior to July 2, 1990, completed at least 2 years of residence college work, consisting of a minimum of one-half the work acceptable for a bachelor's degree granted on the basis of a 4-year period of study, in a college or university accredited by an accrediting agency recognized and approved by the United States Department of Education. However, prior to being certified by the board to sit for the examination, each applicant who has matriculated in a chiropractic college after July 1, 1990, shall have been granted a bachelor's degree, based upon 4 academic years of study, by a college or university accredited by a regional accrediting agency which is a member of the Commission on Recognition of Postsecondary Accreditation.

The minimum qualifications for licensure specified in subsection 460.406(1), Florida Statutes, includes the requirement of completion of a program from a "regionally accredited agency which is a member of the Commission on Recognition of Postsecondary Accreditation."

The United States Department of Education issued a letter of guidance on February 26, 2020, specifying that final regulations published this year omit references to "Regional" and "National" accreditation. The letter specifies, "Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded." Provisions implemented in 34 C.F.R. § 602.32(d), relating to the recognition of accrediting agencies, will become effective January 1, 2021.

Section 8
As the statute is currently written, it could be argued that the regardless of adjudication language only applies to licensees who were found guilty to an offense prohibited by section 435.04, Florida Statutes, or an offense which constitutes domestic violence under section 741.20, Florida Statutes. If this argument were successful, it would prohibit the Department from successfully prosecuting any licensee who received a withhold of adjudication upon entering a plea of guilty nolo contendre to an offense prohibited by section 435.04, Florida Statutes, or an act of domestic violence.

Sections 9, 10, 11, 12 and 13 Midwifery
Chapter 467 of the Florida Statutes, is known as the "Midwifery Practice Act." The last substantial revision of the act took place in 1991 and 1992. Since that time, numerous changes have taken place in the profession, including changes in terminology, the establishment of national examinations, standards, and certifications, and an increase in the number of states licensing midwives. The State of Florida has 249 licensed midwives and four licensed midwifery programs.

Midwifery Programs
A school's program must include a minimum of three years of study and clinical training. However, registered nurses and licensed practical nurses may receive credit for previous nursing or midwifery education to reduce the required midwifery program length to no less than two years.

The training must cover numerous specific topics enumerated in subsection 467.009(1), Florida Statutes. The program must also include the nationally recognized core competencies established by the American College of Nurse Midwives and the Midwives Alliance of North America. Subsection 467.009(6), Florida Statutes, states that the education must have a "particular emphasis on learning the ability to differentiate between low-risk pregnancies and high-risk pregnancies."

The student midwife must also complete clinical training in hospitals, alternative birthing settings, or both by caring for

50 women in the prenatal, intrapartal, and postpartal periods, under the supervision of a preceptor. The student must also observe an additional 25 women in the intrapartal period. “Student midwife” is not defined in the statute.

“Preceptor” is defined in subsection 467.003(12), Florida Statutes, as a physician, licensed midwife, or certified nurse midwife with three years of experience, “who directs, teaches, supervises, and evaluates the learning experiences of the student midwife”.

Prelicensure Course
Subsection 467.0125(1)(b), Florida Statutes, requires that an applicant for licensure by endorsement must complete successfully “a 4-month prelicensure course conducted by an approved program.” This requirement applies to any applicant who received their education out of the state or in another country. There are no statutory provisions that define the term “prelicensure course” or indicate the materials to be covered by such a course.

Rule 64B24-4.010, F.A.C., requires that four-month prelicensure courses include, at a minimum:

- Content review and demonstration of proficiency in the core competencies established by the American College of Nurse Midwives and the Midwives Alliance of North America,
- Florida Laws and Rules, and
- Provisions for five supervised labor and deliveries and ten supervised prenatal visits by each course participant.

Licensure by Examination
To qualify for a license by examination, an applicant must show that they graduated from an approved midwifery program and have passed the required examination.

Licensure by Endorsement
For most professions, a person seeking a license by endorsement must hold a license in another state which has licensure requirements that are equivalent to or more stringent than the licensing requirements in the State of Florida. The Midwifery Practice Act uses the term “endorsement” but does not require the applicant by endorsement to be licensed in the other state. Instead an individual may endorse based on a diploma or certification that allows them to practice in another jurisdiction.

As a result, in cases where the applicant by endorsement does not hold a license in another state, they must submit to the department all of the items required by licensure by examination plus copies of the or diploma or certificate that allows them to practice in the other jurisdiction. This confuses applicants because endorsement applications for other professions to do not require the applicant to provide a transcript.

Examination Requirement
The Midwifery Practice Act contains language referring to a Department administered examination. That language is obsolete. Pursuant to 456.017(c), Florida Statutes, the Department uses a national examination for midwives seeking to become licensed, and the Department no longer administers midwifery examinations.
Temporary Certification

Subsection 467.0125(2), Florida Statutes, contains provisions for temporary certification of a midwife who has applied for a license by endorsement to practice in an area of critical need. However, the language defining an area of critical need differs from the language used to define such areas for other professions where temporary certification is issued. Currently, if the area in which a midwife is practicing ceases to be an area of critical need, the Department must immediately initiate disciplinary action to revoke the temporary certificate. This disciplinary action is then be reported to the National Practitioner Data Bank and will impact the midwife for the rest of their career as a licensed health care professional.

Midwifery Program Approval
To be approved as a midwifery program, a non-public school must be accredited by the Commission on Recognition of Postsecondary Accreditation (which has been succeeded by the Council for Higher Education Accreditation.) The statute

has no provisions addressing midwifery programs who are seeking accreditation and are provisionally approved while awaiting their first graduating class.

Section 467.205, Florida Statutes, allows the Department to place a program on probationary status if it no longer meets the required standards, and if the program fails to correct these conditions, the Department may resend its license. However, the statutes provide no guidance regarding notification to the program or length of time a school may remain in probationary status.

Section 14
Subsection 468.803(2), Florida Statutes, specifies requirements for applicants to be screened for state and national criminal history. Applicants complete fingerprinting requirements electronically through independent vendors and provide an Originating Agency Identifier Number (ORI) number specific to the profession for the results to be submitted to the department. The department no longer collects forms or fees from applicants to process the initial criminal history check for licensure. If a criminal history is indicated, the Board of Orthotists and Prosthetists (Board) reviews the application for consideration of licensure.

Section 468.803, Florida Statutes, provides minimum qualifications for licensure to practice orthotics, prosthetics, and pedorthics. Each profession includes the requirement of completion of a program from a "regionally accredited" institution. The United States Department of Education issued a letter of guidance on February 26, 2020, specifying that final regulations published this year omit references to "Regional" and "National" accreditation. The letter specifies, "Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded." Provisions implemented in 34 C.F.R. § 602.32(d), relating to the recognition of accrediting agencies, will become effective January 1, 2021.

Section 15
Section 483.824, Florida Statutes, requires a clinical laboratory director have 4 years of clinical laboratory experience with 2 years of experience in the specialty to be directed or be nationally board certified in the specialty to be directed, and must meet one of the following requirements:

> (1) Be a physician licensed under chapter 458 or chapter 459;
> (2) Hold an earned doctoral degree in a chemical, physical, or biological science from a regionally accredited institution and maintain national certification requirements equal to those required by the federal Health Care Financing Administration; or
> (3) For the subspecialty of oral pathology, be a physician licensed under chapter 458 or chapter 459 or a dentist licensed under chapter 466.

The minimum qualifications for licensure specified in subsection 483.824, Florida Statutes, includes the requirement of completion of a doctoral degree in a chemical, physical, or biological science from a regionally accredited institution and maintain national certification requirements equal to those required by the federal Health Care Financing Administration." The United States Department of Education issued a letter of guidance on February 26, 2020, specifying that final regulations published this year omit references to "Regional" and "National" accreditation. The letter specifies, "Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded." Provisions implemented in 34 C.F.R. § 602.32(d), relating to the recognition of accrediting agencies, will become effective January 1, 2021.

Sections 16, 17 and 18
The psychologist licensure application method, endorsement of 10 years licensed psychology experience, requires an applicant to have graduated with a doctoral degree in psychology from an educational institution that held institutional accreditation from an agency approved by the United States Department of Education and programmatic accreditation from the American Psychological Association (APA). The lack of APA accreditation, under this application method, is grounds for licensure denial.

Section 19
Examination References
The Department of Health, on behalf of the Board of Clinical Social Work, Marriage and Family Therapy and Mental Health Counseling, establishes no cost contracts with the exam provider approved by the Board in rule 64B4-3.003, Florida Administrative Code. Applicants register and pay fees directly to the provider identified by rule.
Registered Interns – Licensed Professional on Premises

As documented in the Florida Department of Health, Division of Medical Quality Assurance, Annual Report and Long-Range Plan, Fiscal Year 2018/2019, there are 13,474 registered mental health interns in Florida. To qualify as a registered intern, the applicant must have completed a master's or doctoral degree in a clinical counseling field and a practicum including face-to-face psychotherapy (clinical-level therapy sessions) under direct supervision of a licensed practitioner. Some registered interns may also complete internships prior to graduation. Registered interns routinely provide counseling and psychotherapy including the use of methods to evaluate, assess, diagnose, and treat emotional and mental dysfunctions or disorders, behavioral disorders, interpersonal relationships, and addictions.

Psychotherapy and counseling may be provided in a variety of settings. Registered interns provide services at facilities including, but not limited to:

- Crisis Centers – e.g. suicide prevention programs, shelters for abuse victims, child endangerment response; In-patient and out-patient behavioral health centers;
- Private practice settings;
- Hospitals;
- Hospice; and Rehabilitation centers.

Registered interns are required to complete 1,500 face-to-face psychotherapy hours prior to applying for full licensure. The face- to-face psychotherapy hours must be completed within five years in accordance with statute. Registered interns are a force multiplier to increase the number of educated and prepared mental health practitioners to manage growing mental health concerns and already provide these services in a face-to-face setting in mental health facilities statewide.

In accordance with section 491.005, Florida Statutes, registered interns are required to have a licensed professional on the premises during counseling sessions. The licensed professional is not required to be in the counseling room observing the session, but on the premises in the event of necessary intervention. This provision was originally established to ensure that registered interns have a licensed professional readily available, if necessary, during a therapeutic session and to restrict registered interns from operating an independent practice without direct oversight available.

Registered interns currently practice telehealth as part of the scope of their practice as a mechanism for the delivery of health care services. The practice of telehealth is authorized in section 456.47(1)(b), Florida Statutes, for any individual who provides health care and related services using telehealth and who is licensed or certified under chapter 491, Florida Statutes. A registration is included in the definition of a "license" in section 456.001(5), Florida Statutes, which states a license "means any permit, registration, certificate, or license, including a provisional license, issued by the department."

Regional Accreditation
The minimum qualifications for licensure specified in subsection 491.005(3), Florida Statutes, includes the requirement of completion of a graduate program from a "regionally accredited body recognized by the Commission on Recognition of Postsecondary Accreditation." The United States Department of Education issued a letter of guidance on February 26, 2020, specifying that final regulations published this year omit references to "Regional" and "National" accreditation. The letter specifies, "Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded." Provisions implemented in 34 C.F.R. § 602.32(d), relating to the recognition of accrediting agencies, will become effective January 1, 2021.

2. EFFECT OF THE BILL:

Senate Bill 1568 relates to the Department and amends nineteen sections of Florida Statutes:

HIV – Targeted Outreach for Pregnant Women

Section 1
Amends ss. 381.0045(2), F.S., to add pregnant women who are suffering from mental health problems to the list of outreach targets.

Amends paragraph (c) of ss. 381.0045(3), F.S., to refer to the Florida Administrative Code regarding testing recommendations for HIV and other sexually transmissible diseases.

In paragraph (e) of ss. 381.0045(3), F.S., replaces the reference to a single type of antiretroviral with more general information on antiretroviral medications, thus allowing for additional options.

Amends paragraph (f) of ss. 381.0045(3), F.S., to include mental health services as a linkage option.

Amends paragraph (g) of ss. 381.0045(3), F.S. (renumbered to paragraph (h) in the bill), to require additional follow up for HIV-exposed newborns to ensure final HIV status is known and necessary linkages to care are made.

Adds a new paragraph (g) to ss. 381.0045(3), F.S., which requires the Department to educate pregnant women with HIV on the importance of engaging in and continuing HIV care.

Environmental Health

Section 2 amends s. 381.0061 FS to remove authority for DOH to take corrective actions related to the onsite program and septic tank contractor registration that are being transferred to DEP July 1, 2021.

Section 3 creates s. 381.00635, FS to keep DOH authority for corrective actions for private and certain public water systems that remain under the jurisdiction of DOH after the transfer of the Onsite Sewage Program to DEP.

Section 4 amends s. 381.0064, F.S., to remove DEP's responsibility for establishing a continuing education program for the purpose of certification under s. 381.0101, F.S.

Section 5 amends s. 381.0067, FS to remove those references to remaining DOH programs when statute will transfer to DEP jurisdiction.

Section 6 amends s. 381.0101, FS, to add phrase to continue to require onsite evaluations under DEP continue to be done by certified environmental health professionals, a designation that would otherwise only be applicable for certain DOH programs. Under the prior revisions, DEP is required to develop continuing education/training for Onsite Sewage professionals for the purposes of this section.

Medical Marijuana Treatment Centers

Section 7 of the bill amends section 381.986, F.S., by permitting the Department to select samples of marijuana from an MMTC's Department-approved facility to confirm THC and CBD potency or to verify the result of marijuana testing conducted by a marijuana testing laboratory. The bill expressly authorizes the Department to test all marijuana at any MMTC's Department-approved facility.

The proposed language also permits the Department to select samples of marijuana delivery devices from a dispensing facility to determine whether the devices are safe for use by qualified patients.
Additionally, this section of the bill requires an MMTC to recall all marijuana and marijuana products that fail to meet the potency requirements of this section, that are unsafe for human consumption, or for which the labeling of the THC and CBD concentration is inaccurate.

The proposed language also exempts the Department, including its employees, from certain criminal provisions when acquiring, possessing, testing, transporting, and disposing of marijuana and devices under certain circumstances

Section 8
The bill amends subsection 460.406(1), Florida Statutes, by adding clarifying language that all the listed requirements must be met before an applicant for licensure is eligible to sit for the licensing examination. Additionally, the bill deletes reference to a regional accrediting agency and refers to an institutional accrediting agency recognized by the U.S. Department of Education to conform with the United States Department of Education accreditation nomenclature for approving educational institutions. Adhering to this policy change will bring the statute in alignment with the U.S. Department of Education.

Section 9
The bill amends section 464.018, Florida Statutes, to move the regardless of adjudication language after the "entered a plea of nolo contendre or guilty" language so it would encompass all convictions and pleas to offenses included under this statute. This will make the language of the statute clear and applicable to all types of convictions and pleas to offenses listed under section 435.04, Florida Statutes. Section 435.04, Florida Statutes, enumerates some of the most serious criminal offenses chargeable under Florida Law, such as murder, crimes of a sexual nature, crimes against children, and some property crimes.

Sections 10, 11, 12, 13 and 14 Midwifery Programs
Definitions within section 467.003, Florida Statutes, are amended to clarify terminology related to midwifery programs. The term "approved program" is amended to the more specific term "approved midwifery program."
The bill specifically amends the definition of "preceptor" to require that a physician, midwife, or certified nurse midwife serving as a preceptor be licensed in this state and be working as a part of an approved midwifery program.
The bill substantially revises section 467.009, Florida Statutes, regarding approved midwifery program requirements to clarify language and terminology. The bill reformats sections of existing language and removes undefined terms such as "student midwife."

The proposed revisions remove the limitation on how much of the three years of required training a midwifery school can waive for a registered nurse or a licensed practical nurse based on prior equivalent nursing or midwifery training.

Prelicensure Course
First, the bill provides a definition for the term "Prelicensure Course" in section 467.003, Florida Statutes, to specify that it is a course approved by the Department that provides instruction on Florida's laws and rules and demonstrates the competence of the student to practice midwifery under the Florida law. This new definition does not specify how long the course must run, giving programs flexibility in scheduling.

New language in section 467.011, Florida Statutes, explicitly states that an applicant by examination must complete the prelicensure course unless they attended an approved midwifery program which covered the content of the prelicensure course, including Florida laws and rules, during their course of study. Current language already requires that applicants by endorsement complete the prelicensure course.

Licensure by Examination
The bill revises section 467.011, Florida Statutes, regarding licensure by examination. It removes language referring to an examination administered by the Department and changes that language to conform with current practice which requires passing a national examination specified by the Department.

It revises language to allow persons educated outside of this state to apply for a license by examination if they have completed a medical or midwifery program in another jurisdiction. Such an applicant must show that the program requirements were equivalent to or exceed the requirements for an approved midwifery program.
The new language explicitly states that an applicant by examination must complete the prelicensure course unless they attended an approved midwifery program which covered the content of the prelicensure course, including Florida laws and rules, during the course of study. The section is also substantially reworded to improve clarity.

Licensure by Endorsement
The bill addresses applications for licensure by endorsement and the issuance of temporary certificates.
The licensure by endorsement language is substantially revised to improve clarity. The new language clearly states that a person must be licensed in another jurisdiction to apply by endorsement, conforming the terminology used with the terms used by other professions regulated by the Department. Applicants educated out of state who do not hold a license can still qualify for licensure under the same conditions as under present law through the licensure by examination process.

Examination Requirements
The bill removes all language relating to a Department administered examination and replaces that language with reference to the national certification examination.

Temporary Certification
Under this bill, the definition of "area of critical need" contained in the provisions regarding temporary midwifery certificates is revised to match the definitions used by the majority of other professions which have similar temporary certificates. The revised definition specifically includes the following as areas of critical need:

- County health departments;
- Correctional facilities;
- Clinics runs by the Department of Veterans' Affairs;
- Community health centers funded by s. 329, s. 330, or 863 s. 340 of the United States Public Health Service Act;
- Any other agency or institution that is approved by the State Surgeon General and provides health care to meet the needs of an underserved population in this state.

Finally, should an area cease to be designated as an area of critical need while a midwife with a temporary certificate is working in that area , the bill will give that midwife thirty days to either move their practice to another area of critical need and report that information to the department, or to relinquish the temporary certificate. Only if the midwife holding the temporary certificate fails to act within those thirty days will the Department initiate disciplinary action to revoke the certificate.

Midwifery Program Approval
Section 13 of the bill revises section 467.205, Florida Statutes, consolidating provisions regarding the approval of programs in one location. It updates the requirements regarding accreditation and includes specific authority to allow programs who are provisionally accredited to operate.

New provisions specifically require written notice to a program that is not in compliance with the laws and rules, or which has lost its accreditation status, before the program is placed into probationary status. The bill requires the Department to notify the school of the length of the probationary period, giving the school notice of how long they have to comply with statutory requirements, or meet accreditation requirements, before the Department may rescind the program's approval.

Section 15
The bill updates the procedures to current practice for applicants to obtain a criminal history check and the method of transmission to the department for review by the Board.

The bill deletes references to the term “regionally accredited” and replaces it with the term “institutionally accredited” or simply references the programmatic accrediting body to conform with the United States Department of Education accreditation nomenclature for approving educational institutions. Adhering to this policy change will bring the statute in alignment with the U.S. Department of Education.

Section 16
The bill deletes language in subsection 483.824(2), Florida Statutes, which references a regionally accredited institution and refers now to an accredited institution recognized by the U.S. Department of Education to conform with the United States Department of Education accreditation nomenclature for approving educational institutions. Adhering to this policy change will bring the statute in alignment with the U.S. Department of Education.

Sections 17, 18 and 19
The bill amends subsections 490.003(3)(a) and (b), 490.005(1)(b)(1) and (2), and 490.0051(1)(b), Florida Statutes. Outdated language related to an effective date of “July 1, 1999,” is removed and the term “doctoral-level psychological education” is eliminated.

The term “doctoral-level psychological education” as it relates to the examination application method, is renamed “doctoral degree from an American Psychological Association accredited program.” The term “doctoral degree in psychology” as it relates to the application method endorsement of 10 years licensed psychology experience is redefined to no longer require American Psychological Association (APA) accreditation. The effect of these changes is to allow different educational credentials for different application methods.

By redefining the term, “doctoral degree in psychology,” as referenced in section 490.006, Florida Statutes, applicants applying by the application method endorsement of 10 years licensed psychology experience, who did not graduate from an APA accredited program, can be licensed. Graduation from an APA accredited program is critical for first time licensees; however, applicants who have practiced for 10 or more years in another state or jurisdiction have demonstrated the minimum level of competency.

Elimination of the APA accreditation requirement, under endorsement of 10 years licensed psychology experience, will offer expanded opportunities for licensure for those who do not qualify under the examination application method. These changes to chapter 490, Florida Statutes, will streamline and expedite licensure by endorsement while maintaining the needed accreditation and educational standards for licensure by examination.

Section 20
Examination References
The bill amends existing language in subsection 491.005(1), Florida Statutes, to remove obsolete language related to the Department of Health purchasing an examination from the American Association of State Social Worker’s Boards or a similar national organization. This revision clarifies and corrects the statute to be consistent with the language provided in subsection 491.005(1)(d), Florida Statutes, which specifies the examination will be designated by board rule.

Likewise, the bill amends existing language in subsection 491.005(4), Florida Statutes, to remove obsolete language related to the Department of Health purchasing an examination from the National Board for Certified Counselors or a similar national organization. This revision clarifies and corrects the statute to be consistent with the language provided in subsection 491.005(4)(d), Florida Statutes, which specifies the examination will be designated by board rule.

Registered Interns – Licensed Professional on Premises
The bill amends existing language in section 491.005, Florida Statutes, to include a provision for a licensed mental health professional to be on the premises or immediately accessible to intervene when clinical services are being provided by the registered intern by telehealth methods. This provision for immediate intervention would permit the registered intern to provide services by telehealth methods as an alternative to in-person sessions. Since the licensed mental health professional is only presently required to be on the premises, not in the room monitoring the session, immediate intervention could occur by including the professional by telephone or by introducing the professional into the telehealth platform to intervene.

Regional Accreditation
The bill deletes references to the term "regional" in subsection 491.005(3), Florida Statutes, and replaces it with the term "institutional" to conform with the United States Department of Education accreditation nomenclature for approving educational institutions. Additionally, the accrediting body, "Commission on Recognition of Postsecondary Accreditation was dissolved in 1997, according to information provided by the United States Department of Education website. The bill deletes this reference and replaces with "an institutional accrediting body recognized by the United States Department of Education."

Section 21
The bill provides an effective date of July 1, 2021.

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:	Please refer to "Rules Impacted" section below.
Is the change consistent with the agency's core mission?	Y☒ N☐
Rule(s) impacted (provide references to F.A.C., etc.):	Sections 9-13. Numerous rules in Chapter 64B14, F.A.C., will need to be revised including Rules 64B24-2.001, 64B24-2.002, 64B24-2.003, 64B24-2.004, 64B24-4.001, 64B24-4.002, 64B24-4.003, 64B24-4.005, 64B24-4.006, 64B24-4.007, 64B24-4.008, and 64B24-4.010, F.A.C. Sections 16-18. Rule 64B19-11.012, F.A.C.

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

Proponents and summary of position:	Sections 17-19. This proposal is from the Florida Board of Psychology. Section 20. Public comment has been received from licensees and crisis therapy organizations indicating support so that telehealth considerations continue to be an option when a licensed person cannot be physically on the premises but can successfully intervene by phone or electronic methods.
Opponents and summary of position:	Unknown.

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y☐ N☒

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

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

Board:	N/A
Board Purpose:	N/A
Who Appoints:	N/A
Changes:	N/A
Bill Section Number(s):	

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 will incur non-recurring cost for rulemaking, which current budget authority is adequate to absorb. DOH/MQA may experience an increase in workload associated with additional complaints if a midwife holding a temporary certificate fails to comply with the provisions of this bill. It is anticipated that the impact will be minimal and can be absorbed with current resources. DOH/MQA will experience a non-recurring workload associated with updating the online application and websites. The License and Enforcement Database System (LEIDS) must be updated and the Versa Online (on-line application) system will need to be modified. Current resources are adequate to absorb.

	The fiscal impact of conducting medical marijuana testing by the Department of Health's Jacksonville Public Health Laboratory (PHL) is indeterminate but expected to be significant. When this portion is removed, there is no fiscal impact. The Department has submitted a Fiscal Year 2021-2022 Legislative Budget Request, which is included in the Governor's Proposed Budget, to provide the staffing resources and equipment necessary to implement the expanded testing requirements included in the bill.
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:	The fiscal impact to MMTCs created by the expansion of medical marijuana product types which must be provided to the Department for testing at no cost is indeterminate but expected to be insignificant.
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.	Section 15. DOH/MQA will experience a non-recurring workload associated with updating the online application and websites. Sections 17-19. The License and Enforcement Database System (LEIDS) must be updated. The Versa Online (on-line application) system will need to be modified. Section 20. The License and Enforcement Database System and Online Service Portal would need to be updated to support the changes. Additionally, the DOH/MQA will experience a non- recurring workload associated with website changes.

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

DOH/MQA may experience an increase in workload and costs. It is anticipated that the impact will be minimal and can be absorbed with current resources.

When Section 7 is removed, current budget authority is adequate to absorb.

LEGAL - GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	No legal issues, concerns or comments identified at this time.

UNITED STATES DEPARTMENT OF EDUCATION
OFFICE OF THE UNDER SECRETARY

February 26, 2020

Re: FINAL ACCREDITATION AND STATE AUTHORIZATION REGULATIONS

Dear State Leaders:

This letter is to inform you that the U.S. Department of Education (Department) has published final regulations relating to the accreditation of institutions of higher education, as well as State authorization requirements for distance education, which may have an impact on your State.

The final regulations published this year were developed by a diverse negotiated rulemaking panel, which reached consensus in April 2019.[1] The Department published a Notice of Proposed Rule Making based on the consensus language, and received approximately 200 comments from the public regarding the proposed regulations. The Department responded to those comments, as appropriate, in the final regulation. With the exception of a few provisions relating to the recognition of accrediting agencies, which will take effect on January 1, 2021 and July 1, 2021, the accreditation and State authorization regulations will take effect on July 1, 2020.[2]

Below we highlight several key provisions of the final regulation that could have an impact on States. We are providing this notification to help you plan appropriately.

Regional versus National Accreditation

The Department is aware that some States have enacted laws and policies that treat institutions and the students who attend them differently based solely on whether the institution is accredited by a "national" accrediting agency or a "regional" accrediting agency. For example, some States limit opportunities to sit for occupational licensing exams to students who have completed a program at a regionally accredited institution. In other instances, transfer of credit determinations at public institutions, and other benefits provided by States, are limited to students who attended regionally accredited institutions.

Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded. Moreover, we have determined that most regional accreditors operate well outside of their historic geographic borders, primarily through the accreditation of branch campuses and additional locations. As a result, our new regulations have removed geography from an accrediting agency's scope.[3] Instead of distinguishing between regional and national accrediting agencies, the Department will distinguish only between institutional and programmatic accrediting agencies. The Department will no longer use the terms "regional" or "national" to refer to an accrediting agency.

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[1] 84 FR 58834

[2] The new regulations delay implementation of changes to the Department staff's review of accrediting agency applications for initial or renewal of recognition under 34 C.F.R. § 602.32(d) until January 1, 2021. *See* 84 FR 58927. The new regulations also delay implementation of changes to the Department staff's process for responding to accrediting agency applications and allowing agency responses within 180 days under 34 C.F.R. § 602.32(h) until July 1, 2021. *See* 84 FR 58928.

[3] *See* 84 FR 58917-58918 (amending 34 C.F.R. §§ 602.3, 602.11).

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www.ed.gov

Because the Department will no longer distinguish between "regional" and "national" accrediting agencies, we wanted to provide States with advanced notice of this change so that State leaders will have sufficient opportunity to adjust State laws, regulations, or policies accordingly.

State Authorization

The Department's revised Accreditation and State Authorization regulations also make changes to State authorization requirements.[4] For example, in order for a distance education provider to serve students in a State other than the one in which the institution has a physical presence, either the State in which the institution is located or the State in which the student is located must have a process in place to receive and review student complaints.[5] We encourage all States to implement the appropriate policies and processes to accept, investigate, and respond to student complaints.

In addition, because it is important for all students – and not just those who enroll in distance education – to understand whether the program in which they are enrolled will qualify them to work in certain occupations in a given State, the revised regulations require both ground-based and online programs to notify students whether the program will or will not meet licensure requirements in a particular State, or in the event that the institution has not made that determination, where a student may obtain that information.[6]

The revised regulations continue to recognize State reciprocity agreements, such that an institution participating in a State reciprocity agreement will have satisfied the Department's State authorization requirements in any State that also participates in the reciprocity agreement.[7] In response to public comments, the Department provided further clarity that, while States participating in a State authorization reciprocity agreement may still enforce their own general-purpose State laws and regulations outside of the State authorization of distance education, States participating in a reciprocity agreement may not impose additional distance education regulations or requirements upon institutions that participate in such agreements.[8]

The Department of Education has developed informational webinars to help States, institutions of higher education, and accreditors understand what is required of them under our new regulations. The webinars are located on the Department's website at https://www2.ed.gov/policy/highered/reg/hearulemaking/2018/index.html.

Should you have any questions, please feel free to contact the Accreditation Group at the Department of Education at aslrecordsmanager@ed.gov or 202-453-7615.

Sincerely,

Diane Auer Jones

Diane Auer Jones
Principal Deputy Under Secretary
Delegated the Duties of Under Secretary

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[4] *See generally* 84 FR 58914-58915 (amending 34 C.F.R. § 600.2); 84 FR 58915-58916 (amending 34 C.F.R. § 600.9).
[5] *See* 84 FR 58915 (amending 34 C.F.R. § 600.9(c)). *See* 84 FR 58845-58846 (comments and discussion).
[6] *See* 84 FR 58932 (amending 34 C.F.R. § 668.43(a)(5)).
[7] *See* 34 C.F.R. § 600.9(c)(1)(ii).
[8] *See* 84 FR 58841-58842, 58914-58915 (amending 34 C.F.R. § 600.2).

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 718
INTRODUCER:	Health Policy Committee and Senator Bradley
SUBJECT:	Provision of Health Care
DATE:	January 26, 2022
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 718 amends two sections of the Florida Statues, regarding authorization for unlicensed persons to assist patients or residents in the self-administration of medication in home health settings and in assisted living facilities (ALF), respectively, to allow an unlicensed person in a home health setting to assist a patient with the same kinds of self-administration of medication tasks that are allowed in an ALF. Additionally, the bill reorganizes several of the items currently listed under the self-administration of medication into a new category labeled as "other tasks" in both sections.

The bill also makes changes to several sections of the Florida Statutes regarding the treatment of prefilled insulin syringes or pens to allow unlicensed persons to bring such syringe or pen to a patient or resident from where it is stored in a home health setting or in an ALF, and to allow registered nurses to delegate the administration of insulin which is prefilled into such syringe or pen to a certified nursing assistant or home health aide.

The bill also amends several sections of the Florida Statutes relating to the transport of patients by Basic (BLS) and Advanced Life Support (ALS) services to require that permitted ALS ambulances be occupied by at least two specified medical personnel when conducting interfacility transfers of patients and to make conforming changes.

The bill provides an effective date of July 1, 2022.

II. Present Situation:

Home Health Agencies

A "home health agency" is an organization that provides home health services.[1] Home health services are health and medical services and supplies furnished to an individual in the individual's home or place of residence.[2]

Home health aides[3] and certified nursing assistants[4] (CNAs) are unlicensed health care workers employed by a home health agency to provide personal care[5] to patients and assist them with the following activities of daily living:

- Ambulation;
- Bathing;
- Dressing;
- Eating;
- Personal hygiene;
- Toileting;
- Physical transferring;
- Assistance with self-administered medication; and
- Administering medications.[6]

Assisting with the Self-Administration of Medication in a Home Health Setting

Section 400.488, F.S., allows an unlicensed person, defined as an individual not currently licensed to practice nursing or medicine who is employed by or under contract to a home health agency and who has received training with respect to assisting with the self-administration of medication as provided by AHCA rule,[7] to assist a patient with the self-administration of his or her medications. The 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 and includes:

- Taking the medication, in its previously dispensed, properly labeled container, from where it is stored and bringing it to the patient.

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[1] Section 400.462(12), F.S.

[2] Section 400.462(15), F.S., home health services include the following: nursing care; physical, occupational, respiratory, or speech therapy; home health aide services; dietetics and nutrition practice and nutrition counseling; and medical supplies, restricted to drugs and biologics prescribed by a physician.

[3] Section 400.462(14), F.S., a home health aide is 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, assists in administering medications as permitted in rule and for which the person has received training established by the agency, or performs tasks delegated to him or her under ch. 464, F.S.

[4] Section 464.201(3), F.S., a CNA is a person who meets the qualifications of part II of ch. 464, F.S., and who is certified by the Board of Nursing as a certified nursing assistant.

[5] Section 400.462(23), F.S., defines "personal care" as assistance to a patient in the activities of daily living, such as dressing, bathing, eating, or personal hygiene, and assistance in physical transfer, ambulation, and in administering medications as permitted by rule.

[6] Rule 59A-8.002(3), F.A.C.

[7] Rule 59A-8.0095, F.A.C., requires CNA's and home health aides to receive 2 hours of training prior to assisting with the self-administration of medication.

- 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 a prescribed amount of medication from the container, and closing the container.
- 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.
- Applying topical medications, including routine preventive skin care and applying and replacing bandages for minor cuts and abrasions as provided by the AHCA in rule.
- Returning the medication container to proper storage.
- 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.
- Keeping a record of when a patient receives assistance with self-administration under this section.

The section specifies that assistance with the self-administration of medications does not include:
- Mixing, compounding, converting, or calculating medication doses, except for measuring a prescribed amount of liquid medication or breaking a scored tablet or crushing a tablet as prescribed.
- The preparation of syringes for injection or the administration of medications by any injectable route.
- Administration of medications through intermittent positive pressure breathing machines or a nebulizer.
- Administration of medications by way of a tube inserted in a cavity of the body.
- Administration of parenteral preparations.
- Irrigations or debriding agents used in the treatment of a skin condition.
- Rectal, urethral, or vaginal preparations.
- Medications ordered by the physician or health care professional with prescriptive authority to be given "as needed," unless the order is written with specific parameters that preclude independent judgment on the part of the unlicensed person, and at the request of a competent patient.
- Medications for which the time of administration, the amount, the strength of dosage, the method of administration, or the reason for administration requires judgment or discretion on the part of the unlicensed person.

Assisted Living Facilities

An ALF is a residential establishment, or part of a residential establishment, that provides housing, meals, and one or more personal services for a period exceeding 24 hours to one or more adults who are not relatives of the owner or administrator.[8] A personal service is direct physical assistance with, or supervision of, the activities of daily living and the self-

[8] Section 429.02(5), F.S. An ALF does not include an adult family-care home or a non-transient public lodging establishment.

administration of medication.[9] Activities of daily living include ambulation, bathing, dressing, eating, grooming, toileting, and other similar tasks.[10]

An ALF is required to provide care and services that are appropriate to the needs of the residents who are accepted for admission to the facility.[11] The owner or facility administrator determines whether an individual is appropriate for admission to the facility based on a number of criteria.[12] If, as determined by the facility administrator or health care provider, a resident no longer meets the criteria for continued residency or the facility is unable to meet the resident's needs, the resident must be discharged in accordance with the Resident Bill of Rights.[13]

Assisting with the Self-Administration of Medication in an ALF

Section 429.256, F.S., establishes requirements for the assistance with the self-administration of medication. Residents who are capable of administering their own medications are encouraged to do so but an unlicensed person who is 18 years of age or older and has completed the required six hours of training may,[14] consistent with a dispensed prescription's label or the package directions of an over-the-counter medication, assist a resident 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 resident or the resident's surrogate, guardian, or attorney in fact.

The section specifies that the assistance with self-administration of medication includes:

- Taking the medication, in its previously dispensed, properly labeled container, including an insulin syringe that is prefilled with the proper dosage by a pharmacist and an insulin pen that is prefilled by the manufacturer, from where it is stored, and bringing it to the resident.
- In the presence of the resident, confirming that the medication is intended for that resident, orally advising the resident of the medication name and dosage, opening the container, removing a prescribed amount of medication from the container, and closing the container. The resident may sign a written waiver to opt out of being orally advised of the medication name and dosage. The waiver must identify all of the medications intended for the resident, including names and dosages of such medications, and must immediately be updated each time the resident's medications or dosages change.
- Placing an oral dosage in the resident's hand or placing the dosage in another container and helping the resident by lifting the container to his or her mouth.
- Applying topical medications.
- Returning the medication container to proper storage.
- Keeping a record of when a resident receives assistance with self-administration under this section.

[9] Section 429.02(18), F.S.
[10] Section 429.02(1), F.S.
[11] *See* Fla. Admin. Code R. 59A-36.007 (2019), for specific minimum standards.
[12] Section 429.26, F.S., and Fla. Admin. Code R. 59A-36.006 (2019).
[13] Section 429.28, F.S.
[14] *See* Fla. Admin. Code R. 59A-36.008(3)(a) (2019).

- Assisting with the use of a nebulizer, including removing the cap of a nebulizer, opening the unit dose of nebulizer solution, and pouring the prescribed premeasured dose of medication into the dispensing cup of the nebulizer.
- Using a glucometer to perform blood-glucose level checks.
- Assisting with putting on and taking off antiembolism stockings.
- Assisting with applying and removing an oxygen cannula but not with titrating the prescribed oxygen settings.
- Assisting with the use of a continuous positive airway pressure device but not with titrating the prescribed setting of the device.
- Assisting with measuring vital signs.
- Assisting with colostomy bags.

The section also specifies that assistance with self-administration does not include:
- Mixing, compounding, converting, or calculating medication doses, except for measuring a prescribed amount of liquid medication or breaking a scored tablet or crushing a tablet as prescribed.
- The preparation of syringes for injection or the administration of medications by any injectable route.
- Administration of medications by way of a tube inserted in a cavity of the body.
- Administration of parenteral preparations.
- The use of irrigations or debriding agents used in the treatment of a skin condition.
- Assisting with rectal, urethral, or vaginal preparations.
- Assisting with medications ordered by the physician or health care professional with prescriptive authority to be given "as needed," unless the order is written with specific parameters that preclude independent judgment on the part of the unlicensed person, and the resident requesting the medication is aware of his or her need for the medication and understands the purpose for taking the medication.
- Medications for which the time of administration, the amount, the strength of dosage, the method of administration, or the reason for administration requires judgment or discretion on the part of the unlicensed person.

Basic and Advanced Life Support Services

Part III of ch. 401, F.S., consisting of ss. 401.2101-401.465, F.S., provides for the regulation of emergency medical services by the Department of Health (DOH). The DOH website reflects that its Emergency Medical Services Section is responsible for the licensure and oversight of over 60,000 emergency medical technicians and paramedics, 270+ advanced and basic life support agencies, and over 4,500 EMS vehicles.[15] The DOH licenses three types of emergency medical services: air ambulance,[16] basic life support, and advanced life support services.

A basic life support service is an emergency medical service that uses *only* basic life support techniques.[17] In contrast, an advanced life support service is an emergency medical transport or

[15] Florida Department of Health, Emergency Medical Services System, *available at* http://www.floridahealth.gov/licensing-and-regulation/ems-system/index.html (last visited Jan. 12, 2022).
[16] Sections 401.23(3) and (4) and 401.251, F.S.
[17] Section 401.23(8), F.S.

non-transport service that uses advanced life support techniques.[18] Similarly, an emergency medical technician (EMT) is certified to perform basic life support,[19] but a paramedic is certified to perform basic and advanced life support.[20]

"Basic life support" is the assessment or treatment through the use of techniques described in the EMT-Basic National Standard Curriculum or the National EMS Education Standards of the U.S. Department of Transportation and approved by the DOH. The term includes the administration of oxygen and other techniques that have been approved by the DOH.[21] When transporting a person who is sick, injured, wounded, incapacitated, or helpless, each basic life support ambulance must be occupied by at least two persons:

- One patient attendant who is a certified emergency medical technician, certified paramedic, or licensed physician; and
- One ambulance driver who meets the requirements of s. 401.281, F.S.[22]

"Advanced life support" is the assessment or treatment through the use of techniques such as endotracheal intubation, the administration of drugs or intravenous fluids, telemetry, cardiac monitoring, cardiac defibrillation, and other techniques described in the EMT-Paramedic National Standard Curriculum or the National EMS Education Standards, pursuant to DOH rules.[23]

When transporting a person who is sick, injured, wounded, incapacitated, or helpless, each advanced life support ambulance must be occupied by at least one certified paramedic or licensed physician and one certified emergency medical technician, certified paramedic, or licensed physician who also meets the requirements of s. 401.281, F.S., for drivers.[24] Interfacility transfers[25] under s. 401.252, F.S., are exempt from this requirement.

The person occupying the advanced life support ambulance with the highest medical certifications is in charge of patient care.[26]

Section 401.25, F.S., provides requirements for licensure as basic and advanced life support services. Every licensee must possess a valid permit for each vehicle in use.[27]

[18] Section 401.23(2), F.S.
[19] Section 401.23(11), F.S.
[20] Section 401.23(17), F.S.
[21] Section 401.23(7), F.S.
[22] Section 401.25(7)(a), F.S.
[23] Section 401.23(1), F.S.
[24] Section 401.25(7)(b), F.S.
[25] Interfacility transfer is defined in s. 401.23, F.S., as the transportation by ambulance of a patient between two facilities licensed under chs. 393, 395, 400, or 429, F.S., pursuant to part III of ch. 401, F.S.
[26] *Id.*
[27] Section 401.26, F.S.

III. Effect of Proposed Changes:

Prefilled Insulin Pens and Syringes

SB 718 amend ss. 400.488 and 429.256, F.S., respectively, to specify that assistance with the self-administration of medication in home health and ALF settings includes the unlicensed person, as defined in those sections, being able to take an insulin syringe that is prefilled with the proper dose by a pharmacist or an insulin pen that is prefilled by the manufacturer from the place where those items are stored and bring it to the patient or resident. Additionally, the bill amends s. 464.0156, F.S., to allow a registered nurse to delegate to a CNA or home health aide the administration of medication in an insulin syringe that has been prefilled with the proper dose by a pharmacist or an insulin pen that is prefilled by the manufacturer.

Assistance with the Self-administration of Medication

The bill amends ss. 400.488 and 429.256, F.S., to reorganize several of the items currently listed under the assistance with the self-administration of medication into a new category labeled "other tasks." Specifically the bill moves:

- Using a glucometer to perform blood-glucose level checks.
- Assisting with putting on and taking off antiembolism stockings.
- Assisting with applying and removing an oxygen cannula but not with titrating the prescribed oxygen settings.
- Assisting with the use of a continuous positive airway pressure device but not with titrating the prescribed setting of the device.
- Assisting with measuring vital signs.
- Assisting with colostomy bags.

Additionally, the bill amends s. 400.488, F.S., (allowing and specifying what is included in the assistance with self-administration of medications in a home health setting) to match what is allowed for the assistance with self-administration of medications in ALFs under s. 429.256, F.S. Specifically, the bill adds the following items to the list of activities that qualify as assistance with self-administration of medication in a home health setting:

- Assisting with transdermal patches.
- Using a glucometer to perform blood-glucose level checks.
- Assisting with putting on and taking off antiembolism stockings.
- Assisting with applying and removing an oxygen cannula but not with titrating the prescribed oxygen settings.
- Assisting with the use of a continuous positive airway pressure device but not with titrating the prescribed setting of the device.
- Assisting with measuring vital signs.
- Assisting with colostomy bags.

The bill also revises how assistance may be given in using a nebulizer in a home health setting to match how such assistance is authorized in an ALF. Specifically, the bill removes the authorization to set up and clean the nebulizer and confirm that the medication is intended for the patient.

Interfacility Transfers of Patients

The bill amends s. 401.252, F.S., to require that a permitted ALS ambulance be occupied by at least two persons when conducting an interfacility transfer:

- One patient attendant who is a certified paramedic, a registered nurse who qualifies under the provisions specified in the section, or a licensed physician; and
- One other person who is a certified EMT, certified paramedic, a licensed physician, or an ambulance driver who meets the driver requirements of s. 401.281, F.S.

The bill specifies that the person occupying the vehicle who has the highest medical certification in this state is in charge of patient care during the transfer.

Other Provisions

The bill amends ss. 401.25 and 401.27, F.S., to make conforming changes.

The bill provides an effective date of July 1, 2022.

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 718 may have an indeterminate negative fiscal impact on ALS service providers that may be required to have a second person in the ambulance when performing an interfacility transfer.

CS/SB 718 may have an indeterminate positive fiscal impact on home health service providers who are able to use unlicensed persons to provide additional services that are not currently authorized.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 400.488, 401.252, 464.0156, 401.25, 401.27, and 429.256.

IX. Additional Information:

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

CS by Health Policy on January 26, 2022:
The CS reorganizes sections related to the assistance with self-administration of medication in ALFs and home health to add a new category entitled "other tasks." The CS authorizes the same staff to perform these "other tasks" as may currently perform the assistance with self-administration of medication and moves tasks that are currently listed under the assistance with self-administration of medication into the new category. Specifically the bill moves:

- Using a glucometer to perform blood-glucose level checks.
- Assisting with putting on and taking off antiembolism stockings.
- Assisting with applying and removing an oxygen cannula but not with titrating the prescribed oxygen settings.
- Assisting with the use of a continuous positive airway pressure device but not with titrating the prescribed setting of the device.
- Assisting with measuring vital signs.
- Assisting with colostomy bags.

The CS also renumbers sections 3, 4, and 5 as sections 4, 5, and 6 and retitles the bill as "An act relating to the provision of health care."

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/26/2022	.	
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The Committee on Health Policy (Bradley) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 400.488, Florida Statutes, is amended to read:

400.488 Assistance with self-administration of medication and with other tasks.—

(1) For purposes of this section, the term:

(a) "Informed consent" means advising the patient, or the

patient's surrogate, guardian, or attorney in fact, that the patient may be receiving assistance with self-administration of medication or other tasks from an unlicensed person.

(b) "Unlicensed person" means an individual not currently licensed to practice nursing or medicine who is employed by or under contract to a home health agency and who has received training with respect to assisting with the self-administration of medication or other tasks as provided by agency rule.

(2) Patients who are capable of self-administering their own medications and performing other tasks 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. An unlicensed person may also provide assistance with other tasks specified in subsection (6). Assistance with self-administration of medication or such other tasks ~~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, transdermal patches, and topical ophthalmic, otic, and nasal dosage forms, including solutions, suspensions, sprays, inhalers, 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. For purposes of this paragraph, an insulin syringe that is prefilled with the proper dosage by a pharmacist and an insulin pen that is prefilled by the manufacturer are considered medications in previously dispensed, properly labeled containers.

(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, 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 routine preventive skin care and applying and replacing bandages for minor cuts and abrasions as provided by the agency in rule~~.

(e) Returning the medication container to proper storage.

(f) ~~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)~~ Keeping a record of when a patient receives assistance with self-administration under this section.

(g) Assisting with the use of a nebulizer, including removing the cap of a nebulizer, opening the unit dose of nebulizer solutions, and pouring the prescribed premeasured dose of medication into the dispensing cup of the nebulizer.

(4) Assistance with self-administration of medication does not include:

(a) Mixing, compounding, converting, or calculating medication doses, except for measuring a prescribed amount of liquid medication or breaking a scored tablet or crushing a tablet as prescribed.

(b) The preparation of syringes for injection or the administration of medications by any injectable route.

(c) ~~Administration of medications through intermittent positive pressure breathing machines or a nebulizer.~~

~~(d)~~ Administration of medications by way of a tube inserted in a cavity of the body.

(d) ~~(e)~~ Administration of parenteral preparations.

(e) ~~(f)~~ The use of irrigations or debriding agents used in the treatment of a skin condition.

(f) ~~(g)~~ Assisting with rectal, urethral, or vaginal preparations.

(g) ~~(h)~~ Assisting with medications ordered by the physician or health care professional with prescriptive authority to be given "as needed," unless the order is written with specific parameters that preclude independent judgment on the part of the unlicensed person, and at the request of a competent patient.

(h) ~~(i)~~ Assisting with medications for which the time of administration, the amount, the strength of dosage, the method of administration, or the reason for administration requires

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judgment or discretion on the part of the unlicensed person.

(5) Assistance with the self-administration of medication by an unlicensed person as described in this section does not constitute administration as defined in s. 465.003.

(6) Assistance with other tasks includes:

(a) Assisting with the use of a glucometer to perform blood-glucose level checks.

(b) Assisting with putting on and taking off antiembolism stockings.

(c) Assisting with applying and removing an oxygen cannula but not with titrating the prescribed oxygen settings.

(d) Assisting with the use of a continuous positive airway pressure device but not with titrating the prescribed setting of the device.

(e) Assisting with measuring vital signs.

(f) Assisting with colostomy bags.

(7) ~~(6)~~ The agency may by rule establish procedures and interpret terms as necessary to administer this section.

Section 2. Section 401.252, Florida Statutes, is amended to read:

401.252 Interfacility transfer.—

(1) When conducting an interfacility transfer, a permitted advanced life support ambulance must be occupied by at least two persons: one patient attendant who is a certified paramedic, a registered nurse authorized under subsection (2), or a licensed physician; and one person who is a certified emergency medical technician, a certified paramedic, a licensed physician, or an ambulance driver who meets the driver requirements of s. 401.281. The person occupying the ambulance who has the highest

medical certification in this state is in charge of patient care during the interfacility transfer.

(2) A licensed basic or advanced life support ambulance service may conduct interfacility transfers in a permitted ambulance~~,~~ using a registered nurse in place of an emergency medical technician or paramedic~~,~~ if:

(a) The registered nurse holds a current certificate of successful course completion in advanced cardiac life support;

(b) The physician in charge has granted permission for such a transfer, has designated the level of service required for such transfer, and has deemed the patient to be in such a condition appropriate to this type of ambulance staffing; and

(c) The registered nurse operates within the scope of part I of chapter 464.

(3)~~(2)~~ A licensed basic or advanced life support service may conduct interfacility transfers in a permitted ambulance if the patient’s treating physician certifies that the transfer is medically appropriate and the physician provides reasonable transfer orders. An interfacility transfer must be conducted in a permitted ambulance if it is determined that the patient needs, or is likely to need, medical attention during transport. If the emergency medical technician or paramedic believes the level of patient care required during the transfer is beyond his or her capability, the medical director, or his or her designee, must be contacted for clearance prior to conducting the transfer. If necessary, the medical director, or his or her designee, shall attempt to contact the treating physician for consultation to determine the appropriateness of the transfer.

(4)~~(3)~~ Infants younger ~~less~~ than 28 days old or ~~infants~~

weighing less than 5 kilograms~~,~~ who require critical care interfacility transport to a neonatal intensive care unit must~~,~~ ~~shall~~ be transported in a permitted advanced life support or basic life support transport ambulance, or in a permitted advanced life support or basic life support ambulance that is recognized by the department as meeting designated criteria for neonatal interfacility critical care transport.

Section 3. Section 429.256, Florida Statutes, is amended to read:

429.256 Assistance with self-administration of medication and with other tasks.—

(1) For the purposes of this section, the term:

(a) "Informed consent" means advising the resident, or the resident's surrogate, guardian, or attorney in fact, that an assisted living facility is not required to have a licensed nurse on staff, that the resident may be receiving assistance with self-administration of medication or other tasks from an unlicensed person, and that such assistance, if provided by an unlicensed person, will or will not be overseen by a licensed nurse.

(b) "Unlicensed person" means an individual not currently licensed to practice nursing or medicine who is employed by or under contract to an assisted living facility and who has received training with respect to assisting with the self-administration of medication or other tasks in an assisted living facility as provided under s. 429.52 prior to providing such assistance as described in this section.

(2) Residents who are capable of self-administering their own medications and performing other tasks 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 resident whose condition is medically stable with the self-administration of routine, regularly scheduled medications that are intended to be self-administered. An unlicensed person may also provide assistance with other tasks specified in subsection (6). Assistance with self-administration of medication or such other tasks ~~self-medication~~ by an unlicensed person may occur only upon a documented request by, and the written informed consent of, a resident or the resident's surrogate, guardian, or attorney in fact. For the purposes of this section, self-administered medications include both legend and over-the-counter oral dosage forms, topical dosage forms, transdermal patches, and topical ophthalmic, otic, and nasal dosage forms including solutions, suspensions, sprays, and inhalers.

(3) Assistance with self-administration of medication includes:

(a) Taking the medication, in its previously dispensed, properly labeled container, ~~including an insulin syringe that is prefilled with the proper dosage by a pharmacist and an insulin pen that is prefilled by the manufacturer,~~ from where it is stored~~,~~ and bringing it to the resident. For purposes of this paragraph, an insulin syringe that is prefilled with the proper dosage by a pharmacist and an insulin pen that is prefilled by the manufacturer are considered medications in previously dispensed, properly labeled containers.

(b) In the presence of the resident, confirming that the medication is intended for that resident, orally advising the

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resident of the medication name and dosage, opening the container, removing a prescribed amount of medication from the container, and closing the container. The resident may sign a written waiver to opt out of being orally advised of the medication name and dosage. The waiver must identify all of the medications intended for the resident, including names and dosages of such medications, and must immediately be updated each time the resident's medications or dosages change.

(c) Placing an oral dosage in the resident's hand or placing the dosage in another container and helping the resident by lifting the container to his or her mouth.

(d) Applying topical medications.

(e) Returning the medication container to proper storage.

(f) Keeping a record of when a resident receives assistance with self-administration under this section.

(g) Assisting with the use of a nebulizer, including removing the cap of a nebulizer, opening the unit dose of nebulizer solution, and pouring the prescribed premeasured dose of medication into the dispensing cup of the nebulizer.

~~(h) Using a glucometer to perform blood-glucose level checks.~~

~~(i) Assisting with putting on and taking off antiembolism stockings.~~

~~(j) Assisting with applying and removing an oxygen cannula but not with titrating the prescribed oxygen settings.~~

~~(k) Assisting with the use of a continuous positive airway pressure device but not with titrating the prescribed setting of the device.~~

~~(l) Assisting with measuring vital signs.~~

~~(m) Assisting with colostomy bags.~~

(4) Assistance with self-administration of medication does not include:

(a) Mixing, compounding, converting, or calculating medication doses, except for measuring a prescribed amount of liquid medication or breaking a scored tablet or crushing a tablet as prescribed.

(b) The preparation of syringes for injection or the administration of medications by any injectable route.

(c) Administration of medications by way of a tube inserted in a cavity of the body.

(d) Administration of parenteral preparations.

(e) The use of irrigations or debriding agents used in the treatment of a skin condition.

(f) Assisting with rectal, urethral, or vaginal preparations.

(g) Assisting with medications ordered by the physician or health care professional with prescriptive authority to be given "as needed," unless the order is written with specific parameters that preclude independent judgment on the part of the unlicensed person, and the resident requesting the medication is aware of his or her need for the medication and understands the purpose for taking the medication.

(h) Assisting with medications for which the time of administration, the amount, the strength of dosage, the method of administration, or the reason for administration requires judgment or discretion on the part of the unlicensed person.

(5) Assistance with the self-administration of medication by an unlicensed person as described in this section shall not

be considered administration as defined in s. 465.003.

(6) Assistance with other tasks includes:

(a) Assisting with the use of a glucometer to perform blood-glucose level checks.

(b) Assisting with putting on and taking off antiembolism stockings.

(c) Assisting with applying and removing an oxygen cannula but not with titrating the prescribed oxygen settings.

(d) Assisting with the use of a continuous positive airway pressure device but not with titrating the prescribed setting of the device.

(e) Assisting with measuring vital signs.

(f) Assisting with colostomy bags.

(7) ~~(6)~~ The agency may by rule establish facility procedures and interpret terms as necessary to implement this section.

Section 4. Subsection (2) of section 464.0156, Florida Statutes, is amended to read:

464.0156 Delegation of duties.—

(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 to a patient of a home health agency, 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, except for the administration of an insulin syringe that is prefilled with the proper dosage by a pharmacist or an insulin

pen that is prefilled by the manufacturer.

Section 5. Subsection (7) of section 401.25, Florida Statutes, is amended to read:

401.25 Licensure as a basic life support or an advanced life support service.—

(7)(a) Each permitted basic life support ambulance not specifically exempted from this part, when transporting a person who is sick, injured, wounded, incapacitated, or helpless, must be occupied by at least two persons: one patient attendant who is a certified emergency medical technician, certified paramedic, or licensed physician; and one ambulance driver who meets the requirements of s. 401.281. This paragraph does not apply to interfacility transfers governed by s. 401.252 ~~s. 401.252(1)~~.

(b) Each permitted advanced life support ambulance not specifically exempted from this part, when transporting a person who is sick, injured, wounded, incapacitated, or helpless, must be occupied by at least two persons: one who is a certified paramedic or licensed physician; and one who is a certified emergency medical technician, certified paramedic, or licensed physician who also meets the requirements of s. 401.281 for drivers. The person with the highest medical certifications shall be in charge of patient care. This paragraph does not apply to interfacility transfers governed by s. 401.252 ~~s. 401.252(1)~~.

Section 6. Subsection (1) of section 401.27, Florida Statutes, is amended to read:

401.27 Personnel; standards and certification.—

(1) Each permitted ambulance not specifically exempted from

this part, when transporting a person who is sick, injured, wounded, incapacitated, or helpless, must be occupied by at least two persons, one of whom must be a certified emergency medical technician, certified paramedic, or licensed physician and one of whom must be a driver who meets the requirements for ambulance drivers. This subsection does not apply to interfacility transfers governed by s. 401.252 ~~s. 401.252(1)~~.

Section 7. This act shall take effect July 1, 2022.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to the provision of health care; amending s. 400.488, F.S.; revising the definitions of the terms "informed consent" and "unlicensed person"; authorizing unlicensed persons to assist patients with other specified tasks; revising provisions relating to medications and devices with which unlicensed persons may assist patients in self-administration under certain circumstances; amending s. 401.252, F.S.; specifying staffing requirements for advanced life support ambulances during interfacility transfers; providing that the person occupying the ambulance who has the highest medical certification in this state is in charge of patient care during the transfer; amending s. 429.256, F.S.; revising the definitions of the terms "informed consent" and "unlicensed person";


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authorizing unlicensed persons to assist patients with other specified tasks; revising provisions relating to medications and devices with which unlicensed persons may assist patients in self-administration under certain circumstances; amending s. 464.0156, F.S.; revising the list of medications that a registered nurse may delegate the administration of to a certified nursing assistant or home health aide; amending ss. 401.25 and 401.27, F.S.; conforming cross-references; providing an effective date.

883280

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
01/24/2022	.	
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	.	
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The Committee on Health Policy (Bradley) recommended the following:

Senate Amendment

In title, delete lines 2 - 3
and insert:
An act relating to the provision of health care;
amending s. 400.488, F.S.; revising

By Senator Bradley

5-00716A-22 2022718__

A bill to be entitled

An act relating to patient care in health care facilities; amending s. 400.488, F.S.; revising provisions relating to medications and devices with which unlicensed individuals may assist patients in self-administration under certain circumstances; amending s. 401.252, F.S.; specifying staffing requirements for advanced life support ambulances during interfacility transfers; providing that the person occupying the ambulance who has the highest medical certification in this state is in charge of patient care during the transfer; amending s. 464.0156, F.S.; revising the list of medications that a registered nurse may delegate the administration of to a certified nursing assistant or home health aide; amending ss. 401.25, 401.27, and 429.256, F.S.; conforming provisions to changes made by the act; providing an effective date.

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

Section 1. Subsections (2), (3), and (4) 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 must ~~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

5-00716A-22 2022718__

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, transdermal patches, and topical ophthalmic, otic, and nasal dosage forms, including solutions, suspensions, sprays, inhalers, 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. For purposes of this paragraph, an insulin syringe that is prefilled with the proper dosage by a pharmacist and an insulin pen that is prefilled by the manufacturer are considered medications in previously dispensed, properly labeled containers.

(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, 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 routine~~

~~preventive skin care and applying and replacing bandages for minor cuts and abrasions as provided by the agency in rule~~.

(e) Returning the medication container to proper storage.

(f) ~~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)~~ Keeping a record of when a patient receives assistance with self-administration under this section.

(g) Assisting with the use of a nebulizer, including removing the cap of a nebulizer, opening the unit dose of nebulizer solutions, and pouring the prescribed premeasured dose of medication into the dispensing cup of the nebulizer.

(h) Using a glucometer to perform blood-glucose level checks.

(i) Assisting with putting on and taking off antiembolism stockings.

(j) Assisting with applying and removing an oxygen cannula but not with titrating the prescribed oxygen settings.

(k) Assisting with the use of a continuous positive airway pressure device but not with titrating the prescribed setting of the device.

(l) Assisting with measuring vital signs.

(m) Assisting with colostomy bags.

(4) Assistance with self-administration does not include:

(a) Mixing, compounding, converting, or calculating medication doses, except for measuring a prescribed amount of liquid medication or breaking a scored tablet or crushing a tablet as prescribed.

(b) The preparation of syringes for injection or the administration of medications by any injectable route.

(c) ~~Administration of medications through intermittent positive pressure breathing machines or a nebulizer.~~

~~(d)~~ Administration of medications by way of a tube inserted in a cavity of the body.

(d) ~~(c)~~ Administration of parenteral preparations.

(e) ~~(f)~~ Irrigations or debriding agents used in the treatment of a skin condition.

(f) ~~(g)~~ Rectal, urethral, or vaginal preparations.

(g) ~~(h)~~ Medications ordered by the physician or health care professional with prescriptive authority to be given "as needed," unless the order is written with specific parameters that preclude independent judgment on the part of the unlicensed person, and at the request of a competent patient.

(h) ~~(i)~~ Medications for which the time of administration, the amount, the strength of dosage, the method of administration, or the reason for administration requires judgment or discretion on the part of the unlicensed person.

Section 2. Section 401.252, Florida Statutes, is amended to read:

401.252 Interfacility transfer.—

(1) When conducting an interfacility transfer, a permitted advanced life support ambulance must be occupied by at least two persons: one patient attendant who is a certified paramedic, a

registered nurse authorized under subsection (2), or a licensed physician; and one who is a certified emergency medical technician, a certified paramedic, a licensed physician, or an ambulance driver who meets the driver requirements of s. 401.281. The person occupying the ambulance who has the highest medical certification in this state is in charge of patient care during the interfacility transfer.

(2) A licensed basic or advanced life support ambulance service may conduct interfacility transfers in a permitted ambulance~~,~~ using a registered nurse in place of an emergency medical technician or paramedic~~,~~ if:

(a) The registered nurse holds a current certificate of successful course completion in advanced cardiac life support;

(b) The physician in charge has granted permission for such a transfer, has designated the level of service required for such transfer, and has deemed the patient to be in such a condition appropriate to this type of ambulance staffing; and

(c) The registered nurse operates within the scope of part I of chapter 464.

(3)~~(2)~~ A licensed basic or advanced life support service may conduct interfacility transfers in a permitted ambulance if the patient's treating physician certifies that the transfer is medically appropriate and the physician provides reasonable transfer orders. An interfacility transfer must be conducted in a permitted ambulance if it is determined that the patient needs, or is likely to need, medical attention during transport. If the emergency medical technician or paramedic believes the level of patient care required during the transfer is beyond his or her capability, the medical director, or his or her designee,

must be contacted for clearance prior to conducting the transfer. If necessary, the medical director, or his or her designee, shall attempt to contact the treating physician for consultation to determine the appropriateness of the transfer.

(4)~~(3)~~ Infants younger ~~less~~ than 28 days old or ~~infants~~ weighing less than 5 kilograms~~,~~ who require critical care interfacility transport to a neonatal intensive care unit must~~,~~ ~~shall~~ be transported in a permitted advanced life support or basic life support transport ambulance, or in a permitted advanced life support or basic life support ambulance that is recognized by the department as meeting designated criteria for neonatal interfacility critical care transport.

Section 3. Subsection (2) of section 464.0156, Florida Statutes, is amended to read:

464.0156 Delegation of duties.—

(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 to a patient of a home health agency, 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, except for the administration of an insulin syringe that is prefilled with the proper dosage by a pharmacist or an insulin pen that is prefilled by the manufacturer.

Section 4. Subsection (7) of section 401.25, Florida Statutes, is amended to read:

401.25 Licensure as a basic life support or an advanced life support service.—

(7)(a) Each permitted basic life support ambulance not specifically exempted from this part, when transporting a person who is sick, injured, wounded, incapacitated, or helpless, must be occupied by at least two persons: one patient attendant who is a certified emergency medical technician, certified paramedic, or licensed physician; and one ambulance driver who meets the requirements of s. 401.281. This paragraph does not apply to interfacility transfers governed by s. 401.252 ~~s. 401.252(1)~~.

(b) Each permitted advanced life support ambulance not specifically exempted from this part, when transporting a person who is sick, injured, wounded, incapacitated, or helpless, must be occupied by at least two persons: one who is a certified paramedic or licensed physician; and one who is a certified emergency medical technician, certified paramedic, or licensed physician who also meets the requirements of s. 401.281 for drivers. The person with the highest medical certifications shall be in charge of patient care. This paragraph does not apply to interfacility transfers governed by s. 401.252 ~~s. 401.252(1)~~.

Section 5. Subsection (1) of section 401.27, Florida Statutes, is amended to read:

401.27 Personnel; standards and certification.—

(1) Each permitted ambulance not specifically exempted from this part, when transporting a person who is sick, injured, wounded, incapacitated, or helpless, must be occupied by at least two persons, one of whom must be a certified emergency

medical technician, certified paramedic, or licensed physician and one of whom must be a driver who meets the requirements for ambulance drivers. This subsection does not apply to interfacility transfers governed by s. 401.252 ~~s. 401.252(1)~~.

Section 6. Paragraph (a) of subsection (3) of section 429.256, Florida Statutes, is amended to read:

429.256 Assistance with self-administration of medication.—

(3) Assistance with self-administration of medication includes:

(a) Taking the medication, in its previously dispensed, properly labeled container, ~~including an insulin syringe that is prefilled with the proper dosage by a pharmacist and an insulin pen that is prefilled by the manufacturer,~~ from where it is stored~~,~~ and bringing it to the resident. For purposes of this paragraph, an insulin syringe that is prefilled with the proper dosage by a pharmacist and an insulin pen that is prefilled by the manufacturer are considered medications in previously dispensed, properly labeled containers.

Section 7. This act shall take effect July 1, 2022.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR JENNIFER BRADLEY
5th District

COMMITTEES:
Community Affairs, *Chair*
Agriculture, *Vice Chair*
Appropriations Subcommittee on Agriculture, Environment, and General Government
Education
Ethics and Elections
Judiciary
Reapportionment

SELECT SUBCOMMITTEE:
Select Subcommittee on Congressional Reapportionment, *Chair*

JOINT COMMITTEES:
Joint Legislative Auditing Committee
Joint Select Committee on Collective Bargaining

November 16, 2021

Senator Manny Diaz, Chairman
Senate Health Policy Committee
306 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Mr. Chairman:

I respectfully request that Senate Bill 718 be placed on the agenda of the Health Policy Committee at your earliest convenience. The bill includes a provision that mirrors the duties of a home health aide or a CNA with the assistance of a patient's self-administration of medicine in the home health statute to the assisted living facility statute (ALF). It also allows for flexibility for ambulance providers related to the persons staffing the vehicle for non-emergency transports only.

Thank you for your consideration of this request.

Sincerely,

Jennifer Bradley

Jennifer Bradley

cc: Allen Brown, Staff Director
Tori Denson, Administrative Assistant

REPLY TO:
❒ 1279 Kingsley Avenue, Kingsley Center, Suite 117, Orange Park, Florida 32073 (904) 278-2085
❒ 324 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5005

Senate's Website: *www.flsenate.gov*

WILTON SIMPSON
President of the Senate

AARON BEAN
President Pro Tempore

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

1/26/2022
Meeting Date

Health Policy
Committee

718
Bill Number or Topic

Amendment Barcode (if applicable)

Name Jason Hand

Phone 850-443-0024

Address 2292 Wakulla St Ste 1
Street

Email jhand@floridaseniorliving.org

Tallahassee FL 32308
City State Zip

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

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☒ I am a registered lobbyist, representing: Florida Senior Living Association

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

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1/26/22
Meeting Date

S. Health Policy
Committee

718
Bill Number or Topic

Amendment Barcode (if applicable)

Name Jennifer Ungru

Phone 850-999-4100

Address
Street

Email

City *State* *Zip*

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

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☒ I am a registered lobbyist, representing:
Home Care Association of America

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

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JAN 26, 2022
Meeting Date

Health Policy
Committee

SB 718
Bill Number or Topic

Amendment Barcode (if applicable)

Name Greg Dewitt

Phone 239-462-2669

Address 24299 Golden Eagle Ln.
Street

Email DeWitt@Bonitafire.org

Bonita Springs FL. 34135
City State Zip

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

PLEASE CHECK ONE OF THE FOLLOWING:

☒ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

Florida Fire Chiefs' Assoc.

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

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1/26/2022
Meeting Date

Health Policy
Committee

718
Bill Number or Topic

Amendment Barcode (if applicable)

Name Zayne Smith - AARP

Phone 850.228.4243

Address 215 S. Monroe St.
Street

Email zsmith@aarp.org

Tallahassee FL 32301
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
AARP

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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

S-001 (08/10/2021)

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 1770
INTRODUCER:	Senator Book
SUBJECT:	Donor Human Milk Bank Services
DATE:	January 25, 2022
REVISED:	

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

I. Summary:

SB 1770 authorizes Florida Medicaid to pay for donor human milk bank services as an optional covered service in the fee-for service delivery system and requires health plans participating in the Statewide Medicaid Managed Care program to cover donor human milk bank services. The bill specifies health conditions for which human donor milk services would be medically necessary and provides requirements that milk banks must meet in order to qualify as Medicaid providers. The bill establishes that Medicaid's reimbursement rates for donor human milk cannot be less than the milk bank's cost to procure it plus reasonable processing and handling fees.

Because human donor milk is not currently a covered service, the bill will have an indeterminate negative fiscal impact on Florida Medicaid. *See* Section V of this analysis.

The bill provides an effective date of July 1, 2022.

II. Present Situation:

Donor Human Breast Milk

According to the federal Centers for Disease Control and Prevention (CDC), breast milk is the best source of nutrition for most infants.[1] Ideally, an infant should be fed his or her own mother's breast milk because nutritional components within the mother's breast milk change to meet the infant's needs as he or she ages.[2] Mothers of infants born prematurely are sometimes unable to produce milk because their bodies aren't ready, they too are sick, or they're affected by the stress

[1] Centers for Disease Control and Prevention, *Frequently Asked Questions* (FAQ) (Aug. 10, 2021) *available at* https://www.cdc.gov/breastfeeding/faq/index.htm (last visited Jan. 22, 2022).
[2] *Id.*

of having their premature infant in intensive care.[3] Breast milk donated by nursing mothers provides an option for infants who are unable to receive adequate nutrition from their mother's own milk or from commercial infant formulas. Very few illnesses are transmitted via breast milk, even in cases where someone else's breast milk is given to another child.[4]

The American Academy of Pediatrics (AAP) notes that human donor breast milk can be effective for high-risk and very low birthweight infants if the child's mother is unable to provide enough milk.[5] Additionally, the World Health Organization (WHO) indicates that human donor breast milk can prevent some digestive disorders but specifies that any donor milk must come from safe facilities and is not recommended for sick infants or those weighing less than 1000 grams.[6, 7] In the absence of a mother's milk, the WHO notes that standard formula is also an acceptable alternative.[8]

Currently, the federal Food and Drug Administration (FDA) considers human donor breast milk a "food" source rather than a medical product. The FDA does not have established guidelines or standards for human donor breast milk or milk banks, although it does recommend consulting with a health care provider before feeding it to an infant.[9] Additionally, the FDA recommends that the caregiver only feed an infant milk from a source that has screened its donors and has taken precautions to ensure milk safety, such as a milk bank.[10]

The Human Milk Banking Association of North America (HMBANA)

Founded in 1985, the Human Milk Banking Association of North America (HMBANA) serves as the professional organization that accredits nonprofit milk banks in the United States and Canada.[11] The HMBANA is funded by membership fees from its 31 member nonprofit milk banks, foundation funds, and individual donors.[12] There is one HMBANA-accredited location in Florida – the Mother's Milk Bank of Florida located in Orlando.[13] The Mother's Milk Bank of

[3] Naseem S. Miller, *Bill aims to get Medicaid coverage for donor breast milk: 'Something like this makes smart policy'*, Orlando Sentinel (Mar. 15, 2019) *available at* https://www.orlandosentinel.com/health/os-ne-mothers-milk-bank-bill-20190315-story.html (last visited Jan. 22, 2022).
[4] *Supra* note 1.
[5] American Academy of Pediatrics Committee on Nutrition, Section on Breastfeeding and Committee on Fetus and Newborn, Policy Statement, *Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States* (Jan. 2017) *available at* https://publications.aap.org/pediatrics/article/139/1/e20163440/52000/Donor-Human-Milk-for-the-High-Risk-Infant (last visited Jan. 22, 2022).
[6] Agency for Health Care Administration, *Senate Bill 240 Fiscal Analysis* (Dec. 28, 2020) (on file with Senate Committee on Health Policy).
[7] World Health Organization, *Recommendations for the Feeding of low-birth-weight infants in low- and middle-income countries, available at* https://www.who.int/elena/titles/full_recommendations/feeding_lbw/en/ (last visited Jan. 22, 2022).
[8] *Id.*
[9] U.S. Food and Drug Administration, *Use of Donor Human Milk* (Mar. 22, 2018) *available at* https://www.fda.gov/science-research/pediatrics/use-donor-human-milk (last visited Jan. 22, 2022).
[10] *Id.*
[11] Human Milk Banking Association of North America, *About Us*, *available at* https://www.hmbana.org/about-us/ (last visited Jan. 22, 2022).
[12] *Id.*
[13] Human Milk Banking Association of North America, *Find a Milk Bank*, *available at* https://www.hmbana.org/find-a-milk-bank/ (last visited Jan. 22, 2022).

Florida supplies pasteurized donor human milk to 38 of the 68[14] neonatal intensive care units (NICUs) in Florida, as well as to medically fragile babies at home.[15]

HMBANA Safety Guidelines[16]

The HMBANA reports that its member milk banks follow guidelines that were developed by the HMBANA in consultation with the CDC and the FDA. The FDA reports that it has not been involved in establishing these voluntary guidelines.[17] According to the AHCA, no federal or state regulations are in place to oversee the Mother's Milk Bank of Florida.[18]

Under the HMBANA's guidelines, before milk is collected, each donor is strictly screened for medical and lifestyle risk factors and serum is screened for HIV, HTLV, syphilis, and Hepatitis B and C.[19] After the milk is collected, it is mixed and pooled so that each pool includes human milk from three to five donors. This is done to ensure an even distribution of nutritional components. Bottles are filled with the pooled milk and then the milk is pasteurized to eliminate potentially harmful bacteria while retaining the majority of the milk's beneficial nutrients. Milk samples are taken during the pasteurization process and cultured to check for bacterial growth. Any contaminated milk is discarded. No milk is dispensed after pasteurization until a culture is found to be negative for bacteriological growth. After pasteurization, the milk is frozen and shipped to hospitals and outpatient families.

AHCA Report on Donor Human Milk[20]

In 2021, the Florida Legislature passed the General Appropriations Act, SB 2500, which required the AHCA, in consultation with the Department of Health (DOH), to study and report on the use of donor human milk as a supplement to newborn care and health specific to newborn infants born prematurely and hospitalized within the NICU.[21] On November 1, 2021, the report was published. It includes recommendations of best practices for the oversight of milk banks and their staff, operating procedures, standards for donor screening, and recommendations for the collection, storage, handling, processing, and dispending of donor human milk. The report also addresses the need for high-quality clinical studies to quantity the efficacy and cost-effectiveness of donor human milk derivatives.[22]

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[14] *Supra* note 3.
[15] Mothers' Milk Bank of Florida, *Covid-19 Update*, *available at* https://milkbankofflorida.org/covid-19-update/ (last visited Jan. 22, 2022).
[16] Human Milk Banking Association of North America, *Milk Processing and Safety*, *available at* https://www.hmbana.org/our-work/milk-processing-safety.html (last visited Jan. 22, 2022).
[17] *Supra* note 9.
[18] *Supra* note 6.
[19] Human Milk Banking Association of North America, *Milk Banking and COVID-19* (Apr. 2, 2020) *available at* https://www.hmbana.org/file_download/inline/a04ca2a1-b32a-4c2e-9375-44b37270cfbd (last visited Jan. 22, 2022).
[20] Agency for Health Care Administration, Donor Human Milk Legislative Report (Nov. 1, 2021) (on file with Senate Committee on Health Policy).
[21] Chapter 2021-36, s. 3, Laws of Fla.
[22] *Supra* note 20 at 45.

Florida Medicaid Program

The Medicaid program is a joint federal-state program that finances health coverage for individuals, including eligible low-income adults, children, pregnant women, elderly adults and persons with disabilities.[23] The Centers for Medicare and Medicaid Services (CMS) within the U.S. Department of Health and Human Services (HHS) is responsible for administering the federal Medicaid program. Florida Medicaid is the health care safety net for low-income Floridians. Florida's program is administered by the AHCA and financed through state and federal funds.[24]

A Medicaid state plan is an agreement between a state and the federal government describing how the state administers its Medicaid programs. The state plan 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 states the flexibility to cover other population groups (optional eligibility groups). 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. States send state plan amendments to the federal CMS for review and approval.[25]

Medicaid enrollees generally receive benefits through one of two service-delivery systems: fee-for-service (FFS) or managed care. Under FFS, health care providers are paid by the state Medicaid program for each service provided to a Medicaid enrollee. Under managed care, the AHCA contracts with private managed care plans for the coordination and payment of services for Medicaid enrollees. The state pays the managed care plans a capitation payment, or fixed monthly payment, per recipient enrolled in the managed care plan.

In Florida, the majority of Medicaid recipients receive their services through a managed care plan contracted with the AHCA under the Statewide Medicaid Managed Care (SMMC) program.[26] The SMMC program has two components, the Managed Medical Assistance (MMA) program and the Long-term Care program. Florida's SMMC offers a health care package covering both acute and long-term care.[27] The SMMC benefits are authorized by federal authority and are specifically required in ss. 409.973 and 409.98, F.S.

The AHCA contracts with managed care plans on a regional basis to provide services to eligible recipients. The MMA program, which covers most medical and acute care services for managed care plan enrollees, was fully implemented in August 2014, and was re-procured for a period beginning December 2018 and ending in 2023.[28]

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[23] Medicaid.gov, *Medicaid, available at* https://www.medicaid.gov/medicaid/index.html (last visited Jan. 22, 2022).
[24] Section 20.42, F.S.
[25] Medicaid.gov, *Medicaid State Plan Amendments, available at* https://www.medicaid.gov/medicaid/medicaid-state-plan-amendments/index.html (last visited Jan. 22, 2022).
[26] *Id.*
[27] *Id.*
[28] *Id.*

Medical Necessity Requirements

Florida Medicaid covers services that are medically necessary, as defined in its Medicaid state plan pursuant to Rule 59G-1.010 of the Florida Administrative Code. The AHCA routinely reviews new health services, products, and supplies to assess potential coverage under Florida Medicaid which depends on whether that service, product, or supply is medically necessary.[29] Pursuant to Rule 59G-1.010 of the Florida Administrative Code care, goods, and services are medically necessary if they are:

- Necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
- Individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
- Consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
- Reflective of the level of service that can be safely furnished, and *for which no equally effective and more conservative or less costly treatment is available statewide*; and
- Furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

Under federal law, Medicaid states must have a process in place to pay for services that are medically necessary but are not covered for recipients under the age of 21.[30] This is often referred to as the federal Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) guidelines. Health plans participating in the SMMC program must also adhere to EPSDT guidelines.[31]

Coverage of Nutritional Supplements for Infants in Florida[32]

Florida Medicaid covers prescription enteral and parenteral commercial formulas under the Durable Medical Equipment and Supplies benefit, when medically necessary. Commercial formula would be considered medically necessary for infants diagnosed with conditions such as metabolic disorders or who are unable to accept nutrition orally. In addition, if an infant needs commercial formula during an inpatient hospital stay, it would be covered as part of the all-inclusive payment to the hospital, just as needed food or medicine would be covered for a patient of any age.

The Women, Infants, and Children (WIC) program is a federally funded program that provides nutritional support for women and children. Administered by the DOH, WIC provides food assistance such as milk and infant and toddler formulas. If a child is not able to consume a contract formula,[33] WIC can make exceptions and provide non-contract formulas with

[29] *Supra* note 6.
[30] 42 C.F.R. s. 441 Subpart B.
[31] *Id.*
[32] *Supra* note 6.
[33] Commercial infant formula manufacturers provide substantial discounts, in the form of rebates, to state WIC programs in return for the exclusive right to provide their products to the state's WIC participants. Commercial formulas whose manufacturers have those exclusive rights are considered "contract formulas." *See* Steven Carlson, Robert Greenstein, and Zoe Neuberger, Center on Budget and Policy Priorities, *WIC's Competitive Bidding Process for Infant Formula Is Highly*

appropriate medical documentation. Contract formulas currently available through WIC include: Enfamil, Enfagrow, Gerber Good Start Soy 1, and Gerber Good Start Soy 3. WIC does not provide human donor breast milk to program participants.

Florida Medicaid does not reimburse separately for human donor breast milk or contract formulas covered through WIC. If an infant needed human donor breast milk outside of the hospital setting, a request would need to be made through the EPSDT coverage process. AHCA reports that it is not aware of any such requests being made for infants in fee-for-service or Medicaid managed care.[34]

Most private insurers do not cover donor human breast milk, which costs approximately $4 an ounce and can add up to over $1,000 per month per infant.[35] Through donations and fundraisers, the Mother's Milk Bank of Florida provides grants to low-income families to make donor human breast milk more affordable.[36]

Medicaid Coverage of Human Donor Breast Milk in Other States

At least seven states (California, Connecticut,[37] New York[38], Missouri, Kansas, Texas, and Utah) and the District of Columbia provide coverage for human donor breast milk under their state Medicaid programs.[39] In July 2017, New York Medicaid began covering pasteurized human donor breast milk, in both its fee-for-service and managed care delivery systems, but only during the infant's inpatient hospital stay.[40] California Medicaid has been covering human donor breast milk since 1998, but only covers it when the mother is unable to utilize her own milk supply and the infant cannot tolerate or has medical contraindications to the use of any formula, including enteral formula.[41]

III. Effect of Proposed Changes:

Section 1 of the bill amends s. 409.906, F.S., to authorize the AHCA to reimburse through Florida Medicaid for the cost of donor human milk for home and inpatient use for an infant who:

- Is medially or physically unable to receive maternal breast milk or whose mother medically or physically unable to produce maternal breast milk or breastfeed; and

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Cost-Effective (Feb. 17, 2017) *available at* https://www.cbpp.org/sites/default/files/atoms/files/6-26-15fa.pdf (last viewed Mar. 4, 2021).

[34] *Supra* note 6.

[35] *Supra* note 3.

[36] *Id*.

[37] Naomi Bar-Yam, Ph.D., Mother's Milk Bank Northeast, *Medicaid Coverage of Donor Milk Now Law in Connecticut* (July 23, 2019) *available at* https://milkbankne.org/2019/07/medicaid-coverage-of-donor-milk-now-law-in-connecticut/ (last visited Jan. 22, 2022).

[38] Anna Berry, Nonprofit Quarterly, *Liquid Gold: 6 States Allow Medicaid Access for Breast Milk* (Apr. 2017) *available at* https://nonprofitquarterly.org/liquid-gold-6-states-allow-medicaid-access-breast-milk/ (last visited Jan. 22, 2022).

[39] Center for Evidence-based Policy, Oregon Health & Science University, *Donor Human Milk for Low-Birthweight Infants: Effectiveness and Policies* (Apr. 2017) at 22 *available at* https://www.health.ny.gov/health_care/medicaid/ebbrac/docs/2017-06-13_donor_human_milk.pdf (last visited Jan. 22, 2022).

[40] New York State Department of Health, Medicaid Update, *NYS Medicaid Coverage of Pasteurized Donor Human Milk* (July 2017) *available at* https://www.health.ny.gov/health_care/medicaid/program/update/2017/2017-07.htm (last visited Jan. 22, 2022).

[41] *Supra* note 6.

- Has a documented birth weight of 1,500 grams or less; has a congenital or acquired intestinal condition and is at high risk for developing a feeding intolerance, necrotizing enterocolitis, or an infection; or otherwise requires nourishment by breast milk.

Because a service covered under Florida Medicaid is only considered to be medically necessary if no equally effective and more conservative or less costly treatment is available, a provider seeking to be reimbursed under the Medicaid program would need to demonstrate that the infant cannot tolerate or has medical contra-indications for commercial formula (available through programs like WIC or prescription formulas already covered under Medicaid) to the extent that these options are more cost effective.

The bill requires the donor human milk to be procured from a nonprofit milk bank certified by the Human Milk Banking Association of North America (HMBANA). For a milk bank to procure donor human milk, it would need to enroll as a Durable Medical Equipment provider under Florida Medicaid and to comply with provider requirements such as providing a surety bond of $50,000 pursuant to s. 409.912(8)(b), F.S.

The bill specifies that coverage for donor human milk may not be for less than the reasonable cost of the milk procured from a HMBANA-certified milk bank, plus reasonable processing and handling fees.

Section 2 of the bill amends s. 409.908, F.S., to authorize Florida Medicaid to pay for donor human milk bank services as an optional covered service in the fee-for service delivery system.

Section 3 of the bill amends s. 409.973, F.S., to require health plans participating in the Statewide Medicaid Managed Care (SMMC) program to cover donor human milk bank services.

Section 4 of the bill provides an effective date of July 1, 2022.

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:

In order to be reimbursed for donor human milk provided to infants enrolled in SMMC plans, milk banks would need to contract with the plans.

C. Government Sector Impact[42]:

Because human donor milk is not currently a covered service, the bill will have indeterminate negative fiscal impact on Florida Medicaid. It is unknown how many infants would satisfy the health conditions specified in the bill and meet Medicaid's medical necessity criteria. Therefore, the AHCA's projected fiscal impact focuses on a percentage of infants with a very low birth weight of 1,500 grams or less in a NICU.

In 2021, the AHCA provided a fiscal estimate for SB 240 which was at the time, identical to this bill with an effective date of July 1, 2021. In the 2019-2020 fiscal year, there were 2,494 infants with a very low birth weight of 1,500 grams or less in a NICU covered by Medicaid. AHCA's analysis assumes that 47.60 percent of these infants will receive donor milk for the first six months of life. (These infants may be eligible to receive donor milk for up to 12 months.) The 47.60 percent figure is based on the count for breastfed babies in Florida who are not breastfeeding at six months according to information from the CDC. Based on those assumptions, the AHCA's estimated cost to the Medicaid program in the 2022-2023 fiscal year was $29,867,890 with $11,657,438 being the state share.

The changes in this bill would require the AHCA to update its rules, fee schedules, and contracts with the SMMC health plans. These actions are part of the AHCA's routine business practices and ACHA reports that this can be accomplished using existing resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

[42] *Supra* note 6.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.906, 409.908, and 409.973.

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 Book

32-00150-22 20221770__

A bill to be entitled

An act relating to donor human milk bank services; amending s. 409.906, F.S.; authorizing the Agency for Health Care Administration to pay for donor human milk bank services as an optional Medicaid service if certain conditions are met; specifying coverage requirements; amending s. 409.908, F.S.; adding donor human milk bank services to the list of Medicaid services authorized for reimbursement on a fee-for-service basis; amending s. 409.973, F.S.; adding donor human milk bank services to the list of minimum benefits required to be covered by Medicaid managed care plans; providing an effective date.

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

Section 1. Subsection (28) is added to section 409.906, Florida Statutes, to read:

409.906 Optional Medicaid services.—Subject to specific appropriations, the agency may make payments for services which are optional to the state under Title XIX of the Social Security Act and are furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any optional service that is provided shall be provided only when medically necessary and in accordance with state and federal law. Optional services rendered by providers in mobile units to Medicaid recipients may be restricted or prohibited by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees,

32-00150-22 20221770__

reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216. If necessary to safeguard the state's systems of providing services to elderly and disabled persons and subject to the notice and review provisions of s. 216.177, the Governor may direct the Agency for Health Care Administration to amend the Medicaid state plan to delete the optional Medicaid service known as "Intermediate Care Facilities for the Developmentally Disabled." Optional services may include:

(28) DONOR HUMAN MILK BANK SERVICES.—The agency may pay for the cost of donor human milk, for home and inpatient use, for which a licensed physician or nurse practitioner has issued an order for an infant who is medically or physically unable to receive maternal breast milk or breastfeed or whose mother is medically or physically unable to produce maternal breast milk or breastfeed. Such infant must have a documented birth weight of 1,500 grams or less; have a congenital or acquired intestinal condition and be at high risk for developing a feeding intolerance, necrotizing enterocolitis, or an infection; or otherwise require nourishment by breast milk. The donor human milk must be procured from a nonprofit milk bank certified by the Human Milk Banking Association of North America (HMBANA). Coverage for donor human milk may not be less than the reasonable cost of such milk procured from an HMBANA-certified milk bank, plus reasonable processing and handling fees.

Section 2. Present paragraphs (f) through (t) of subsection (3) of section 409.908, Florida Statutes, are redesignated as

paragraphs (g) through (u), respectively, and a new paragraph (f) is added to that subsection, to read:

409.908 Reimbursement of Medicaid providers.—Subject to specific appropriations, the agency shall reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in the rules of the agency and in policy manuals and handbooks incorporated by reference therein. These methodologies may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding pursuant to s. 287.057, and other mechanisms the agency considers efficient and effective for purchasing services or goods on behalf of recipients. If a provider is reimbursed based on cost reporting and submits a cost report late and that cost report would have been used to set a lower reimbursement rate for a rate semester, then the provider's rate for that semester shall be retroactively calculated using the new cost report, and full payment at the recalculated rate shall be effected retroactively. Medicare-granted extensions for filing cost reports, if applicable, shall also apply to Medicaid cost reports. Payment for Medicaid compensable services made on behalf of Medicaid-eligible persons is subject to the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216. Further, nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act, provided the

adjustment is consistent with legislative intent.

(3) Subject to any limitations or directions provided for in the General Appropriations Act, the following Medicaid services and goods may be reimbursed on a fee-for-service basis. For each allowable service or goods furnished in accordance with Medicaid rules, policy manuals, handbooks, and state and federal law, the payment shall be the amount billed by the provider, the provider's usual and customary charge, or the maximum allowable fee established by the agency, whichever amount is less, with the exception of those services or goods for which the agency makes payment using a methodology based on capitation rates, average costs, or negotiated fees.

(f) Donor human milk bank services.

Section 3. Present paragraphs (e) through (bb) of subsection (1) of section 409.973, Florida Statutes, are redesignated as paragraphs (f) through (cc), respectively, and a new paragraph (e) is added to that subsection, to read:

409.973 Benefits.—

(1) MINIMUM BENEFITS.—Managed care plans shall cover, at a minimum, the following services:

(e) Donor human milk bank services.

Section 4. This act shall take effect July 1, 2022.

The Florida Senate

Committee Agenda Request

To: Senator Manny Diaz, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 13, 2022

I respectfully request that **Senate Bill 1770**, relating to Donor Human Milk Bank Services, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Thank you for your consideration.

Minority Leader Lauren Book
Florida Senate, District 32

File signed original with committee office

S-020 (03/2004)

2021 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

BILL INFORMATION	
BILL NUMBER:	SB 240
BILL TITLE:	Donor Human Milk Bank Services
BILL SPONSOR:	Senator Book
EFFECTIVE DATE:	July 1, 2021

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

CURRENT COMMITTEE

SIMILAR BILLS	
BILL NUMBER:	
SPONSOR:	

PREVIOUS LEGISLATION	
BILL NUMBER:	SB 42
SPONSOR:	Senator Book
YEAR:	2020
LAST ACTION:	Died in Health Policy, never put on agenda or heard

IDENTICAL BILLS	
BILL NUMBER:	
SPONSOR:	

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

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	December 28, 2020
LEAD AGENCY ANALYST:	
ADDITIONAL ANALYST(S):	
LEGAL ANALYST:	
FISCAL ANALYST:	Ana Rivas

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

Senate Bill (SB) 240 (Donor Human Milk Bank Services) amends sections 409.906, 409.908 and 409.973, Florida Statutes (F.S.), authorizing Florida Medicaid to pay for donor human milk bank services as an optional covered service in the fee-for-service delivery system and requiring health plans participating in the Statewide Medicaid Managed Care (SMMC) program to cover donor human milk bank services. Within s. 409.906, F.S., the bill stipulates health conditions for which human donor milk services would be medically necessary as well as criteria that milk banks must meet to qualify as Medicaid providers. In addition, the bill specifies that Medicaid's reimbursement rates for donor human milk cannot be less than the milk bank's cost to procure it plus reasonable processing and handling fees.

SB 240 poses operational and fiscal impacts to Florida Medicaid. By federal law, Medicaid states can only cover services that are medically necessary. In order to cover human donor breast milk, the provider must meet all elements of Florida Medicaid's medical necessity criteria, which includes that no equally effective and more conservative or cost effective treatment is available to meet the recipient's medical needs. This would require the provider to demonstrate that the infant cannot tolerate or has medical contra-indications for commercial formula available through programs like WIC or prescription formulas already covered under Florida Medicaid (to the extent these options are more cost effective).

The changes in this bill would require the Agency to update its rules, fee schedules, and contracts with the SMMC health plans. These actions are part of the Agency's routine business practices and can be accomplished using existing resources. Because this is not currently a covered service under the Florida Medicaid program, there will be a fiscal impact. Lastly, milk banks would need to enroll as a Durable Medical Equipment provider under Florida Medicaid, which requires a minimum $50,000 surety bond payment as specified in section 409.912, F.S. In order to be reimbursed for donor human milk provided to infants enrolled in SMMC health plans, milk banks would need to contract SMMC plans.

The changes in the bill will have a fiscal impact on Florida Medicaid, but the extent of the fiscal impact is indeterminate based on the specific criteria outlined in the bill. Strictly focusing on the number of infants with a very low birth weight of 1,500 grams or less in a NICU, the estimated impact in SFY 2021-22 would be $29,867,890 with $11,570,821 being the General Revenue impact.

The bill has an effective date of July 1, 2021.

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 (SSA). This authority includes establishing and maintaining a Medicaid state plan approved by the Centers for Medicare and Medicaid Services (CMS) and maintaining any Medicaid waivers needed to operate the Florida Medicaid program as directed by the Florida Legislature.

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. State Medicaid programs may request a formal waiver of the requirements codified in the SSA. Federal waivers give state flexibility not afforded through the Medicaid state plan.

In Florida, the majority of Medicaid recipients receive their services through a managed care plan contracted with the Agency under the Statewide Medicaid Managed Care (SMMC) program. The SMMC program has three components: the integrated Managed Medical Assistance (MMA) program and Long-Term Care (LTC) program, and the Dental program. Florida's SMMC program benefits are authorized through federal waivers and are specifically delineated by the Florida Legislature in sections 409.973 and 409.98, F.S.

Medical Necessity Requirements

Florida Medicaid covers services that are medically necessary, as defined in its Medicaid state plan and codified in Rule 59G-1.010, Florida Administrative Code. As part of its routine work, the Agency reviews new health services, products, and supplies for potential coverage under Florida Medicaid and bases its determinations on whether a service meets medical necessity criteria. This includes ensuring that the service is consistent with generally accepted professional medical standards and is not experimental or investigational.

Under federal law, Medicaid states must have a process in place to pay for services that are medically necessary but are not covered for recipients under the age of 21. This is often referred to as the federal Early and Periodic Screening, Diagnosis and Treatment (EPSDT) guidelines (see Title 42 Code of Federal Regulations Section 441.5). Health plans participating in the SMMC program must also adhere to EPSDT guidelines.

Human Donor Breast Milk

Donated by nursing mothers, human donor breast milk provides an option for infants who are unable to receive adequate nutrition from their mother's own milk or commercially prepared infant formulas. Because it is a biological product, milk banks must screen donors and pasteurize the milk prior to dispensing to mothers and infants.

The American Academy of Pediatrics (AAP) notes that human donor breast milk can be effective for high-risk and very low birth weight infants if the child's mother is unable to provide enough milk. Additionally, the World Health Organization (WHO) indicates that human donor breast milk can prevent some digestive disorders but specifies that any donor milk must come from safe facilities and is not recommended for sick infants or those weighing less than 1.0 kg. In the absence of a mother's milk, the WHO notes that standard formula is also an acceptable alternative. The Centers for Disease Control and Prevention (CDC) and AAP state that using the mother's breast milk is optimal, but when it is not available, a human donor is an option as well as standard infant formula is also a viable choice.

Currently, the U.S. Food and Drug Administration (FDA) considers human donor breast milk a "food" source, rather than a medical product. The FDA does not have any established guidelines or standards for human donor breast milk or milk banks, although it does recommend consulting with a health care provider before deciding to use it to feed an infant. Additionally, the FDA recommends that the caregiver only use milk from a source that has screened its donors and has taken precautions to ensure milk safety. The FDA and AAP further advise avoiding milk from internet-based sharing sites and using milk banks instead.

Serving as the professional organization for U.S. milk banks, the Human Milk Banking Association of North America (HMBANA) is the current source for regulations for milk banks. HMBANA's guidelines are voluntary and do not have to adhere to the FDA's standards. All individuals that donate to an HMBANA milk bank must undergo screening that includes an interview and testing for infectious disease and possible contaminants. Following collection, the milk banks pasteurize the milk to eliminate harmful bacteria or other infecting organisms.

HMBANA lists Mothers' Milk Bank of Florida as the only milk bank in Florida, and it requires a prescription for human donor breast milk. Mothers' Milk Bank of Florida states it uses the HMBANA's established guidelines for milk safety with advisement from the CDC, FDA, and blood and tissue industries. However, no federal or state regulations are in place to oversee the facility.

Coverage of Nutritional Supplements for Infants

Florida Medicaid covers prescription enteral and parenteral nutritional formulas under the Durable Medical Equipment and Supplies benefit, when medically necessary. This service is covered for recipients diagnosed with conditions such as metabolic disorders or who are unable to accept nutrition orally. In addition, if an infant needs formula during an inpatient hospital stay, it would be covered as part of the all-inclusive payment to the hospital (e.g., through a Diagnosis Related Grouper payment [DRG]), just as any food or medicine needed would be covered for child and adult patients.

The Women, Infants, and Children (WIC) program is a federally funded program that provides nutritional support for women and children. Administered by the Florida Department of Health, WIC provides food assistance such as milk and infant and toddler formulas. If a child is not able to consume a contract formula, WIC can make exceptions with appropriate medical documentation. A variety of contract formulas available through WIC include: Enfamil, Enfagrow, Gerber Good Start Soy 1, and Gerber Good Start Soy 3. WIC does not provide human donor breast milk to program participants.

In July 2017, New York Medicaid began covering pasteurized human donor breast milk, in both its fee-for-service and managed care delivery systems. New York's enacting legislation is similar to the requirements specified in this bill, except that services are only provided during an inpatient hospital stay (most likely for infants still in the Neonatal Intensive Care Unit). California Medicaid has been covering human donor breast milk since 1998, but only allows it when the mother is unable to utilize her own milk supply and the infant cannot tolerate or has medical contra-indications to the use of any formula, including enteral formula.

Florida Medicaid does not reimburse separately for human donor breast milk or formulas covered through WIC. If an infant needed human donor breast milk outside of the hospital setting, a request for it would need to be made through the EPSDT coverage process. The Agency is not aware of any such requests being made for infants in fee-for-service or Medicaid managed care.

2. EFFECT OF THE BILL:

Senate Bill (SB) 240 (Donor Human Milk Bank Services) amends sections 409.906, 409.908, and 409.973 Florida Statutes (F.S.), authorizing Florida Medicaid to pay for donor human milk bank services as an optional service for home and inpatient hospital use. Within s. 409.906, F.S., the bill stipulates the health conditions for which donor human milk services would be medically necessary, including:

- requiring a prescription for the product, AND
- the infant must be unable to receive maternal breast milk or breastfeed or the mother must be unable to produce maternal breast milk or breastfeed, AND
- the infant must have one of the following conditions:
    - have a birth weight of 1,500 grams or less
    - have a congenital or acquired intestinal condition and be at high risk for developing a feeding intolerance, necrotizing enterocolitis, or an infection
    - otherwise require nourishment by breast milk.

The language in the bill is more expansive than what is currently covered by other state Medicaid programs such as New York or California. For example, in New York the services are only provided during an inpatient hospital stay (most likely for infants still in the Neonatal Intensive Care Unit).

The bill establishes criteria that milk banks must meet to qualify as Medicaid providers.

The bill specifies that Medicaid's reimbursement rates for donor human milk cannot be less than the milk bank's cost to procure it plus reasonable processing and handling fees. To ensure this requirement is met for infants who need human donor milk in the hospital, it must be reimbursed separately from, and in addition to, the all-inclusive hospital payment.

In section 409.908, F.S., the bill adds donor human milk to the list of services which the Agency may cover under the Florida Medicaid. The bill also amends section 409.973, F.S. to require health plans participating in the Statewide Medicaid Managed Care (SMMC) program to cover donor human milk bank services.

SB 240 poses operational and fiscal impacts to Florida Medicaid. By federal law, Medicaid states can only cover services that are medically necessary. In Florida, in order for a service to be medically necessary, it must:

- Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain

- Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs
- Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational
- Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide
- Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider

In order to cover human donor breast milk, the provider must demonstrate that all elements specified above are met, including that no equally effective and more conservative or cost effective treatment is available to meet the infant's medical needs (e.g., formula available through programs like WIC). The likely outcome is that human donor milk services authorized would more align with California's coverage policy, which requires that the mother is unable to utilize her own milk supply and the infant cannot tolerate or has medical contra-indications to the use of any commercial or prescription formula.

With few exceptions, most enteral formula providers are enrolled in Florida Medicaid as a Durable Medical Equipment and Medical Supplies provider. To add human donor breast milk as a covered service, the Agency will need to update administrative rules, specifically the Durable Medical Equipment and Medical Supplies (DME) Coverage Policy and fee schedule, and update the Florida Medicaid Management Information System to pay claims for these services. These actions are part of the Agency's routine business practices and can be accomplished using existing resources. However, milk banks would need to enroll as DME providers under Florida Medicaid, which requires a minimum $50,000 surety bond payment as specified in section 409.912, F.S. In order to be reimbursed for donor human milk provided to infants enrolled in SMMC health plans, milk banks would need to contract SMMC plans.

The fiscal impact analysis is unable to account for all possible costs, as it is unknown how many infants would meet the criteria specified in the bill and Medicaid's medical necessity criteria. The fiscal impact therefore focuses on a percent of infants with a very low birth weight of 1,500 grams or less in a NICU. In SFY 2019-20 there were 2,494 infants with a very low birth weight of 1,500 grams or less in a NICU covered by Medicaid. The analysis assumes that 47.60% of these infants will receive donor milk for the first 6 months of life. The 47.60% is based on the count for breastfed babies in Florida who are not breast feeding at 6 months according to information from the Centers for Disease Control and Prevention.

Based on these assumptions about very low birth weight infants, the estimated fiscal impact in SFY 2021-22 is $29,867,890 with $11,570,821 being the General Revenue impact. The estimated impact in SFY 2022-23 is $29,867,890 with $11,657,438 being the General Revenue impact.

The bill specifies other requirements for infants to meet in order to receive donor milk, but there is no accurate way to determine the number of infants that may qualify, so the fiscal impact on these infants is indeterminate. These infants may be eligible to receive donor milk for up to 12 months, but this fiscal impact is also indeterminate. Some of the fiscal impact may be offset if the infant was going to be discharged on a medical supplemental formula that is covered by Medicaid, but instead is going to use the human donor breast milk. However, this impact is indeterminate.

The changes in the bill will have an operational impact to the agency, but these changes can be completed using current resources.

The bill takes effect on July 1, 2021.

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 ___ N _X_

Revenues:	None
Expenditures:	Unknown
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 _X__ N ___

Revenues:	Unknown
Expenditures:	The fiscal impact analysis is unable to account for all possible costs, as it is unknown how many infants would meet the criteria specified in the bill and Medicaid's medical necessity criteria. The fiscal impact therefore focuses on infants with a very low birth weight of 1,500 grams or less. In

	SFY 2019-20 there were 2,494 such infants covered by Medicaid. The analysis assumes that 47.60% of these infants will receive donor milk for the first 6 months of life. The 47.60% is based on the count for breastfed babies in Florida who are not breast feeding at 6 months according to information from the Centers for Disease Control and Prevention. Based on these assumptions about very low birth weight infants, the estimated fiscal impact in SFY 2021-22 is $29,867,890 with $11,570,821 being the General Revenue impact. The estimated impact in SFY 2022-23 is $29,867,890 with $11,657,438 being the General Revenue impact. The bill specifies other requirements for infants to meet in order to receive donor milk, but there is no accurate way to determine the number of infants that may qualify, so the fiscal impact on these infants is indeterminate. These infants may be eligible to receive donor milk for up to 12 months, but this fiscal impact is also indeterminate. Some of the fiscal impact may be offset if the infant was going to be discharged on a medical supplement formula that is covered by Medicaid, but instead is going to use the human donor breast milk. However, the impact is indeterminate.
Does the legislation contain a State Government appropriation?	No
If yes, was this appropriated last year?	N/A

Estimated 6 month total in Ounces	6,874
Estimated rate per ounce	$ 3.66
Estimated Total 6 month Cost	$ 25,159
NICU infants that were very low birth weight (<1500 grams)	2,494
Average Breastfed Infant % for Florida for 1st 6 months	**52.40%**
Average Donor Milk Infant % for Florida for 1st 6 months	47.60%
Total Estimated cost for first 6 months of life of Human Donor Milk	$29,867,890

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

Revenues:	N/A
Expenditures:	N/A
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

FISCAL IMPACT:	Year 1 (FY 2021-22)	Year 2 (FY 2022-23)	Year 3 (FY 2023-24)

1. **Non-Recurring Impact:**

Expenditures:	
Total Non-Recurring Expenditures	$ -

2. **Recurring Impact:**

Special Categories/Contracted Services			
102673 Prepaid Health Plans	$ 29,867,890	$ 29,867,890	$ 29,867,890
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
Total Special Categories/Contracted Services	**$ 29,867,890**	**$ 29,867,890**	**$ 29,867,890**
Total Recurring Expenditures	**$ 29,867,890**	**$ 29,867,890**	**$ 29,867,890**

3. **Total Revenues and Expenditures:**

Sub-Total Recurring Revenues	$ -	$ -	$ -
Total Revenues	**$ -**	**$ -**	**$ -**
Sub-Total Non-Recurring Expenditures	$ -	$ -	$ -
Sub-Total Recurring Expenditures	29,867,890	29,867,890	29,867,890
Total Expenditures	**$ 29,867,890**	**$ 29,867,890**	**$ 29,867,890**
Net Impact (Total Revenues minus Total Expenditures)	**$ (29,867,890)**	**$ (29,867,890)**	**$ (29,867,890)**

4. **Net Impact (By Fund)**

General Revenue Fund (1000)	$ (11,570,821)	$ (11,657,438)	$ (11,403,560)
Medical Care Trust Fund (2474)	(18,297,069)	(18,210,453)	(18,464,330)
-	-	-	-
-	-	-	-
Net Impact (By Fund)	**$ (29,867,890)**	**$ (29,867,890)**	**$ (29,867,890)**

TECHNOLOGY IMPACT

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

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

FEDERAL IMPACT

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

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

ADDITIONAL COMMENTS

LEGAL – GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	

RON DESANTIS
GOVERNOR

SIMONE MARSTILLER
SECRETARY

November 1, 2021

Senator Manny Diaz, Chair
Senate Committee on Health Policy
306 The Capitol
404 South Monroe Street
Tallahassee, FL 32399-1100

Representative Colleen Burton, Chair
House Health & Human Services Committee
422 The Capitol
402 South Monroe Street
Tallahassee, FL 32399-1300

Pursuant to Chapter 2021-36, Laws of Florida, please see the attached the report on Donor Human Milk as a supplement to newborn care and health specific to newborn infants born prematurely and hospitalized within newborn intensive care units (NICU).

Please do not hesitate to contact our team if you have any questions.

Sincerely,

Simone Marstiller
Secretary

2727 Mahan Drive • Mail Stop #
Tallahassee, FL 32308
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Donor Human Milk Legislative Report

Report to the Florida Legislature

November 1, 2021

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Table of Contents

Executive Summary

The purpose of this study was to document the use by hospitals of pasteurized donor human milk (PDHM) made available via donor human milk banks, the related safety and efficacy outcomes, and the cost avoidance in using PDHM for newborn care within neonatal intensive care unit (NICU) settings. Infants born before 37 weeks gestation are considered premature and carry a higher risk for health complications, including necrotizing enterocolitis (NEC). The mortality rate for infants who are diagnosed with NEC is higher than premature infants without the diagnosis,[(1)] and there are significant short- and long-term impacts of NEC on infants, families, and health systems.

A key evidence-based strategy to decrease the rate of NEC is the feeding of a human milk diet from either mother's own milk (MOM) if available or PDHM when the MOM supply is insufficient or contraindicated, rather than infant formula. There has been an increasing amount of PDHM dispensed to infants nationally and in Florida. In 2020, approximately 316,500 ounces of PDHM were fed to hospitalized infants in Florida NICUs. PDHM is currently not a Medicaid-reimbursable provision of care or reimbursed through commercial health insurance companies and can be cost-prohibitive to hospitals. The use of PDHM in the NICU is estimated to avoid over $4 million in health care costs to all payers operating in Florida. PDHM is safe and may be safer than infant formula. In a systematic review, although infant formula increased short-term, in-hospital weight gain, linear growth, and head growth, PDHM significantly reduced the rate of NEC, which translated to a significant avoidance of death, morbidity, and cost. Presently, all thirty-one non-profit milk banks nationally are accredited by the Human Milk Bank Association of North America (HMBANA) and must adhere to standards of ethical collection, processing, and distribution of PDHM.

In this report, coverage policies and a summary of minimum policy elements are presented. This report also contains recommendations to implement safe and effective use of PDHM in Florida. Finally, a list of future research questions is posed for PDHM usage in the inpatient and outpatient settings.

Section 1. Background

1.1. Purpose of Report

The 2021 Florida Legislature passed the General Appropriations Act, Senate Bill 2500, which included the below language:

> *The Agency for Health Care Administration, in consultation with the Department of Health, shall study the use of donor human milk as a supplement to newborn care and health specific to newborn infants born prematurely and hospitalized within the newborn intensive care unit (NICU). The purpose of this study is to document the overall increase in use by hospitals of donor human milk made available via donor human milk banks and the related improvement in outcomes and achieved cost-savings for both Medicaid and commercial payors regarding newborn care within a NICU. The study shall contemplate the safety considerations in utilizing human milk for newborns in the NICU and the adulterants and contaminants that can be transmitted via human milk. The agency shall submit a report along with recommendations of best practices which must address, at a minimum: the operation of a donor human milk tissue bank that facilitates the donation, processing and distribution of donor human milk tissue and donor human milk tissue derivatives; procedures for donation and distribution of donor human milk tissue and donor human milk tissue derivatives; and testing of donor human milk tissue and donor human milk tissue derivatives before donation, processing, and distribution to ensure the absence of adulterants and other contaminants as determined by the agency. The agency shall submit the report to the chair of the Senate Committee on Health Policy and the chair of the House Health and Human Services Committee by November 1, 2021.*

1.2. Need for Human Milk Diet for Premature Infants

Infants that are born before 37 completed weeks gestation are considered premature.[2] The more premature infants are when born, the more risk these infants will have in developing health complications associated with prematurity.[3],[4] Very low birth weight infants represent 1.5% of live births, yet account for greater than 50% of infant deaths in the U.S.[5] Those that survive are at high risk for lifelong disabilities and generate substantial health care costs.[6, 7]

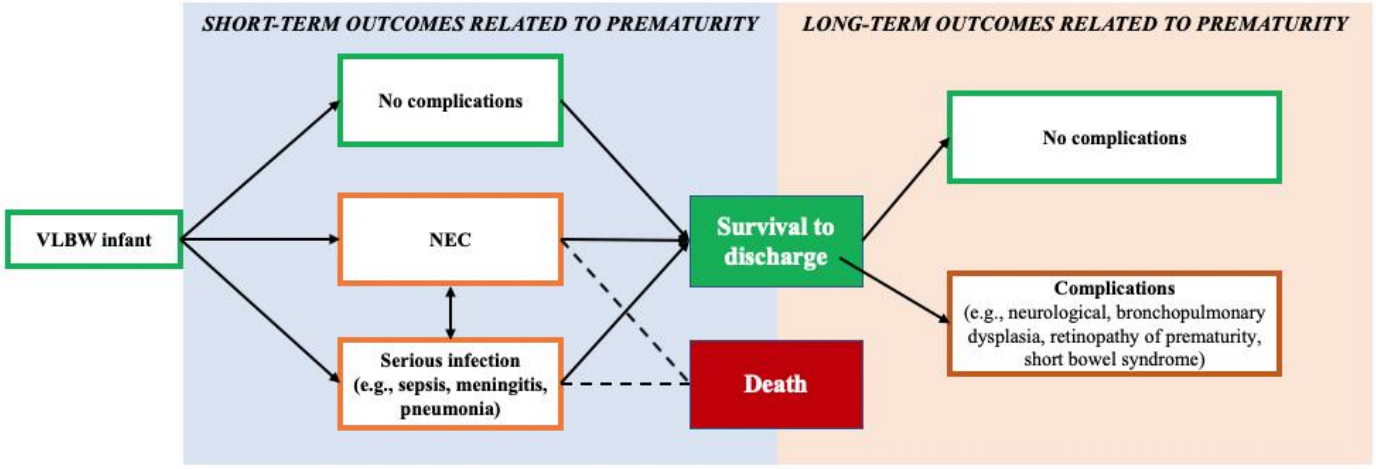
Every year in Florida, approximately 3,500 infants are born with a very low birth weight (VLBW), which means having a birth weight less than 1,500 grams (g) or approximately 3 pounds 5 ounces.[4] Infants at this birth weight are typically less than 32 weeks gestation. These VLBW infants require admission to a neonatal intensive care unit (NICU) and are at risk for serious adverse health outcomes due to their prematurity, such as necrotizing enterocolitis (NEC), life-threatening infections (e.g., sepsis, meningitis, pneumonia), retinopathy of prematurity that can lead to blindness, chronic lung disease causing shortness of breath, and death.[2] When compared to infants that are born at or around their due date (i.e., full term), VLBW premature infants who survive and leave the hospital have higher rates of long-term adverse health conditions such as cerebral palsy, learning disability, blindness, and lung disease.[8-10] (Figure 1).

While premature infants account for a small proportion of pediatric patients, they account for a disproportionately large percentage of health care costs.[11] In fact, the average hospital cost for premature infants with health complications is four to seven times higher than premature infants who do not suffer

from those complications.[12] In 2001, the national hospital cost for premature infant health care was $5.8 billion and that cost will nearly double in 2021.[12]

Driving much of the cost of care to premature infants is a disease of prematurity called necrotizing enterocolitis (NEC). NEC is a severe complication that affects an infant's gastrointestinal tract. NEC is characterized by intestinal inflammation that can progress to perforated intestines, sepsis, multi-organ failure, and death.[13] NEC is thought to arise from multiple causes, including intestinal immaturity, underdeveloped immune system, and gut microbial dysbiosis. Premature infants are at a high risk of developing NEC, and rates in the U.S. range from 5-10%.[14] For infants weighing 500-1500 g who develop NEC, mortality rates are estimated to be 16-42%.[1] Although the development of NEC is multifactorial making it difficult to prevent, one of the few evidence-based strategies for avoiding NEC is feeding infants human milk (HM), whether it be mother's own milk (MOM) or pasteurized donor human milk (PDHM).[14, 15]

Figure 1. **Premature Infant Health Outcomes.** Infants born before 32 completed weeks of gestation are at high risk of being low weight. Very low birth weight (VLBW) infants are at higher risk of developing necrotizing enterocolitis (NEC) and serious infections, such as sepsis, meningitis, and/or pneumonia. NEC and serious infections are life-threatening conditions that may lead to survival with complications or death. Some complications require long-term care and morbidity, which impact the individual, the family, and the health care system.



Human milk provides water, proteins, carbohydrates, fats, electrolytes, digestive enzymes, immunologic factors, growth factors, hormones, other bioactive components, and newly discovered nutritional substances to infants.[16] Feeding infants a diet primarily comprised of human milk reduces the risks of diseases of prematurity and death.[14] Mother's own milk (MOM) is the gold-standard for infant feeding and is proven to improve neonatal health outcomes and decrease health care costs.[14] However, MOM is not always available, such as when the mother is building up her own milk supply, when there is separation of mother and infant (e.g., when mother is no longer in the hospital from her birth admission or infant is transferred to a different hospital), or due to another medical necessity. Mothers of infants in the NICU must express their milk using breast pumps and pump-dependent mothers produce a lower quantity of milk. Furthermore, infants admitted to the NICU are sometimes too premature or ill for direct feeding at the breast. In such settings, pediatricians have relied on PDHM to feed premature infants.

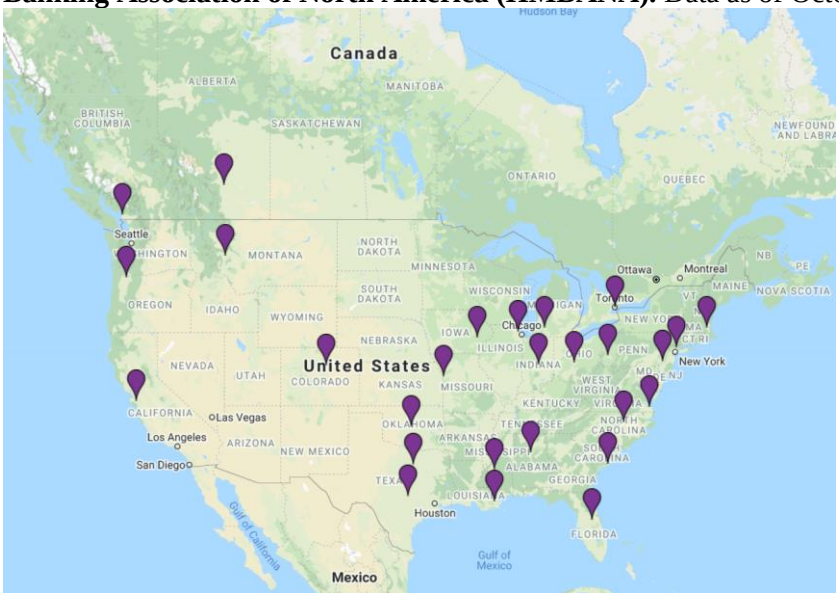
Section 2. Donated Human Milk Usage for Newborns in Florida

The Agency was directed by the Legislature to document the overall increased use by hospitals of donor human milk made available via donor human milk banks.

2.1. Banks Supplying Pasteurized Donor Human Milk

The Human Milk Banking Association of North American (HMBANA) is the only accrediting body for donor human milk banking and was founded in 1985 to advance the safe use of extra breast milk for infants. Currently, there are 31 non-profit milk banks throughout the United States (US) and Canada that collect, process, pasteurize, test, and dispense donor human milk to infants in hospitals and outpatient settings (Figure 2).

Figure 2. US and Canada Locations of Non-Profit Milk Banks Accredited by the Human Milk Banking Association of North America (HMBANA). Data as of October 8, 2021.



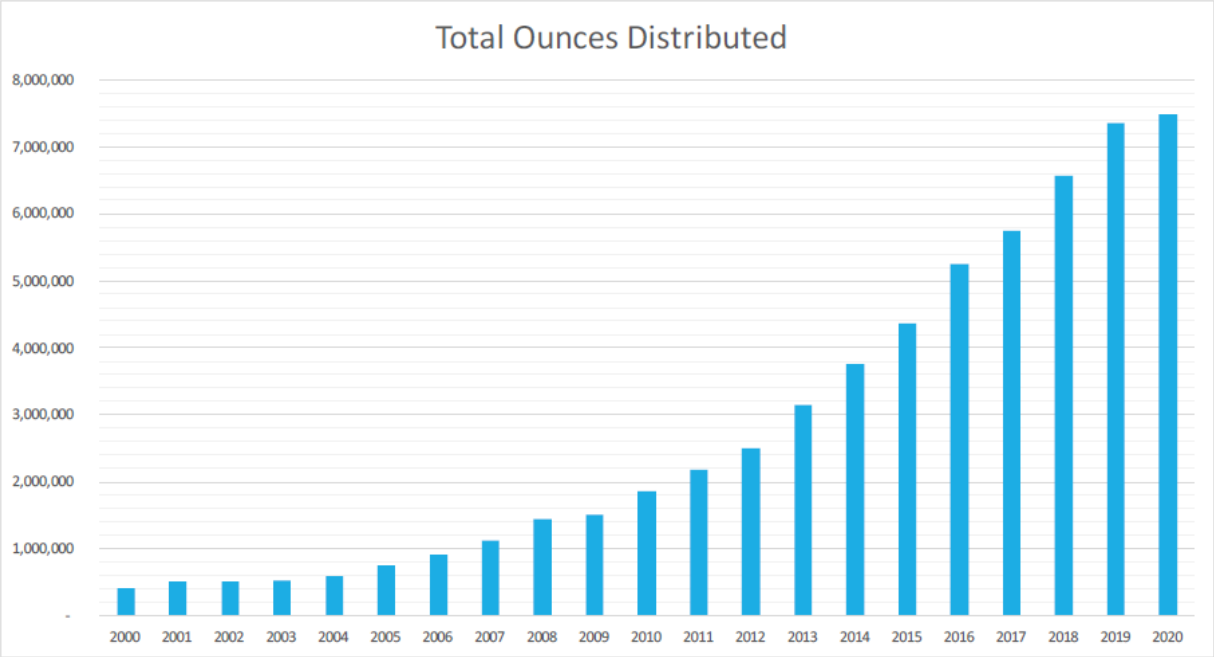
US milk banks are regulated and inspected as food manufacturers by the United States Food and Drug Administration (FDA) and their local health departments. All US milk banks must comply with the Food Safety Modernization Act (FSMA) and register with the FDA as a food manufacturer bi-annually. Canadian milk banks are subject to regulation and inspection by Canada Food Inspections Agency (CFIA). All HMBANA milk banks comply with current good manufacturing practices (cGMPs), which are published in Title 21 of the Code of Federal Regulations Part 110 (21 CFR 110). In addition, at least one person on site in the bank must have training as a Preventive Control Qualified Inspector (PCQI). Food safety training is also required for personnel working in the pasteurization lab spaces within the banks. In addition to these standards, HMBANA has established minimum standards to ensure safe and high-quality pasteurized donor human milk (PDHM) for infants (Appendix B).

Other sources of donor human milk are from for-profit milk banks. Currently, there is no national association that provides minimum standards, oversight, or representation for these for-profit companies.

California and Texas recognize the HMBANA guidelines though legislative action as the standard for human milk banking. New York has its own statutory authority over donor milk banks either operating in or distributing to citizens in the state. Florida and Maryland require state licensure to operate a donor milk bank.

HMBANA operates the only known registry for donor human milk usage. According to the their usage registry, there has been an increase in donor human milk usage since 2015 with a plateau during the COVID-19 Pandemic (March 2020 to current) (Figure 3).

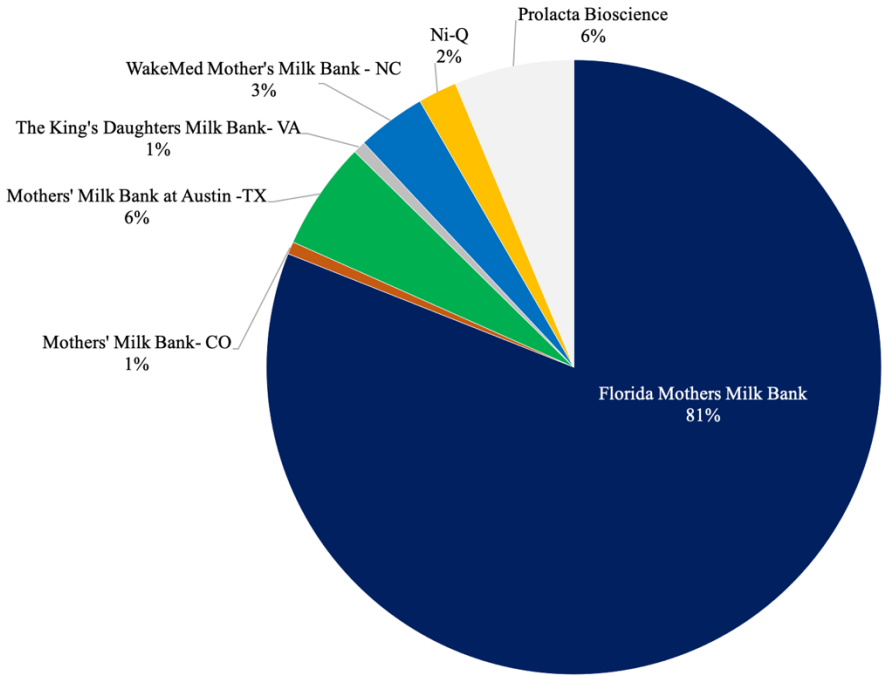
Figure 3. Increasing Amount of Pasteurized Donor Human Milk Distributed from Non-Profit Milk Banks Accredited by HMBANA. The bars indicate the total amount in ounces of milk distributed by year in the United States and Canada. Distribution was to hospitals (75%) and outpatient settings (25%). The Year 2020 was affected by the COVID-19 Pandemic.



To determine which milk banks supply donor human milk specifically to Florida's neonatal intensive care units (NICUs), the Agency for Health Care Administration (AHCA) contracted the statute-chartered Florida Medical School Quality Network (FMSQN) (ss 409.975(2). F.S.). The FMSQN Infant Health Subcommittee surveyed Florida's 73 accredited NICUs (i.e., Level II and III), representing 2,136 NICU beds licensed by AHCA, using a 10-question survey it created (Appendix C). Sixty percent (n=44) of Florida's NICUs responded to the survey, representing 83% (n=1780) of AHCA-licensed NICU beds and all eleven Medicaid regions. NICUs that did not respond to the survey were primarily units with fewer than 20 beds and held an AHCA Level II designation, indicating that they were not licensed to provide health care for extremely premature infants (birth weight less than 1,000 grams).

Eight companies were reported by Florida NICUs as source companies for donor human milk (Appendix D). In 2020, an estimated total of 316,500 ounces of DHM were dispensed to Florida NICUs (Figure 4). The survey identified Mother's Milk Bank of Florida (MMBFL, Orlando, FL) as the lead supplier, providing 81% of PDHM to Florida NICUs.

Figure 4. Sources of Donor Human Milk to Florida Neonatal Intensive Care Units in 2020. Data from a survey of Florida hospitals in 2021.



MMBFL is a 501(c)(3) charitable organization that is accredited by HMBANA. According to MMBFL records, there has been an increase in the amount of PDHM distributed to Florida hospitals since 2018 (Figure 5). Moreover, there has been an increase in number of hospitals purchasing PDHM since 2018 (Figure 6).

Figure 5. Pasteurized Donor Human Milk Donated to Florida Hospitals. Bar graph showing the amount of pasteurized donor human milk (PDHM) distributed to hospitals in Florida by year since 2018. There was an increase in distribution between 2018 and 2020. * Distribution in years 2020-2021 were dampened by changes in hospitalization practice related to the COVID-19 pandemic. ** Year 2021 data are Year-to-Date (YTD), as of October 8, 2021. The projected amount for Calendar Year 2021 is expected to be approximately 300,000 ounces, which will be a significant increase compared to the past four years.

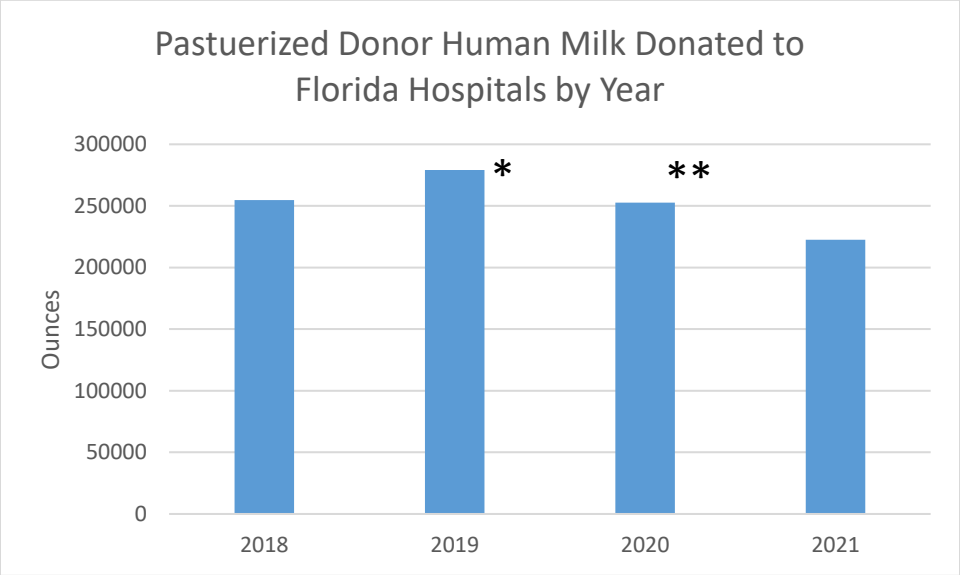
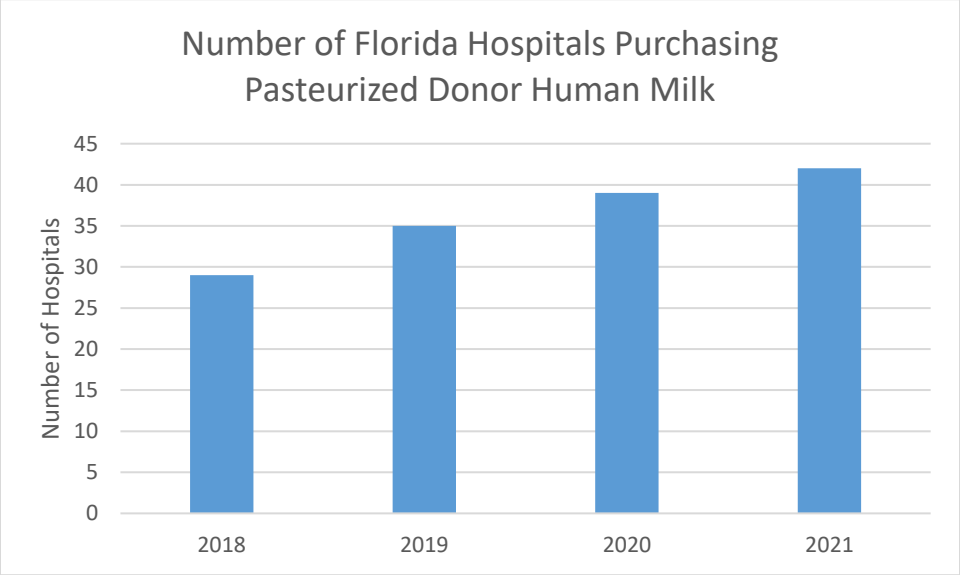


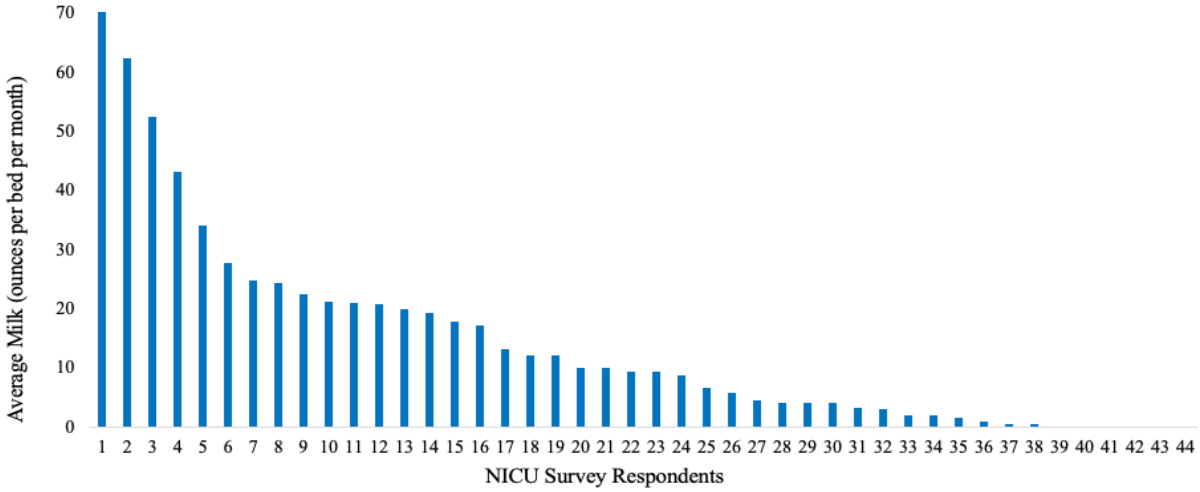
Figure 6. Number of Florida Hospitals Purchasing Pasteurized Donor Human Milk by Year. Bar graph showing an increasing number of Florida hospitals purchasing pasteurized donor human milk (PDHM) since 2018.



2.2. Usage of Donor Human Milk by Florida NICUs

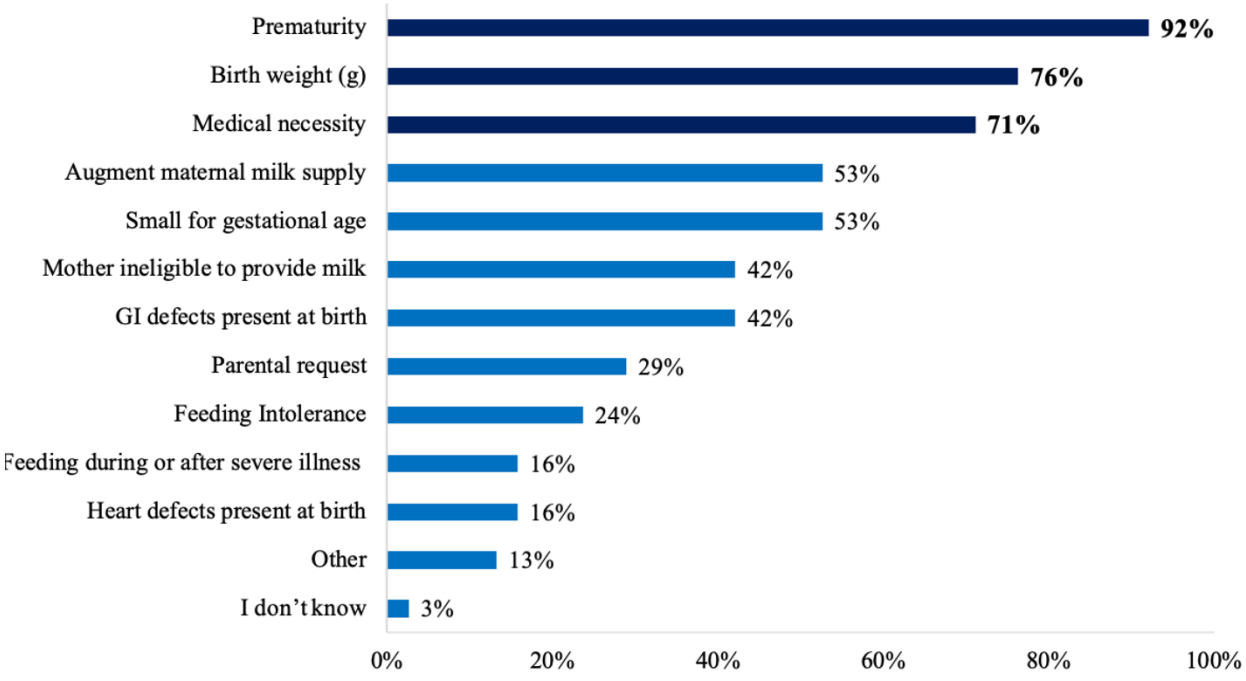
The survey of Florida NICUs in 2021 determined that 86% of them use PDHM (Figure 7). Of the six responding NICUs that did not use PDHM, five were Level II NICUs that had less than 20 NICU beds and did not treat extremely premature newborns – defined as birthweight less than 1000 grams. Three of the six non-users also stated cost as the reason for not using PDHM, including the only Level III NICU not using DHM. These results confirm a prior publication where PDHM use associated with intensity level of care,[11] yet extend this observation by finding a cost component to the NICU decision to administer PDHM.

Figure 7. Use of PDHM by Florida hospital NICUs. Survey data from 2021. Centers are de-identified and rank ordered based on the average DHM administered per month. Centers 39-44 report no use of PDHM.



The most common reasons for administering PDHM were prematurity (92%), birth weight threshold (76%), and medical necessity (71%) determined by the attending physician based on diagnosis and symptoms (Figure 8).

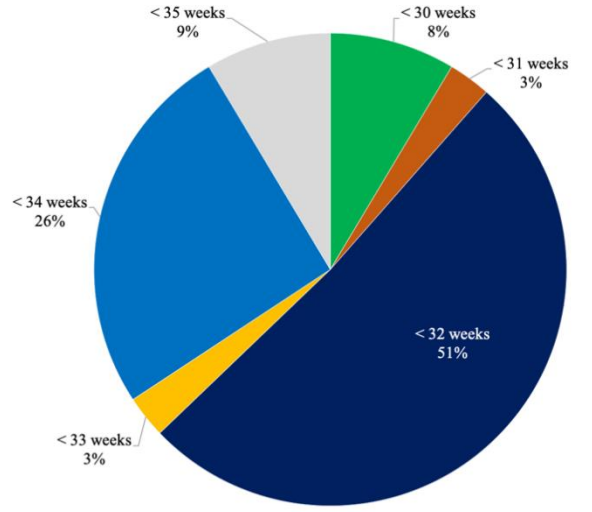
Figure 8. Reasons For Donor Human Milk Use by Florida NICUs. Survey of Florida NICUs in 2021. Multiple selections were allowed.



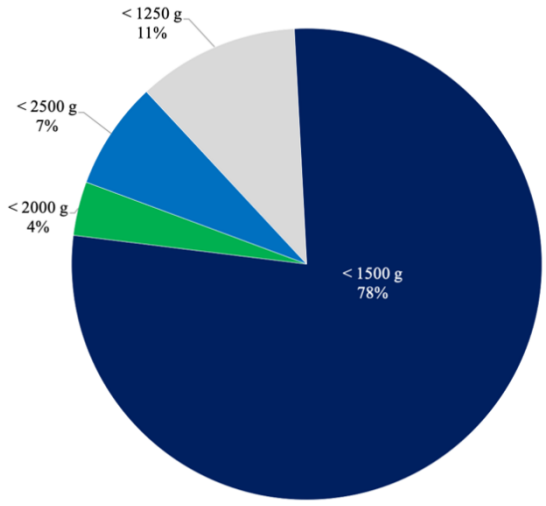
There was significant variation in practice when prematurity or the birth gestational age were used as criteria for providing PDHM. The most common criteria were a gestational age of less than 32 weeks at birth or birth weight less than 1500 g (i.e., 3.3 pounds) (Figure 9).

Figure 9. Criteria for Use of Donor Human Milk by Prematurity and Birth Weight. Results from a survey of Florida NICUs using PDHM (n=38 NICUs) in 2021. (A) When prematurity was used as criterion for administering PDHM, the most common age was < 32 weeks gestation. However, there was significant variation among clinical units. (B) When birth weight was used as criterion for administering PDHM, the most common weight was < 1,500 grams (g). However, there was some variation in exact weight cut-off.

A. Prematurity (weeks gestational age)



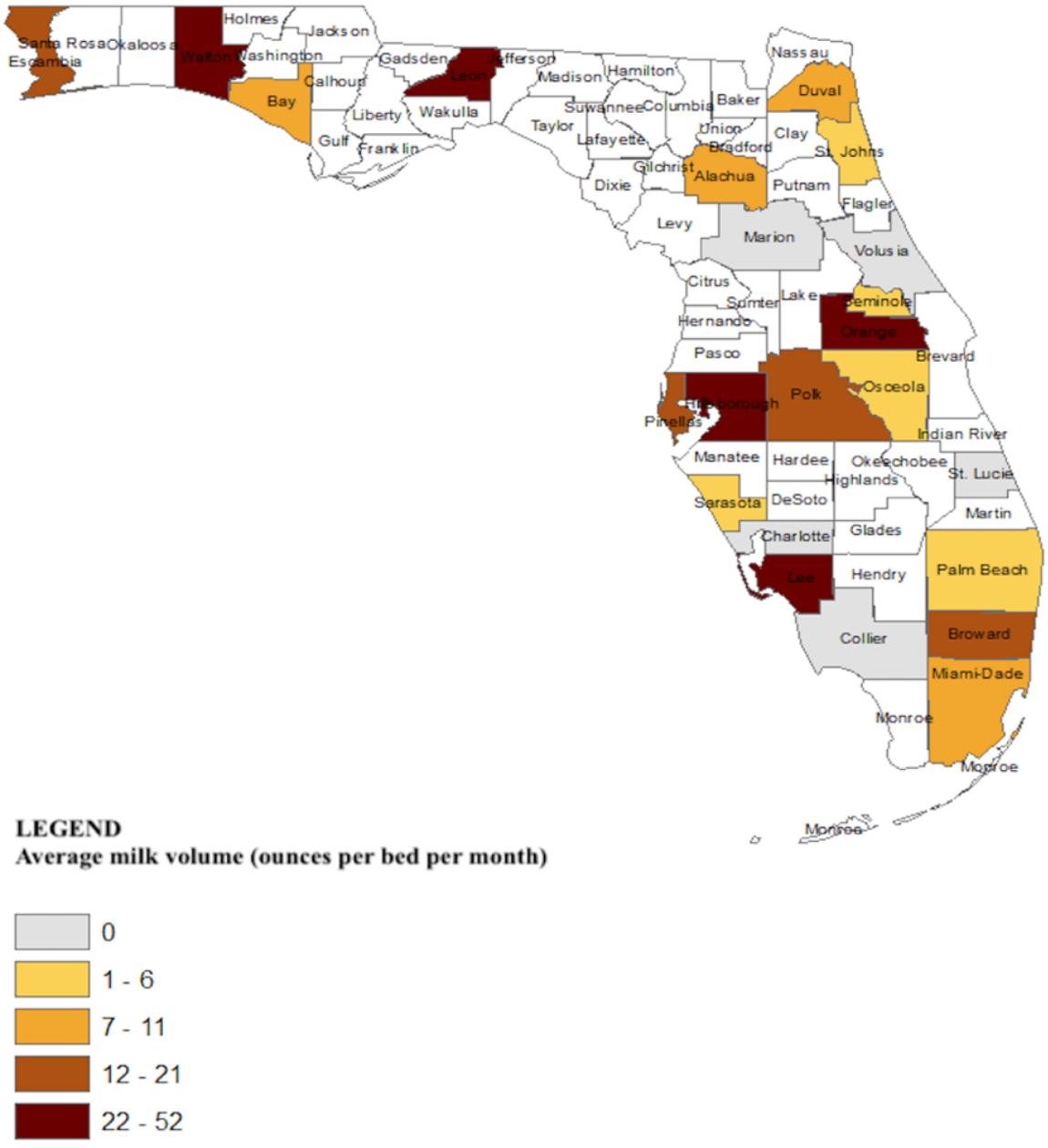
B. Birth weight in grams (g)



2.3. Geographic Variation in DHM Usage

The survey also identified variable access to PDHM based on geographic location in Florida (Figure 10). Whereas PDHM was used by NICUs situated in counties with large populations, PDHM was not used in over half of Florida counties in part because those counties did not have a hospital with a Level II NICU (n=37 of 67 counties, 2019).[4]

Figure 10. Use of DHM by Florida county. Results are from a survey of Florida NICUs in 2021. Counties are depicted with respect to the average DHM volume in ounces per bed per month (Legend). Counties colored white have an unknown use of DHM.



Section 3. Outcomes of Donated Human Milk in Newborns

3.1. Health Outcomes with Donor Human Milk Compared to Infant Formula

A systematic review of 238 medical reports of DHM identified 11 clinical trials involving 1,809 infants comparing health outcomes after usage of DHM versus infant formula.(17) Although the 11 trials were deemed highest quality, there were limitations in their study design including allocation concealment and lack of blinding in most of the trials. Nonetheless, the systematic review found that formula-fed infants had higher in-hospital weight gain, linear growth, and head growth. However, DHM-fed infants had half the rate of NEC compared to formula-fed infants. There were no differences in long-term growth or neurodevelopment. This observation of DHM reducing NEC was recently confirmed by another systematic review.(18)

3.2. Economic Outcomes with Donor Human Milk

Pasteurized donor human milk (PDHM) use is not currently a reimbursable health care expense in Florida by Medicaid or commercial health insurance companies. While some Florida hospitals have earned grant funding or donations to support the provision of PDHM, most large facilities using PDHM have chosen to do so knowing that the cost will not be reimbursed. These facilities balance the direct costs of PDHM use with better outcomes, in hopes that improved outcomes will ultimately decrease total cost of care by reducing risk and severity of NEC and other illnesses associated with prematurity.

The cost of PDHM is difficult to estimate due to bundled payments and lack of reimbursement specific to its use. From estimates found in the peer-reviewed, published medical literature and survey responses from individual milk banks, PDHM is estimated to cost a hospital $4 to $5 per ounce. In the state of Florida, approximately 3,500 infants are born VLBW annually and cared for in one of the approximately 2,136 NICU beds in the state.[(4)] In the survey of Florida NICUs, 1,682 (79%) of these NICU beds were in facilities routinely using PDHM. With a median use of 11 ounces per bed per month, an estimated $1,110,120 (at $5 per ounce) was spent annually for PDHM in Florida in 2020. This translates to less than $320 per VLBW infant per year or $660 per NICU bed per year. For context, the estimated total cost of care for a birth hospitalization for a VLBW infant can be in excess of $500,000.[(19)]

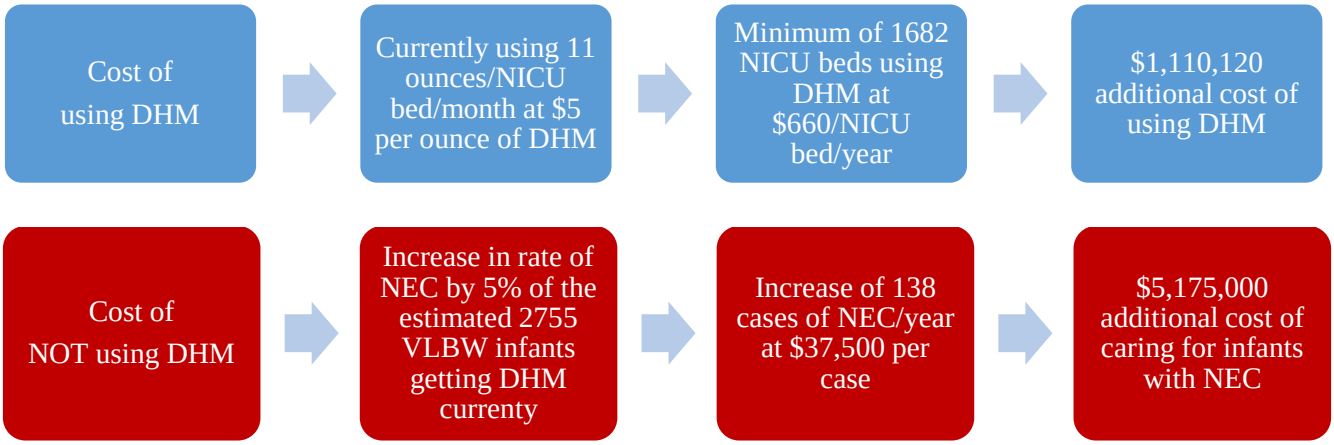
Although PDHM is more expensive than formula, PDHM associates with a greater health care cost avoidance. Specifically, the use of PDHM has been shown to be cost-effective related to a variety of outcomes, most commonly NEC.[(20)] For infants who develop NEC, there are costs related to the acute phase of illness such as healthcare utilization (e.g., need for increased level of care, medications, surgical interventions) and increased length of hospital stay. Long term, these infants have increased costs related to both medical needs (e.g., readmissions, follow-up care) and societal impact (e.g., parents' time off work, child's missed school days, use of community resources) (Figure 1).

When the entire hospitalization is considered, the cost of care for an infant with NEC is estimated to be about 1.4 times higher than the baseline cost for an infant without NEC.[(21, 22)] This can add from $15,000 to over $60,000 to the total cost of care.[(12),(22),(21)] A conservative estimate of NEC cost is $37,500 (the median of the range reported in literature) per case for the birth hospitalization.

If Florida NICUs were to stop using PDHM, then there would be a 5% increase in the number NEC cases from the 2,755 VLBW infants born annually in Florida (Figure 11). This calculates to an absolute

increase of 138 NEC cases annually (2,755 births x 5% rate of NEC). Using the estimate of $37,500 per case of NEC, the statewide cost would increase by $5,175,000 ($37,500 per case x 138 cases). The difference between statewide health care cost increase ($5,175,000) minus additional cost of providing PDHM ($1,110,120) is an estimated $4,064,880 (Figure 11). This cost-avoidance is among all payers; however, it is particularly relevant to Florida Medicaid given its coverage of over 50% of births in the State of Florida. Furthermore, this cost-avoidance with PDHM is an underestimate, as it does not factor in additional benefits after the birth hospitalization with respect to readmissions, home nursing, and emergency room visits.

Figure 11. Comparison of Costs of Using Pasteurized Donor Human Milk. The cost of using pasteurized donor human milk (PDHM) in the neonatal intensive care unit (NICU) is estimated from a survey of NICUs in 2021. The avoided cost is largely predicated on the management of necrotizing enterocolitis (NEC) which is a severe and lethal complication affecting premature and low birth weight infants. When comparing costs of providing PDHM to estimated costs of not using PDHM, there is an estimated $4 million cost avoidance statewide among all payers.



3.3. State Medicaid Coverage Policies for Donor Human Milk

Currently, ten state Medicaid programs have coverage policy for pasteurized donor human milk (PDHM) (Table 1). Six of the ten (60%) states have a milk bank accredited by HMBANA.[23]

TABLE 1. SUMMARY OF STATE MEDICAID COVERAGE OF PASTEURIZED DONOR HUMAN MILK

STATE	*DESCRIPTION OF COVERAGE*	*HMBANA BANK IN STATE*
California	Coverage when mother's own milk is insufficient, or infant cannot breastfeed, or contraindication to formula. Cover for inpatient and outpatient.	Yes
Iowa	Coverage for infants in the inpatient setting.	Yes
Missouri	Coverage for infants under 3 months of age who are critically ill and have medical necessity for human	Yes

	milk diet. Coverage for neonatal intensive care unit (NICU) only.	
New York	Coverage for infants with birth weights less than 1,500 grams, infant unable to breastfeed, mother unable to produce sufficient milk, or medical necessity. Coverage for inpatient. Prior authorization required.	Yes
Texas	Coverage for inpatient infants at or under six months of age with medical necessity. Coverage for outpatient infants at or under 11 months of age but may be extended through 20 years with inability to tolerate formula and medical necessity. Prior authorization for outpatient. Subsequent reauthorization for both inpatient and outpatient.	Yes
Kansas	Coverage for infants under 3 months of age who are critically ill and have medical necessity. Coverage for NICU only. Prior authorization required.	No
New Jersey	Coverage for infants under 6 months of age, infant unable to breastfeed, mother unable to produce sufficient milk, infant body weight below healthy level, or medically necessary. Coverage for inpatient and outpatient.	No
Utah	Coverage for infants under 11 months of age with medical necessity. Cover for outpatient only. Prior authorization with reauthorization.	Yes
District of Columbia	Coverage of infants under 11 months of age who are unable to tolerate formula and have medical necessity. Coverage for inpatient and outpatient. Prior authorization and reauthorization required.	No
Connecticut	Coverage when medically necessary, infant unable to breastfeed, or mother unable to produce insufficient milk.	No

3.4. Commercial Insurance Coverage Policy for Donor Human Milk

Tricare (TRICARE), a health insurance program that provides civilian health care benefits for U.S. Armed Forces military personnel, military retirees, their dependents, and some members of the Reserve Component, commissioned a study and enacted policies, reimbursement criteria, and reimbursement rates for the use of PDHM as a Medically Necessary Food (Appendix E).

3.5. Summary of Coverage Policy for Donor Human Milk

Model health insurance coverage policy for PDHM, includes at minimum:

- Coverage of infants through a certain age with documented medical necessity for human milk. In 2001, the World Health Organization recommended making accessible human breast milk for infants through two (2) years of age.
- Coverage when mother is unable to produce sufficient milk or contraindicated.
- Coverage for inpatient and outpatient infants.

- Coverage of PDHM from HMBANA-accredited milk bank or a milk bank in compliance with federal regulations governing the production and labeling of such items as covered by statutes in 21 CFR 100-169, in particular parts 105-107 dealing with infant foods.

An additional policy consideration is

- Permitting a foster mother to breastfeed the foster child without the child losing coverage for supplemental PDHM.

Section 4. Safety Considerations of Donor Human Milk

The Legislature directed that the Agency contemplate the safety considerations in utilizing donated human milk for newborns in the NICU and the adulterants and contaminants that can be transmitted via human milk.

4.1. Introduction to Safety Considerations

The gold standard for infant feeding is mother's own milk (MOM). When MOM is unavailable, pasteurized donor human milk (PDHM) is a safe supplement or alternative if appropriate and ethical measures are used to screen donors and collect, store, pasteurize, and distribute it. In addition to providing essential nutritional components, human milk (HM), whether MOM or PDHM, provides other medical benefits and influences growth and development of multiple body systems, regulates the newborn's immune system, and introduces aspects of the environment, such as flavor and scent, to the infant. It is important to understand that it is possible that environmental substances can be transmitted by HM.[24-29]

The United States Food and Drug Administration (FDA) states that DHM from a source other than the infant's mother may present possible health and safety risks for the recipient infant.[30] These risks include exposure to infectious pathogens, chemical contaminants, and various medications and illicit drugs that might be transferred in the DHM. Additionally, without proper handling and storage, DHM from mother or donor can become contaminated and unsafe for consumption.

Milk banks have been established for the purposes of standardizing donor screening, milk collection, processing, and distribution. Milk banks safeguard PDHM supply with voluntary policies governing donor screening, collection, storage, shipping, handling, processing, and distribution of milk.

Potential donors are screened using a lifestyle questionnaire and blood tests for certain blood-borne infections (e.g., human immunodeficiency virus [HIV], syphilis, hepatitis B virus [HBV] and hepatitis C virus [HCV]).

Most milk banks in North America use validated heat-treatment methods (e.g., vat or Holder pasteurization, which exposes the milk to 62.5°C heat for 30 minutes) to inactivate infectious

pathogens.[31-33),(34)] A few states, such as California and New York, have adopted required safety standards for milk banks. Milk banks in other states voluntarily follow their own proprietary guidelines such as those from the Human Milk Bank Association of North America (HMBANA) and other milk bank associations (Appendix B). Currently, the United States Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) do not publish either voluntary guidelines or minimum standards for human milk banking.[(30)]

Clinically, PDHM is preferred over infant formula for high-risk infants when their MOM supply is insufficient or absent, such as for foster infants. Another preferential situation for PDHM is when MOM is contraindicated, such as if the mother is receiving chemotherapy. PDHM is intended to be used as temporary, supplemental nutrition for fragile, high-risk newborns, such as those born extremely premature (i.e., gestational age at birth of less than 32 weeks) or when birth weight is less than 1,500 grams.[(35)]

PDHM carries risks inherent in the human milk from which it is derived. Milk banks screen candidate donors and process milk so that, if all safety measures are applied appropriately, risk is minimized. When removal of all potentially harmful substances is not possible, risks posed to the infant must be weighed against the risks of modest feeding with infant formula and withholding enhanced beneficial aspects of PDHM.

4.2. Methods for Considering Safety of Donor Human Milk

Peer-reviewed data on biological, pharmaceutical, and chemical contaminants in breast milk and formula were identified by searching PubMed, EMBASE, CINAHL and Web of Science for publications appearing between 1 January 2010 and 31 July 2021.

4.3. Safety Findings

Safety concerns with DHM can be categorized into general contaminants (Tables 2-5) or adulterants (Table 6).

4.3.1. General Contaminants

Contamination is usually unintentional and can occur due to system failures, shortcomings or lapses in quality assurance. Contamination of both MOM and DHM may result from natural causes, such as heavy metals or pesticide residue in maternal food that transfers to her milk. Contamination can also be introduced in the processes of collecting, cryopreserving, storing, or thawing milk. Contamination is generally predictable, and risks from contamination involve hazards that manufacturers know require careful control.[(36)]

4.3.1.1. Infectious Agents

Table 2 lists concerns attributable to infectious agents, and milk bank efforts to mitigate associated risks. Concern is primarily focused on limiting the transmission risk of viruses and bacteria in the milk (e.g., HIV, HBV, HCV, or syphilis) to the recipient infant. While any step of the donation process has the potential to introduce bacteria or viruses, careful handling and pasteurization nearly eliminates infectious risk.[37] At the time of this study, there have been no reports in the literature or to HMBANA of infectious agents transferred via PDHM to an infant-recipient.

TABLE 2. GENERAL CONTAMINANTS: INFECTIOUS AGENTS

TYPE OF CONTAMINANT	*MITIGATION EFFORTS*	*REFER-ENCES*
Pathogens transmitted from blood to human milk. • Bacteria (e.g., syphilis, rubella) • Viruses (e.g., HIV, HTLV, CMV, HBV, and HCV)	• Screen donors by blood test for evidence of infectious agents. • Some organizations test for presence of infectious agents in milk. • Pasteurization to kill pathogens for near-complete elimination.	(37, 38)
Bacteria that are introduced after pasteurization or not inactivated due to suboptimal pasteurization conditions	• Standardized quality assurance and quality control processes for routinely performing pathogenic bacterial culture testing of every batch of milk using a representative milk sample after pasteurization. If samples show any pathogenic bacterial growth after pasteurization, the entire batch is discarded. • Standardized quality assurance and quality control processes for routinely validating the pasteurization process. This includes confirming that adequate temperatures are met in all areas of the pasteurizer.	(31, 32, 39, 40)
Bacterial toxins that are not destroyed by pasteurization (heat-stable toxins)	• One milk bank reports that it tests milk directly for the presence of toxins. • An alternative mitigation technique is to test milk for presence of pathogenic bacteria-producing heat-stable toxins before the bacteria are inactivated by pasteurization. *NOTE: Neither mitigation technique listed above is required or routinely performed in the United States.*	(39, 41)
Non-blood transmission of bacteria or viruses (e.g., herpes infection from skin near breast or mastitis)	• Donor instructed to notify the milk bank of illness or infection as soon as possible. The milk bank determines whether donations should be interrupted, and if so, for how long.	(32, 39)

	• Include questions in donor screening form about breast health. *NOTE: If milk is accepted, pasteurization should inactivate these bacterial or viral pathogens.*	
Transmission of bacteria or viruses that are spread by respiratory droplet or direct contact (e.g., mumps, pertussis, rubella and respiratory syncytial virus, adenovirus, influenza, *Haemophilus* species, mycoplasma, *Neisseria* species) during collection or handling by an infected donor or milk bank personnel.	• Compliance with pasteurization procedures • Personal Protection Equipment (PPE) worn by banking personnel during collection, processing, and distribution.. • Include questions about vaccination status and infection history in donor screening and personnel files.	(37)
Transmission of SARS-CoV-2	• Mitigation efforts are in development. *NOTE: Pasteurization should inactivate the SARS-COv-2 virus.*	(42, 43)

Contamination of preterm infant formula and the morbidity associated with its contamination are underappreciated. The use of infant formula presents higher intrinsic and extrinsic risks of bacterial contamination compared with the use of DHM. For example, contamination with bacteria such as *Cronobacter* and *Salmonella* remain significant identifiable causes of infant morbidity and mortality, and is more likely to occur with infant formula.(38) The use of infant formula also has significant negative impacts on the development of the gut microbiome and increases the risk of necrotizing enterocolitis.(44, 45),(46)

4.3.1.2. Medications

While maternal medications can be transferred in breast milk, the vast majority of these agents are safe for use while breastfeeding, and the presence of a medication in human milk (HM) does not necessarily confer high risk to the infant-recipient.(47) When assessing the safety of a maternal medication, LactMed is a reliable online resource used by clinicians.(48) For example, caffeine is a commonly consumed agent and is often found in HM. Caffeine is also a medication that is prescribed to most premature infants cared for in NICUs, typically in much higher doses than what is found in HM.(49),(50) If milk with some amount of medication enters the donor milk pool, it is very unlikely that the quantity of the medication or its metabolite would reach a clinically significant or hazardous concentration for the infant-recipient. Despite the low risks of clinically significant medication contamination in breast milk, most HM banks will not qualify women as donors if they regularly take medications, even if the medications are common and "generally regarded as safe."(51) Thus, the current screening standard for donating human milk at most HMBANA-accredited banks is very high.

Social use of licit and illicit substances is more challenging to quantify because of under-reporting. Donors may not feel comfortable revealing illicit, addictive substance use. There is a layperson perception that cannabis is harmless and does not transfer into breast milk, but the true transfer rate of cannabis and its health impacts on the infant-recipient are unknown.[52]

Table 3 lists concerns attributable to medications and addictive substances, and milk bank efforts to mitigate associated risks.

TABLE 3. GENERAL CONTAMINANTS: MEDICATIONS

TYPE OF CONTAMINANT	*MITIGATION EFFORTS*	*REFERENCES*
Medications and licit substances (e.g., caffeine, nicotine, alcohol, prescribed opioids)	• Banks use a lifestyle screening questionnaire to identify medication use. Most milk banks exclude mothers if they routinely use medications and/or exceed allowed amounts of licit substances. • Donors and milk banks maintain an ongoing relationship to ensure medication exposures are updated. Exposures may result in temporary deferment of milk donations while the donor is taking a medication. • Donors receive education about allowable amounts of licit substances.	(49),(50, 53)
Illicit substances (e.g., cannabis, cocaine, heroin, LSD, unprescribed opioids)	• Banks use a lifestyle screening questionnaire to identify potential donors if they admit to using illicit substances. • Some milk banks directly test milk donations for illicit substances, though validated methods are cost-prohibitive for most banks. *NOTE: Testing of donors using validated urine or serum drug tests is not a current milk bank practice.*	(49),(50, 52, 53)

4.3.1.3. Chemical Substances

Currently, there are no robust human milk biomonitoring programs in the United States, making it challenging to accurately assess chemical contamination of PDHM. Introduction of environmental chemicals into human milk is difficult to control due to the ubiquity of chemicals in the environment. The primary route of introduction is from the donor to the milk through the process of milk production whereby chemicals transfer from the donor's bloodstream into the milk. This occurs before the donor expresses her milk. Another route of introduction is leaching of chemicals from milk storage containers used after the donor expressed her milk. The Centers for Disease Control and Prevention (CDC) estimates there to be more than 400 potential

environmental contaminants.[54] While published systematic reviews attempt to clarify the status of chemical exposure from human milk and infant formula, none specifically address PDHM.[26, 55]

Table 4 lists concerns attributable to chemical substances found in human milk and banking efforts to mitigate associated risks. Strategies focus on the main exposure routes which include the environment, dietary intake, drinking water, and indoor air quality. Dietary intake refers to the infant's diet or their mother's diet if breastfeeding. It should be noted that infant exposures to environmental contaminants in the air and water far exceed their risk of exposure in human milk. For example, in models of arsenic exposure, the risks from human and powdered formula were low throughout the first year of life, unless formula was prepared with arsenic-contaminated tap water.[26, 55, 56]

TABLE 4. GENERAL CONTAMINANTS: CHEMICAL SUBSTANCES

TYPE OF CONTAMINANT	*MITIGATION EFFORTS*	*REFERENCES*
Organic pollutants: • Pesticides (e.g., pyrethroid, organochlorine and organophosphorus) • Organochlorines (e.g., polychlorinated dibenzo-p-dioxins, dibenzofurans, polychlorinated biphenyls, bisphenols [BPA], parabens, octylphenols) • Phthalates, brominated flame retardants and perfluorinated compounds	• One milk bank reports using a lifestyle questionnaire for screening donors for environmental exposures.	(26, 55, 57)
Volatile organic compounds (VOCs; e.g., methyl tert-butyl ether [MTBE], chloroform, benzene, toluene)	• It is unknown if current screening procedures address exposures to VOCs.	(26)
Heavy metals (e.g., arsenic, cadmium, lead)	• One milk bank reports lifestyle questionnaire screening donors for heavy metal exposures.	(26)

4.3.1.4. Human Milk Product Management

Table 5 lists concerns attributable to human or systems-based errors in the handling of donor human milk and banking efforts to mitigate associated risks.

TABLE 5. GENERAL CONTAMINANTS: PRODUCT MANAGEMENT		
TYPE OF CONTAMINANT	***MITIGATION EFFORTS***	***REFERENCES***
Contamination from non-compliance with optimal storage guidelines resulting in milk spoiling	• Need for focused and isolated handling of expressed human milk in NICUs to decrease risk of preparation errors. • Hospitals should have human milk storage, handling, and preparation audit procedures in place to identify vulnerabilities. • Quality control validation of adherence to guidelines during shipping, receiving, handling, and storage through cold chain verification techniques.	(58)
Patient identification errors.	• Ensure accurate methods to track each bottle of donor human milk, including provenance and receipt accounting, using barcoding or other machine-readable labeling.	(58)

4.3.2. Adulterants

Adulteration is the intentional introduction, replacement, or dilution of a product, typically for economic gain. An adulterant is a different substance used, instead of the expected ingredient. In manufacturing, most cases of adulteration are not dangerous to health and may never be known. Risk associated with the addition of adulterants cannot be assessed until, or if, the adulteration is exposed. Consumer safety depends upon the adulterator's knowledge of the safety of the substitution, and a willingness to reveal it.

An example of adulteration – not directly involving human milk – was the melamine milk powder misconduct that resulted in 300,000 adverse events, including six infant deaths from kidney stones and other kidney damage. Those incidents prompted an investigation and the discovery that melamine was added to infant formula.(59)

Adulteration introduces elements into the food supply chain without consumers or regulatory agencies being aware. They may be harmless or devastating and are difficult to identify because they are often designed to bypass detection.

One approach to mitigating the risk of adulterants is to verify the presence of expected ingredients rather than test for the presence of potential adulterants.(36, 60-62)

Adulteration is an uncommon phenomenon in milk donation.(49) Table 6 lists categories of potential adulterants to PDHM and milk bank mitigation efforts to reduce the risk of product adulteration.

TABLE 6. ADULTERANTS		
TYPE OF ADULTERANT	***MITIGATION EFFORTS***	***REFERENCES***
Milk from an unqualified donor	• One milk bank reports the use of DNA testing to ensure that the donations are from the qualified donor.	(49)
Milk from a non-human species (e.g., cows' milk, sheep's milk)	• One milk bank reports the use of DNA testing to ensure that the donations do not contain non-human milk.	(49),(61)
Milk diluted with water	• There are no current mitigation techniques to assess dilution of milk with water. *Note: The result is lower calorie density than expected, though the normal range of milk calorie density is wide. The milk can be discarded or pooled with higher calorie milk during processing.*	None

Section 5. Recommendations of Best Practices

The Legislature also directed the Agency to submit recommendations of best practices for donor human milk.

5.1. Methods for Determining Recommendations for Donor Human Milk Usage for Newborns in Florida NICUs

As directed by the Legislature, AHCA collaborated with the Florida Department of Health (FDOH) through meetings with department lactation personnel in June 2021 and providing a report draft for their edits and comments in October 2021. In July 2021, the Chief Medical Officer for Florida Medicaid at AHCA also met with Mother's Milk Bank of Florida in their Orlando, Florida laboratory to study first-hand best practices in milk banking.

AHCA also contracted the FMSQN to review the medical literature, FDA guidelines, and HMBANA guidelines for best practices in using PDHM. The FMSQN also met with HMBANA and Prolacta Bioscience, Inc. to interview them for best practice information.

Sources are summarized in Table 7. Areas where consensus existed were formed into recommendations (Tables 8-12). Areas without significant evidence or consensus were identified as areas in need of further research (Section 5.4).

Recommendations represent minimum safety standards adapted from multiple sources.

5.2. Sources of Information

Table 7 summarizes sources used to determine recommendations for best practice in donor human milk banking.

TABLE 7. SOURCES REVIEWED TO DETERMINE RECOMMENDATIONS OF BEST PRACTICES	
A	PATH's Strengthening Human Milk Banking: A Resource Toolkit for Establishing & Integrating Human Milk Bank Programs, section 2C "Establishing Quality Assurance: A Guide for Creating Operational Standards"[63]
B	HMBANA's "Standards for Donor Human Milk Banking: an Overview"[64]
C	Recommendations for the Establishment and Operation of Human Milk Banks in Europe: A Consensus Statement from the European Milk Bank Association[65]
D	Best practice guidelines for the operation of a donor human milk bank in an Australian NICU[66]
E	American Academy of Pediatrics Policy Statement: Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States. Committee on Nutrition, Section on Breastfeeding, Committee on Fetus and Newborn[35]
F	Donor Human Milk Bank Data Collection in North America: An Assessment of Current Status and Future Needs[67]
G	Human milk banking at Sorrento Maternity Hospital, Birmingham[68]
H	Processing of Donor Human Milk: Update and Recommendations From the European Milk Bank Association[69]
I	Expert opinion
J	Model guidelines for the Establishment and Operation of a Donor Human Milk Bank from Prolacta Bioscience, Inc.[70]
K	United States Food and Drug Administration (FDA) • Code of Federal Regulations Title 21, Part 117 (21 CFR Part 117)[71] • Food Safety Modernization Act (FSMA)[72] • Food Code 2017[73] • Current Good Manufacturing Practices for Food and Dietary Supplements (CGMPs)[74] • Pasteurized Milk Ordinance (US FDA, 2011b)[75] • Bacteriological Analytical Manual (US FDA, 2021)[76]
L	New York State Department of Health State of New York Codes, Rules and Regulations Sub-Part 52-9 Human Milk Banks[77]

5.3. Recommendations

Recommendations and considerations are listed below in Tables 8-12.

TABLE 8. ORGANIZATIONAL STRUCTURE RECOMMENDATIONS	
RECOMMENDATIONS	***SOURCES***

1. Each milk bank should have a Medical Advisory Board made up of medical professionals with expertise in relevant fields. These include, at a minimum, one physician with pediatric expertise, one physician with microbiology/clinical pathology/infectious disease expertise, and one expert in human lactation. Representation from practitioners with expertise in neonatology and neonatal nutrition is also encouraged.	A, I
2. Ensure milk bank staff: • have knowledge on food safety and processing, established milk banking standards and any relevant regulations • undergo training to become Preventive Controls Qualified Individuals as described by the FDA • participate in continuing education and training with documentation	B, J, K
3. Standard Operating Procedures (SOPs) should be: • established for all steps of donor screening, milk processing, recalls, sanitation, Current Good Manufacturing Practices (CGMPs) and emergency preparedness • updated annually at a minimum • made available to all staff • monitored for adherence	A, B, D, J
4. Ensure Good Manufacturing Practice (GMP) and set Hazard Analysis Critical Control Point (this is a safety monitoring system that uses identified critical control points to prevent hazards in donor milk processing from donation to distribution).	A-D, J, K
5. Comply with Food Safety Modernization Act.	B, J, K
6. Register with the FDA as a food manufacturer bi-annually.	B, J, K
7. Undergo inspection by FDA and local health departments.	A, B, J, K
8. Ensure a quality assurance plan is in place for: • Current Good Manufacturing Practice (CGMP) monitoring • record keeping • records for safety meeting and root cause analysis • SOP and Food Safety Plan annual review and revisions • mock recalls • verification and validation activities	A-D, J
9. Confirm that milk banks that process derivatives comply with Good Laboratory Practices.	J, K
10. Conduct internal auditing by advisory/accreditation committee annually.	A, B, J

TABLE 9. DONOR RECRUITMENT AND SCREENING RECOMMENDATIONS	
RECOMMENDATIONS	***SOURCES***
1. Donor screening should include, at a minimum, assessment of: • donor and infant health • vaccination or medication exposures • infectious disease exposures • potentially detrimental lifestyle/environmental exposures	A-E, J
2. Donor screeners must be trained and demonstrate proficiency in the screening process. Screeners should have continued training at a predetermined frequency with documentation.	B
3. Ensure use of the following exclusion criteria for initial potential donor screening (any criterion met temporarily or permanently disqualifies the individual): • tobacco use • recreational drug use • risk of Creutzfeldt-Jakob disease • positive infectious serology test results • use of non-approved medications (prescription or over the counter) • history of recent blood transfusion • risk of blood-borne illnesses • body piercing, tattoos, or permanent makeup • organ or tissue transplant • vegans without B12 supplementation • have an at-risk sex partner • regular alcohol use (deferral required)	A-E, J
4. Update donor screening qualification standards to reflect new medications, novel diseases, and emerging environmental/lifestyle exposures.	B, J
5. Obtain attestation from health care providers to ensure mother and baby are healthy, and that mother has enough supply to donate.	A, J
6. Provide verbal and written education material to potential donors in clear, nontechnical language.	A-E, J
7. Give each potential donor documents that describe donor rights and responsibilities, which should include: • confidentiality of records • serology testing explanation • potential disqualification for positive serology test results • statement indicating that approval as a milk donor does not constitute informal selling or safe sharing of milk	B
8. Obtain and save written informed consent from potential donors prior to serological testing and milk handling.	A, C, D, J
9. Offer accommodations for non-English speaking potential donors.	B
10. Conduct serology testing on potential donors for HIV-1 and 2, hepatitis B and C, human T-lymphotropic virus I and II, and syphilis.	A-E, J
11. All donor verbal and written screening data must be Health Insurance Portability and Accountability Act compliant.	B
12. Obtain updates regarding donor's health, medication use, lifestyle/environmental exposures at least every two months.	B

TABLE 9. DONOR RECRUITMENT AND SCREENING RECOMMENDATIONS, CONTINUED.	
13. Properly instruct donors about situations resulting in temporary or permanent discontinuation of donation and instruct them to report such events. Reasons for temporary discontinuation of donation include: • the presence of mastitis • temporary use of some medications that may be transferred into breast milk • the presence of acute infectious diseases and skin diseases such as herpes simplex or varicella zoster • fungal infection of the nipple, areola, mammary or thoracic region The extent of the temporary deferral of donors will vary according to the duration of the circumstances, and medical advice should be sought by the DHM bank to exclude the possibility of acceptance of contaminated, unsuitable, or suboptimal milk from donor.	B, C
14. Provide support and education to ineligible donors. • Educate ineligible donors on reason for ineligibility. Eligibility criteria for donation of human milk is more stringent than contraindications to breastfeed one's own infant. • Support ineligible donor to continue breastfeeding their own infant unless there are contraindications to breastfeeding. If the ineligible donor has uncertainty regarding safety of her milk for her infant, the donor should seek medical advice. • Educate mothers who have high bacterial counts in their milk on the proper maintenance of breast pumps, as well as optimal expression and storage of milk.	A, C
15. Requalify donors at minimum every 6 months. This includes repeat screening using a lifestyle questionnaire and testing for infectious diseases that can be transmitted through human milk. *NOTE: Qualification frequency may need to be readdressed after impact of re-qualification frequency for donors on milk donation is assessed.*	D, F, J, L

TABLE 10. DHM COLLECTION, STORAGE, AND HANDLING/TRANSPORT RECOMMENDATIONS	
RECOMMENDATIONS	***SOURCES***
1. Discourage acceptance of "dripped" milk (i.e., milk that is passively collected from one breast while the other is expressed by hand, pump, or by feeding the donor's infant).	C
2. Educate donors regarding: • clean technique for milk collection (hand hygiene, washing milk collection equipment and milk storage containers) • when to refrain from donating milk and lifestyle choices that impact eligibility • steps after milk collection including labeling (donor identification and date of collection), storage, and safe transportation to the milk bank	A-E, J
3. Decline any milk that is heat treated, improperly handled/stored. Milk banks should determine the maximum acceptable duration between milk expression and donation. Milk expires 12 months from expression, regardless of date of processing.	B

4. Ensure milk stored in refrigerators is held at a constant temperature of 18°C or less and milk stored in freezers is held between 1- 4°C at the milk bank.	B

TABLE 11. DHM PROCESSING RECOMMENDATIONS	
RECOMMENDATIONS	***SOURCES***
1. Apply a well-constructed electronic inventory system to account for donor milk received (including incoming shipping records, receiving date, volume, and milk condition), processed, distributed, disposed, and used for research purposes. Confirm the inventory system is applied in a way that allows traceability of samples within each milk processing step.	A-D, J
2. Prevent contamination by: • thawing milk in gradual manner (per FDA Food Code) • ensuring that temperature and time requirements are met by monitoring the processing documents	B-D, K
3. Pool milk from multiple donors to ensure even distribution of macronutrients.	B-D
4. Test each batch of milk after pasteurization using appropriate bacterial culture media and qualified laboratories that adhere to the FDA Bacteriological Analytical Manual. Discard the batch if there is any pathogenic microbial growth.	A-E, J, K
5. Use vat heat treatment or pasteurization by Holder methods.	A-J
6. Routinely validate pasteurization processes, at minimum annually.	A, C, I, J
7. Ensure rapid chilling of milk after pasteurization using processing equipment designed to cool milk, or ice baths.	A-D
8. Use glass/food-grade plastic bottles meeting FDA requirements that are air-tight and leak-proof for milk bottling.	B, K
9. The maximum duration of storage of pasteurized donor milk in the freezer prior to distribution and consumption should be determined by the organization. *Note: Organizations have considered the maximum duration of storage to be between 3-12 months.*	A, B, D
10. Labeling should conform to federal requirements regarding nutritional content of food.	C, I, J, K
11. Verify that the processing facility is adequate in size, construction, and design for sanitary milk processing and compliant with FDA safety requirements for food manufacturers.	B, D, J, K

TABLE 12. DHM DISTRIBUTION RECOMMENDATIONS	
RECOMMENDATIONS	***SOURCES***
1. Maintain separation of pasteurized milk from raw milk.	A, C, J
2. Dispense DHM primarily to hospitals. If dispensed to outpatients, a prescription from licensed healthcare provider is required.	A, C, E, J
3. Individual hospitals should comply with their own policies related to management and distribution of DHM.	A, C, E
4. Hospitals that use frozen DHM must have properly regulated freezers and other methods that ensure safe donor milk handling and tracking.	E

5. Establish shipping guidelines that ensure frozen DHM is maintained at appropriate temperature for the duration of transit time AND provide guidance to receiving organizations related to temperature and other storage conditions for the milk.	E
6. Establish guidelines for DHM distribution in times of shortage.	E, J

5.4. Considerations for Future Investigation

The following considerations require further investigation to determine their impact on improving the safety and benefit of PDHM fed to infants.

5.4.1. Safety

1. Create standards for donor intake process and screening that include the assessment of maternal occupational, dietary, and environmental factors that could pose a risk for the safety DHM. Additionally, the frequency and consistency of performing screening should be monitored.
2. Advocate for the inclusion of PDHM as part of biomonitoring programs, such as the CDC National Report on Human Exposure to Environmental Chemicals (NHANES) program.
3. Work with scientific organizations such as Society for Toxicology, the American Chemical Society and Society of Environmental Toxicology and Chemistry to encourage conference programming and regional meetings on HM contamination control.
4. Create a team to develop evidence-based standards for screening and/or testing for toxic environmental exposures and assess how these would impact the milk banking industry.
5. Create a team to develop evidence-based standards for screening and/or testing for drug exposures and assess how these would impact milk banking industry.

5.4.2. Clinical and Laboratory Practice

1. Ethics and safety of remuneration for milk.
2. Validating milk testing tools and procedures for adulterants, medications, and illegal substances.
3. New pasteurization or bio-burden control methods and effects on nutritional composition and bioactive components in donor milk.
4. Determine the ideal number of PDHM samples to be pooled to ensure even distribution of macronutrients.

5.4.3. Health Outcomes

1. High-quality clinical studies with appropriate control groups, cohort masking, and good clinical research practice (GCP) are needed to determine the quantitative benefit of fortifiers or nutrients to PDHM.
2. High-quality clinical studies of micronutrients and personalized PDHM for sub-populations of infants.
3. High-quality clinical studies of mixing PDHM with MOM to examine effects on infant intestinal microbiota and related health outcomes.

5.4.4. Processing

1. Testing of all pools of milk for pathogenic bacterial growth prior to pasteurization and discard sample pools that do not meet this standard.[63], [65], [66], [68]-[70]
2. Directly test milk for heat stable bacterial toxins. Many milk banks exclude milk that contains bacteria which produce heat-stable toxins or spores (e.g., *Staphylococcus aureus, Bacillus cereus)* instead of testing for the toxins directly. Before or after pasteurization, testing for the associated toxins from these bacteria (e.g., Staphylococcal enterotoxin types A, B, or C; cereulide) is possible. If any of these toxins are present, the milk should be discarded because while pasteurization may kill the bacteria, the toxins could cause culture negative sepsis-like illness.[75]
3. To assess safety, retain aliquots of PDHM for future safety testing, if the need arises. Milk banks can retain aliquots of PDHM samples for a period and analyze them if there are concerns regarding safety of the batch from which the milk originated. Considerations should include required freezer farm space, cryopreservation conditions, length of time, and volume to retain.

5.4.5. Distribution

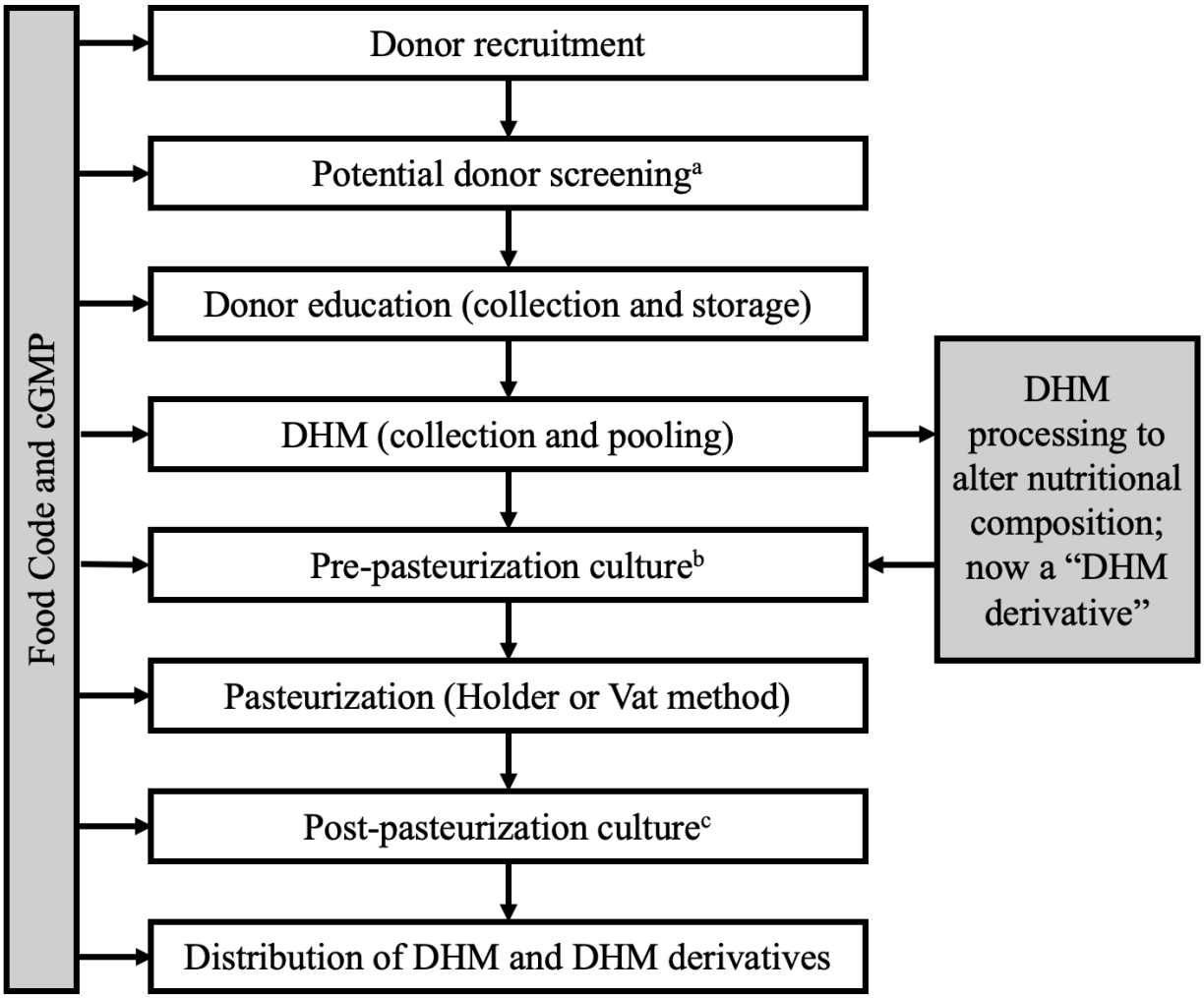
1. Develop and provide instructions for hand-off and documented receipt to infants in inpatient units and outpatient settings. Hospitals and recipient individuals should be instructed on how to properly handle PDHM to decrease the risk of contamination and subsequent illnesses especially in vulnerable infants. At a minimum, these instructions should include information on hand hygiene, required temperature and time regulation for optimal storage, proper labeling, and documentation and verification of processes.[63]

5.5. Derivatives from Donor Human Milk

Donor human milk derivatives are nutritional products comprised of donor human milk or a fraction thereof that have been processed to be nutritionally distinct from unprocessed donor human milk. Examples include skim milk, human milk-derived protein, and mineral fortifier for use with human milk, human milk cream supplement, and human milk oligosaccharide supplement. Milk derivatives are processed in human milk banks, which are required to adhere to the same standards as PDHM processing facilities.

When milk derivatives are made, there is an added step to the process. After pooling donor milk units, but before pasteurization, the donor milk undergoes processing to alter its nutritional composition. Once the nutritional composition meets the target levels, the milk derivative is typically subjected to the standard process for pasteurization, labeling and distribution, consistent with PDHM as outlined below (Figure 12).

Figure 12. Flow diagram representing donor human milk (DHM) and milk derivative processing.



[a] Includes oral interview, health questionnaire, and serology testing
[b] Encouraged, not required. Any pre-pasteurization sample with $>10^5$ CFU/ml microbial growth should be excluded.
[c] Samples with any pathogenic microbial growth are excluded.

High quality clinical studies are needed to quantify the efficacy and cost-effectiveness of donor human milk derivatives. Furthermore, claims of improved health outcomes with milk derivatives in the infant population and older populations need to examined using rigorous good clinical research practice (GCP) principles.

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Appendices

Appendix A. Abbreviations and Definitions

Abbreviations

TABLE A.1. ABBREVIATIONS IN THIS REPORT	
ABBREVIATION	***FULL NAME***
AHCA	Agency for Health Care Administration
CDC	Centers for Disease Control and Prevention
CFIA	Canada Food Inspections Agency
CFR	Code of Federal Regulations
CGMP	Current Good Manufacturing Practice (CGMP)
DHM	Donor Human Milk
FDA	Food and Drug Administration
FDOH	Florida Department of Health
FMSQN	Florida Medical Schools Quality Network
FSMA	Food Safety Modernization Act
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HMBANA	Human Milk Bank Association of North America
MMBFL	Mother's Milk Bank of Florida (Orlando, FL)
MOM	Mother's Own Milk
MTBE	Methyl Tert-Butyl Ether
NEC	Necrotizing Enterocolitis
NHANES	National Report on Human Exposure to Environmental Chemicals
NICU	Neonatal Intensive Care Unit
PCQI	Preventive Control Qualified Inspector
PDHM	Pasteurized Donor Human Milk
SOP	Standard Operating Procedure
VLBW	Very Low Birth Weight
VOC	Volatile Organic Compounds

Definitions

Current Good Manufacturing Practice (CGMP): FDA Title 21, Part 117, Subpart B - outlines minimum standards for safe and sanitary food manufacturing.(71) CGMPs include staff training, staff hygiene and illness reporting, plant layout, sanitation procedures, and pest control.

Donor human milk: milk expressed and donated by lactating women, pasteurized and dispensed for use by a recipient who is not the donor's own baby.

Donor human milk bank: an organization established for the purpose of collecting, screening, processing, and distributing donor human milk**.**

Donor human milk derivative: a nutritional product comprised of human donor milk or a fraction thereof that has been processed to be nutritionally distinct from unprocessed donor human milk.

Human milk donor: a healthy lactating woman who willingly provides her milk for processing and administration to a child other than her own after meeting her own infant's current and future needs.(78)

Appendix B. HMBANA Standards for Donor Human Milk Banking

This page is intentionally blank and is followed by a document of standards.

Appendix C. Survey of Florida NICUs for Donor Human Milk Usage

A. Survey of Florida NICUs for Current Clinical Practice in Utilizing Donor Human Breast Milk

Introduction: *Please respond to the following questions focusing on your hospital's use of banked donated human milk (BDHM) for premature infants in the NICU. Banked Donor*

Human Milk (BDHM) is defined as human milk, donated by screened lactating women, tested for infectious agents and heat treated.

Demographics:

- Your First Name (1) _____
- Your Last Name (2) _____
- Email (3) _____

Q1. Choose your hospital from the drop-down menu.

AdventHealth Altamonte Springs
AdventHealth Celebration
AdventHealth Daytona Beach
AdventHealth Ocala
AdventHealth Orlando
AdventHealth Tampa
AdventHealth Winter Park
Arnold Palmer Medical Center/Winnie Palmer Hospital for Women & Babies
Ascension Sacred Heart Emerald Coast
Ascension Sacred Heart Pensacola
Ascension St Vincent's Riverside
Ascension St Vincent's Southside
Baptist Hospital of Miami/Baptist Children's Hospital
Baptist Medical Center South
Bayfront Health - Port Charlotte
Bayfront Health Spring Hill
Bethesda Hospital East
Boca Raton Regional Hospital
Brandon Regional Hospital
Broward Health Coral Springs
Broward Health Medical Center
Cleveland Clinic Martin Medical Center
Cleveland Clinic Tradition Hospital
Flagler Hospital
Fort Walton Beach Medical Center
Good Samaritan Medical Center
Gulf Coast Regional Medical Center
Halifax Health Medical Center
Healthpark Medical Center / Golisano Children's Hosp of SW Florida
Holmes Regional Medical Center
Holy Cross Hospital
Jackson Memorial Hospital / Holtz Children’s Hospital
Jackson North Medical Center
Johns Hopkins All Children's Hospital
Jupiter Medical Center
Kendall Regional Medical Center
Lakeland Regional Medical Center
Lawnwood Regional Medical Center & Heart Institute
Manatee Memorial Hospital
Mease Countryside Hospital
Medical Center of Trinity
Memorial Hospital Jacksonville
Memorial Hospital Miramar
Memorial Hospital West
Memorial Regional Hospital/Joe DiMaggio Children's Hospital
Mercy Hospital, A Campus of Plantation General Hospital
Morton Plant Hospital
Mount Sinai Medical Center/ Kravis Children's Hospital
NCH Healthcare System North Naples Hospital Campus

Nemours Children's Hospital
Nicklaus Children's Hospital formerly, Miami Children's Hospital
North Florida Regional Medical Center
North Shore Medical Center
Northwest Medical Center
Oak Hill Hospital
Orange Park Medical Center
Osceola Regional Medical Center
Palmetto General Hospital
Palms West Hospital

Q2. Does your hospital use banked donor human milk (BDHM)?

- Yes (1)
- No (2)
- I don't know (3)

Skip To: End of Survey If Q2. = 3 / I don't know

Display This Question: If Q2. = No / 2

Q2.a. What are the primary reasons that your hospital does not provide BDHM?

_____

Skip To: End of Survey If Condition: What are the primary reason... Is Not Empty. Skip To: End of Survey.

Display This Question: If Q2. = 1 / Yes

Q2.b. Date use began (Month and Year):_____

Display This Question: If Q2. = 1 / Yes

Q2.c. What were the primary reasons your hospital began providing BDHM?

_____

Q3. Who currently provides your hospital's BDHM (select all that apply)?

- Internally pasteurize donor milk for use (1)
- Medolac (2)
- Mothers' Milk Bank at Austin (Austin, TX) (3)
- Mothers' Milk Bank of Colorado (Arvada, CO) (4)
- Mothers' Milk Bank of Florida (Orlando, FL) (5)
- Ni-Q (6)
- Prolacta BioScience (7)
- The King's Daughters Milk Bank (9)
- WakeMed Mothers' Milk Bank (Cary, NC) (8)
- Other (10) _____
- I don't know (11)

Q4. On average, how many ounces per month of BDHM does your hospital use (round to the nearest 10, provide actual whole number, cannot enter range)?

Q5. Does your hospital attempt to get reimbursement for use of BDHM?

- Yes (1)
- No (2)
- I don't know (3)

Display This Question: If Q5. = 1/ Yes

Q5.a. Who does your hospital seek reimbursement from (select all that apply)?

- ▢ Insurance Companies (1)
- ▢ Family/out of pocket payment (2)
- ▢ Other (3) _____
- ▢ I don't know (4)

Q6. Describe the permission process for BDHM administration in your hospital (select all that apply).

- ▢ Written permission from parent or guardian (1)
- ▢ "Opt out" opportunity after verbal discussion (2)
- ▢ Considered standard practice (3)
- ▢ Other (4) _____
- ▢ I don't know (5)

Q7. What are your routine uses for BDHM in your hospital (select all that apply)?

- ▢ Prematurity (1)
- ▢ Birth weight (2)
- ▢ Small for gestational age (3)
- ▢ After prolonged course of NPO as determined by your hospital (4)
- ▢ Congenital gastrointestinal disorders (e.g., gastroschisis, omphalocele, intestinal atresia) (5)
- ▢ Significant congenital heart disease (6)
- ▢ During or after hypothermia therapy for hypoxic-ischemic encephalopathy (7)
- ▢ Medical necessity as determined by attending physician (8)
- ▢ Augment maternal milk supply (9)
- ▢ Mother ineligible to provide her own milk per hospital criteria (10)
- ▢ Parental request (11)
- ▢ Other (12) _____
- ▢ I don't know (13)

Display This Question: If Q7. = 1 Prematurity

Q7.a. Prematurity: Less than how many completed weeks at birth gestational age?

_____

Display This Question: If Q7. = 2 Birth Weight

Q7.b. Birth Weight: Less than how many grams?

_____

Q8. Which of the following criteria are routinely used in your hospital for transitioning from BDHM to formula when mother's milk is unavailable (select all that apply)?

- ▢ Infant reaches a specified postmenstrual gestational age (1)
- ▢ Goal Weight (2)
- ▢ Infant is nearing discharge (3)
- ▢ Reimbursement for cost not available (4)
- ▢ Other Criteria (5) _____
- ▢ I don't know (6)

Display This Question:
If Q8. = 1 / Infant reaches a specificied postmenstrual gestational age (1)

Q8.a. Greater than what postmenstrual gestational age in completed weeks? Enter number below.

_____

Display This Question: If Q8. = 2 / Goal Weight

Q8.b. Goal Weight: Patient weighs greater than how many grams? Enter number below.

_____

Q9. Does your hospital have written policies or guidelines for use of BDHM?

- ○ Yes (1)
- ○ No (2)

Q10. Does your hospital routinely fortify human milk for premature infants?

- Yes (1)
- No (2)
- I don't know (3)

Display This Question: If Q10. = 1 / Yes

Q10.a. What is your primary method of fortification for premature infants?

- HMF (e.g. Similac or Enfamil, cows' milk based) (1)
- ProlactPlus (Prolacta, human milk based) (2)
- Formula (3)
- I don't know (4)

Display This Question: If Q10. a. = 2 / ProlactPlus

Q10.b. Describe the criteria for use of ProlactPlus.

_____

Display This Question: If Q10. a. = 2

Q10.c. Enter the date use began of ProlactPlus (month and year):

_____

Appendix D. Donor Human Milk Banks

Donor human milk bank or company	**Medolac**
Address	1031 Boulder City Pkwy. Boulder City, NV 89005
Website	https://www.medolac.com
Phone number	866-599-6552
Fax number	866-239-3654
Email	info@medolac.com
Contact	Elena Medo Chief Executive Officer 866-599-6552 info@medolac.com

Donor human milk bank or company	**Mothers' Milk Bank of Florida, Inc.**
Address	8669 Commodity Circle, Suite 490 Orlando, FL 32819
Website	https://milkbankofflorida.org
Phone number	407-248-5050
Fax number	407-370-4340
Email	info@milkbankofflorida.org
Contact	Kandis Natoli, PhD, RN, IBCLC Executive Director 407-248-5050 knatoli@milkbankofflorida.org

Donor human milk bank or company	**Mothers' Milk Bank at Austin**
Address	5925 Dillard Circle Austin, TX 78752
Website	https://milkbank.org
Phone number	512-494-0800
Fax number	N/A
Email	Info@milkbank.org
Contact	Kim Updegrove, CNM, MSN, MPH Executive Director 512-494-0800 kim@milkbank.org

Donor human milk bank or company	**Ni-Q, LLC**
Address	28050 SW Boberg Rd. Wilsonville, OR 97070
Website	https://www.ni-q.com
Phone number	844-305-7674
Fax number	503-218-4805
Email	info@ni-q.com
Contact	Peter Lamb Chief Executive Officer plamb@ni-q.com Erica Richardson Customer Relations 844-305-7674 erica@ni-q.com

Donor human milk bank or company	**Prolacta BioScience Inc.**
Address	757 Baldwin Park Blvd. City of Industry, CA 91746-1504 1800 Highland Ave. Duarte, CA 91010
Website	https://www.prolacta.com/en/
Phone number	888-776-5228 (general) 844-707-7482 (policy-related issues)
Fax number	N/A
Email	info@prolacta.com
Contact	Cari Dittman Senior Account Manager 214-748-3647 cdittman@prolacta.com

Donor human milk bank or company	**Rocky Mountain Children's Foundation, Mothers' Milk Bank**
Address	5394 Marshall Street, Suite 400 Arvada, CO 80002
Website	https://rmchildren.org/mothers-milk-bank/
Phone number	303-869-1888
Fax number	303-839-7336
Email	mothersmilk@rmchildren.org
Contact	Rebecca Heinrich, CLC

	Chief Operations Officer 303-869-1888 rebecca.heinrich@rmchildren.org

Donor human milk bank or company	**The Children's Hospital of the King's Daughters, The King's Daughters Milk Bank**
Address	Medical Tower Building 400 Gresham Drive Norfolk, VA 23507
Website	https://www.chkd.org/our-services/specialty-care-and-programs/milk-bank/
Phone number	844-798-6455
Fax number	757-668-5233
Email	KDmilkbank@chkd.org
Contact	Ashlynn Baker, BSN, RN, IBCLC Director 757-668-6455 ashlynn.baker@chkd.org

Donor human milk bank or company	**WakeMed Mothers' Milk Bank**
Address	1900 Kildaire Farm Road WakeMed Cary Hospital Cary, NC 27518
Website	https://www.wakemed.org/care-and-services/womens/support-for-baby/mothers-milk-bank/
Phone number	919-350-8599
Fax number	919-350-8923
Email	mothersmilkbank@wakemed.org
Contact	Montana Wagner-Gillespie Manager 919-350-4012 mothersmilkbank@wakemed.org

Appendix E. TRICARE Coverage of Donor Human Milk

TRICARE Policy Manual 6010.63-M, April 2021
For Dates Of Service On Or After December 23, 2017

Chapter 8 Other Services - Section 7.1 Medically Necessary Food

3.8 Banked Donor Milk (BDM)

3.8.1 Effective for dates of service on or after January 1, 2019, BDM may be cost-shared as a medically necessary food when all of the following conditions are met:

3.8.1.1 The infant has one or more of the following conditions:

- Infant born at Very Low Birth Weight (VLBW) (less than 1,500g) or lower (e.g., Extremely Low Birth Weight (ELBW) infants, < 1,000g);
- Gastrointestinal anomaly, metabolic/digestive disorder, or recovery from intestinal surgery where digestive needs require additional support;
- Diagnosed Failure-to-Thrive where other feeding options have been exhausted or are contraindicated;
- Formula intolerance with either (1) documented feeding difficulty or (2) weight loss (where other feeding options have been exhausted or are contraindicated);
- Infant hypoglycemia;
- Congenital heart disease;
- Pre-or post-organ transplant; or
- Other serious health conditions when the use of BDM is medically necessary and will support the treatment and recovery of the infant.

3.8.1.2 And own mother's milk is contraindicated, unavailable due to medical or psychological condition, or mother's milk is available but is insufficient in quantity or quality to meet the infant's dietary needs.
Note: If the birth mother is unavailable due to the physical absence of the birth mother in extraordinary circumstances (i.e., adoption, maternal death, deployment of Active Duty Service Member (ADSM) mother), the own mother's milk is considered to be unavailable for the purposes of this paragraph.

3.8.2 BDM must be prescribed by a TRICARE authorized individual professional provider described in 32 CFR 199.6 (e.g., physician). As required by 32 CFR 199.6 , the authorized provider must be licensed by the state in which the care is provided and must be under the supervision of a physician (if not a physician) who is overseeing the episode of treatment or the covered program of services.

3.8.3 Coverage shall be extended for as long as medically necessary, not to exceed 12 months of age.

3.8.4 BDM must be procured through a HMBANA (Human Milk Banking Association of North America) accredited milk bank, and delivered through a TRICARE authorized provider (e.g., pediatrician or inpatient hospital, or the supplier [HMBANA-accredited milk bank]).
Note: Currently HMBANA-accredited milk banks only exist in the United States (US) and Canada. Therefore, BDM is not available overseas, except for Canada.

3.8.5 Coverage shall be limited to no more than 35 ounces per day, per infant.

3.8.6 Discontinuation of coverage for BDM for ELBW/VLBW infants shall be considered on a case-by-case basis. In general, this is considered to occur concluding the 36th post-menstrual week for otherwise healthy infants; however, continuation of coverage for BDM for healthy but ELBW/VLBW infants after 36 weeks post-menses may be appropriate in certain cases upon medical review. Continuation past 36 weeks post-menses may be covered when BDM is documented as being medically necessary or appropriate and all other conditions of coverage are met.

3.8.7 The initial prescription shall describe the quantity and frequency of the required BDM, and shall only be valid for 30 calendar days.

3.8.8 Subsequent prescriptions shall describe the quantity and frequency of the required BDM, and must be renewed every 30 calendar days.

3.8.9 In accordance with this section, prescriptions for BDM require active medical management by the prescribing provider. The contractor may require medical documentation demonstrating active medical management, as well as documentation of medical necessity to validate both the initial as well as ongoing prescriptions for BDM, and to validate the frequency, quantity, and duration of treatment with BDM.

3.8.10 BDM provided during an inpatient stay shall be cost-shared the same as any other medical supply provided during an inpatient stay.

3.8.11 BDM provided on an outpatient basis shall be subject to the same copays and cost-sharing requirements as other outpatient medical supplies.

4.0 REIMBURSEMENT

4.3 BDM shall be reimbursed in accordance with TRM, Chapter 1, Section 39 . The beneficiary may be required to pay out-of-pocket for BDM and submit a claim to the contractor for reimbursement. Provisions are outlined in TOM, Chapter 8, Section 1 .

5.0 EXCLUSIONS

TRICARE covered medically necessary food and vitamins do not include:

5.12 BDM from any milk bank not accredited by HMBANA.
5.13 Peer-to-peer donation or sale of BDM.
5.14 More than 35 ounces of BDM per day, per infant.
5.15 BDM for healthy, normal birth weight infants (even if own mother's milk is unavailable).
5.16 BDM provided for convenience (e.g., to facilitate the mother's return to work).

TRICARE Reimbursement Manual
6010.64-M, April 2021
General

Chapter 1 Section 39

CHAMPUS Maximum Allowable Charge (CMAC) For BANKED DONOR MILK (BDM)

Issue Date: March 19, 2019

Authority: 32 CFR 199.2 ; 32 CFR 199.4(a)(1)(i) , (d)(3)(iii) , (g)(39) , (g)(57) , (g)(66) , 32 CFR 199.5(c) , 32 CFR 199.6(c)(3) (iii)(L) , (c)(3)(iii)(M) ; 32 CFR 199.14 , and National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017, Section 714r

Revision:

1.0 APPLICABILITY
This policy is mandatory for reimbursement of BDM provided by either network or non-network providers. However, alternative network reimbursement methodologies are permitted when approved by the Defense Health Agency (DHA) and specifically included in the network provider agreement.

2.0 DESCRIPTION
This section provides the payment amounts and procedures for reimbursing BDM. TRICARE has established a per-ounce CMAC rate for Healthcare Common Procedural Coding System (HCPCS) code T2101 (processing, storage and distribution of BDM).
For network providers, the contractor may negotiate rates that would be less than the rates established under this section, in accordance with contractual agreements.

3.0 POLICY
Reimbursement for BDM will be effective for service dates on or after January 1, 2019. See TRICARE Policy Manual (TPM), Chapter 8, Section 7.1 , for coverage of Medically Necessary Foods.

4.0 REIMBURSEMENT

4.1 Acute care hospitals paid under the Diagnosis Related Group (DRG) methodology and other hospitals may bill for BDM utilizing HCPCS code T2101 along with Revenue Code 220.

Note: In general, BDM provided in the inpatient setting would be included in the overall charge and DRG reimbursement.

However, there may be cases where hospitals that are not subject to DRG bill separately, or that a hospital does not routinely provide BDM but goes to extraordinary lengths to obtain it for a specific patient and would otherwise bill the patient separately for the BDM. In these cases, the billing as noted in this paragraph would apply.

Also, reference the definition of abusive billing practices within the TRICARE regulation at 32 CFR 199.9. If a hospital routinely provides BDM and does not charge other payers separately for it, then it may not charge TRICARE separately. Separate charges may be reviewed by the contractor for abusive and excessive billing practices.

4.2 TRICARE shall also reimburse non-institutional providers, to include Human Milk Banking Association of North America (HMBANA)-accredited milk banks, based on the CMAC for HCPCS code T2101. See Chapter 5, Section 3 .

Note: The policy requirement is that only BDM that is processed and distributed by HMBANA-accredited milk banks is eligible for cost-sharing. However, TRICARE authorized providers (e.g., a pediatrician) may purchase BDM from HMBANA accredited milk banks, and may make the milk available for patients in their practice. In this case, the claim may be submitted by the pediatrician rather than the milk bank. The claim shall include documentation or verification that the BDM that was provided was obtained from a HMBANA-accredited milk bank.

4.3 Effective with the 2019 CMAC update, the national reimbursement rate for HCPCS code T2101 is $4.50 per ounce (one unit is equivalent to one ounce). This rate shall be adjusted by locality and updated annually by the same conversion factors used to update the annual CMAC file, and will be made available at http://www.health.mil/rates.

4.4 Pricing will be made available at http://www.health.mil/rates.

4.5 The contractor shall establish network agreements with HMBANA-accredited milk banks to the extent practical and authorized by contractual agreements.

4.6 The contractor shall utilize the provisions in the TRICARE Operations Manual (TOM) regarding the reimbursement of beneficiary-submitted claims, in the case that beneficiaries purchase BDM and request reimbursement.

4.7 Reimbursement for HCPCS code T2101 includes the processing, storage, and distribution of BDM. Separate charges for shipping or other services are not separately payable.

The Florida Senate

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City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

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While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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The Florida Senate

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Health Policy
Committee

1770
Bill Number or Topic

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PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

S-001 (08/10/2021)

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

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 836
INTRODUCER:	Health Policy Committee and Senator Brodeur
SUBJECT:	Medication Technicians
DATE:	January 26, 2022
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 836 amends s. 429.256, F.S., to replace the definition of "unlicensed person" with a new definition of "medication technician." The new definition is functionally the same as the previous definition but includes the use of point-of-care devices. The bill requires that a medication technician must have six hours of training and amends s. 429.52, F.S., to specify what must be included in the training. The bill also allows a medication technician to assist a resident in an assisted living facility (ALF) with his or her self-administration of medications and with his or her use of point-of-care devices (PCD).

The bill establishes an effective date of July 1, 2022.

II. Present Situation:

An ALF is a residential establishment, or part of a residential establishment, that provides housing, meals, and one or more personal services for a period exceeding 24 hours to one or more adults who are not relatives of the owner or administrator.[1] A personal service is direct physical assistance with, or supervision of, the activities of daily living and the self-administration of medication.[2] Activities of daily living include ambulation, bathing, dressing, eating, grooming, toileting, and other similar tasks.[3]

[1] Section 429.02(5), F.S. An ALF does not include an adult family-care home or a non-transient public lodging establishment.
[2] Section 429.02(18), F.S.
[3] Section 429.02(1), F.S.

An ALF is required to provide care and services that are appropriate to the needs of the residents who are accepted for admission to the facility.[4] The owner or facility administrator determines whether an individual is appropriate for admission to the facility based on a number of criteria.[5] If, as determined by the facility administrator or health care provider, a resident no longer meets the criteria for continued residency or the facility is unable to meet the resident's needs, the resident must be discharged in accordance with the Resident Bill of Rights.[6]

There are currently 3,129 licensed ALFs in Florida with a total of 114,919 beds.[7] An ALF must have a standard license issued by the Agency for Health Care Administration (AHCA) under part I of ch. 429, F.S., and part II of ch. 408, F.S. In addition to a standard license, an ALF may have one or more specialty licenses that allow an ALF to provide additional care. These specialty licenses include limited nursing services (LNS),[8] limited mental health services (LMH),[9] and extended congregate care services (ECC).[10]

Assistance with the Self-Administration of Medications

Section 429.256, F.S., establishes requirements for the assistance with the self-administration of medication. Residents who are capable of administering their own medications are encouraged to do so, but an unlicensed person who is 18 years of age or older and has completed the required six hours of training may,[11] consistent with a dispensed prescription's label or the package directions of an over-the-counter medication, assist a resident 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 resident or the resident's surrogate, guardian, or attorney in fact.

The section specifies that the assistance with self-administration of medication includes:

- Taking the medication, in its previously dispensed, properly labeled container, including an insulin syringe that is prefilled with the proper dosage by a pharmacist and an insulin pen that is prefilled by the manufacturer, from where it is stored, and bringing it to the resident.
- In the presence of the resident, confirming that the medication is intended for that resident, orally advising the resident of the medication name and dosage, opening the container, removing a prescribed amount of medication from the container, and closing the container. The resident may sign a written waiver to opt out of being orally advised of the medication name and dosage. The waiver must identify all of the medications intended for the resident, including names and dosages of such medications, and must immediately be updated each time the resident's medications or dosages change.

[4] *See* Fla. Admin. Code R. 59A-36.007 (2019), for specific minimum standards.
[5] Section 429.26, F.S., and Fla. Admin. Code R. 59A-36.006 (2019).
[6] Section 429.28, F.S.
[7] Florida health finder data, available at https://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (last visited Jan 13, 2022).
[8] Section 429.07(3)(c), F.S.
[9] Section 429.075, F.S.
[10] Section 429.07(3)(b), F.S.
[11] *See* Fla. Admin. Code R. 59A-36.008(3)(a) (2019).

- Placing an oral dosage in the resident's hand or placing the dosage in another container and helping the resident by lifting the container to his or her mouth.
- Applying topical medications.
- Returning the medication container to proper storage.
- Keeping a record of when a resident receives assistance with self-administration under this section.
- Assisting with the use of a nebulizer, including removing the cap of a nebulizer, opening the unit dose of nebulizer solution, and pouring the prescribed premeasured dose of medication into the dispensing cup of the nebulizer.
- Using a glucometer to perform blood-glucose level checks.
- Assisting with putting on and taking off antiembolism stockings.
- Assisting with applying and removing an oxygen cannula but not with titrating the prescribed oxygen settings.
- Assisting with the use of a continuous positive airway pressure device but not with titrating the prescribed setting of the device.
- Assisting with measuring vital signs.
- Assisting with colostomy bags.

The section also specifies that assistance with self-administration does not include:

- Mixing, compounding, converting, or calculating medication doses, except for measuring a prescribed amount of liquid medication or breaking a scored tablet or crushing a tablet as prescribed.
- The preparation of syringes for injection or the administration of medications by any injectable route.
- Administration of medications by way of a tube inserted in a cavity of the body.
- Administration of parenteral preparations.
- The use of irrigations or debriding agents used in the treatment of a skin condition.
- Assisting with rectal, urethral, or vaginal preparations.
- Assisting with medications ordered by the physician or health care professional with prescriptive authority to be given “as needed,” unless the order is written with specific parameters that preclude independent judgment on the part of the unlicensed person, and the resident requesting the medication is aware of his or her need for the medication and understands the purpose for taking the medication.
- Medications for which the time of administration, the amount, the strength of dosage, the method of administration, or the reason for administration requires judgment or discretion on the part of the unlicensed person.

Point-of-Care Devices

A PCD is a device that allows for diagnostic tests to be performed at or near where the patient is located or at the site where care or treatment is provided. Devices for point-of-care tests come in an array of forms. They may use basic dipsticks as with urinalysis, handheld devices like glucose meters, or sophisticated molecular analyzers to detect infectious diseases. The most common point-of-care tests are blood glucose monitoring and home pregnancy tests. Many point-of-care

tests can be performed by the patient at home, including the two mentioned above, as well as rapid HIV tests and colorectal cancer screening.[12]

III. Effect of Proposed Changes:

CS/SB 836 amends s. 429.256, F.S., to replace the definition of "unlicensed person" with a new definition of "medication technician." The new definition is functionally the same as the previous definition but includes the use of point-of-care devices. The bill requires that a medication technician must have six hours of training and amends s. 429.52, F.S., to specify that the training must include infection control, safe handling and use of PCDs, communicating with case managers and health care providers, standard of care protocols for the provision of care in a licensed ALF, identification of nursing standards, and methods of assisting residents with the self-administration of medications. The bill allows a medication technician to assist a resident in an ALF with his or her self-administration of medications and with his or her use of PCDs.

The bill establishes an effective date of July 1, 2022.

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.

[12] *What is point-of-care testing?* Testing.com, 11/9/21, available at https://www.testing.com/articles/point-of-care-testing/ (last visited Jan. 14, 2022).

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 429.256 and 429.52.

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 January 26, 2022:
The CS moves the definition of "Medication Technician" from s. 429.02, F.S., to s. 429.256, F.S., and replaces the definition of "unlicensed person" in order to clarify that medication technicians will be the only staff authorized to assist with the self-administration of medications in an ALF. The CS also makes conforming changes in s. 429.256, F.S.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/26/2022	.	
	.	
	.	
	.	

The Committee on Health Policy (Brodeur) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Paragraph (b) of subsection (1), subsection (2), paragraphs (g) and (h) of subsection (4), and subsection (5) of section 429.256, Florida Statutes, are amended to read:

429.256 Assistance with self-administration of medication.—

(1) For the purposes of this section, the term:

(b) "Medication technician" ~~"Unlicensed person"~~ means an

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individual not currently licensed to practice nursing or medicine who is employed by or under contract with ~~to~~ an assisted living facility and who has received training on ~~with respect to~~ assisting with the self-administration of medication and use of point-of-care devices in an assisted living facility as provided under s. 429.52 before ~~prior to~~ providing such assistance as described in this section.

(2) Residents who are capable of self-administering their own medications or using their point-of-care devices without assistance shall be encouraged and allowed to do so. However, a medication technician ~~an unlicensed person~~ may, consistent with a dispensed prescription's label or the package directions of an over-the-counter medication or point-of-care device, assist a resident whose condition is medically stable with the self-administration of routine, regularly scheduled medications that are intended to be self-administered and may assist with a resident's use of point-of-care devices. Assistance with self-medication by a medication technician ~~an unlicensed person~~ may occur only upon a documented request by, and the written informed consent of, a resident or the resident's surrogate, guardian, or attorney in fact. For the purposes of this section, self-administered medications include both legend and over-the-counter oral dosage forms, topical dosage forms, transdermal patches, and topical ophthalmic, otic, and nasal dosage forms including solutions, suspensions, sprays, and inhalers.

(4) Assistance with self-administration does not include:

(g) Assisting with medications ordered by the physician or health care professional with prescriptive authority to be given "as needed," unless the order is written with specific

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parameters that preclude independent judgment on the part of the medication technician ~~unlicensed person~~, and the resident requesting the medication is aware of his or her need for the medication and understands the purpose for taking the medication.

(h) Medications for which the time of administration, the amount, the strength of dosage, the method of administration, or the reason for administration requires judgment or discretion on the part of the medication technician ~~unlicensed person~~.

(5) Assistance with the self-administration of medication by a medication technician ~~an unlicensed person~~ as described in this section is ~~shall~~ not ~~be~~ considered administration as defined in s. 465.003.

Section 2. Subsection (6) of section 429.52, Florida Statutes, is amended to read:

429.52 Staff training and educational requirements.—

(6) Medication technicians ~~Staff~~ assisting with the self-administration of medications and point-of-care devices under s. 429.256 must complete a minimum of 6 additional hours of training provided by a registered nurse or a licensed pharmacist before providing assistance. Two hours of continuing education are required annually thereafter. The agency shall establish by rule the minimum requirements for medication technician ~~of this~~ training, which must address infection control, safe handling and use of point-of-care devices, communicating with case managers and health care providers, standard of care protocols for the provision of care in a licensed assisted living facility, identification of nursing standards, and methods of assisting residents with the self-administration of medications.

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Section 3. This act shall take effect July 1, 2022.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to medication technicians; amending s. 429.256, F.S.; defining the term "medication technician"; requiring that assisted living facility residents who are able to use their point-of-care devices without assistance be encouraged and allowed to do so; authorizing medication technicians to assist assisted living facility residents with their use of point-of-care devices under certain circumstances; conforming provisions to changes made by the act; amending s. 429.52, F.S.; providing minimum requirements and specifications for the training of medication technicians; requiring the Agency for Health Care Administration to adopt rules establishing such requirements; providing an effective date.

By Senator Brodeur

9-00914A-22 2022836__

A bill to be entitled

An act relating to medication technicians; amending s. 429.02, F.S.; defining the term "medication technician"; amending s. 429.52, F.S.; providing minimum requirements and specifications for training of medication technicians; providing an effective date.

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

Section 1. Present subsections (16) through (28) of section 429.02, Florida Statutes, are redesignated as subsections (17) through (29), respectively, a new subsection (16) is added to that section, and subsection (12) of that section is amended, to read:

429.02 Definitions.—When used in this part, the term:

(12) "Extended congregate care" means acts beyond those authorized in subsection (19) ~~(18)~~ which may be performed pursuant to part I of chapter 464 by persons licensed thereunder while carrying out their professional duties, and other supportive services that may be specified by rule. The purpose of such services is to enable residents to age in place in a residential environment despite mental or physical limitations that might otherwise disqualify them from residency in a facility licensed under this part.

(16) "Medication technician" means an unlicensed staff member who has completed 6 hours of training. A medication technician may provide assistance with a resident's self-administration of medications and with his or her use of point-of-care devices.

9-00914A-22 2022836__

Section 2. Subsection (6) of section 429.52, Florida Statutes, is amended to read:

429.52 Staff training and educational requirements.—

(6) Medication technicians shall ~~Staff assisting with the self-administration of medications under s. 429.256 must~~ complete a minimum of 6 additional hours of training provided by a registered nurse or a licensed pharmacist before providing assistance. Two hours of continuing education are required annually thereafter. The agency shall establish by rule the minimum requirements of medication technician ~~this~~ training, which must address infection control, safe handling and use of point-of-care devices, communicating with case managers and health care providers, standard of care protocols for the provision of care in a licensed assisted living facility, identification of nursing standards, and methods of assisting residents with the self-administration of medications.

Section 3. This act shall take effect July 1, 2022.

The Florida Senate

Committee Agenda Request

To: Senator Manny Diaz, Jr., Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 11, 2022

I respectfully request that **Senate Bill 836**, relating to **Medication Technicians**, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Jason Brodeur

Senator Jason Brodeur
Florida Senate, District 9

File signed original with committee office

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

January 26, 2022
Meeting Date

Health Policy
Committee

SB 836
Bill Number or Topic

Amendment Barcode (if applicable)

Name Rebecca Bush

Phone 850-559-0257

Address 307 W. Park Avenue
Street

Email bbush@fhca.org

Tallahassee FL 32301
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
Florida Health Care Association

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

1/26/2022
Meeting Date

Health Policy
Committee

836
Bill Number or Topic

Amendment Barcode (if applicable)

Name Zayne Smith – AARP

Phone 850.228.4243

Address 215 S. Monroe St.
Street

Email zsmith@aarp.org

Tallahassee FL 32301
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
AARP

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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

S-001 (08/10/2021)

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 1258
INTRODUCER:	Senator Jones
SUBJECT:	Managed Care Plan Performance
DATE:	January 25, 2022
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Smith	Brown	HP	**Favorable**
2.			BI	
3.			RC	

I. Summary:

SB 1258 statutorily requires managed care plans contracted with the Agency for Health Care Administration (AHCA) under the Statewide Medicaid Managed Care (SMMC) program to collect and annually report an expanded set of performance measures, including Healthcare Effectiveness Data and Information Set (HEDIS) measures, the federal Core Set of Children's Health Care Quality measures, and the federal Core Set of Adult Health Care Quality performance measures, as specified by the AHCA.

Beginning in calendar year 2025, the bill requires each managed care plan to collect and report all of the Adult Core Set behavioral health measures, which are not currently required by statute to be reported. Beginning in calendar year 2026, the bill requires each managed care plan to stratify all performance measure data by recipient age, race, ethnicity, primary language, sex, and disability status.

The bill poses an indeterminate negative fiscal impact to the Florida Medicaid Program and its managed care plans.

The bill provides an effective date of July 1, 2022.

II. Present Situation:

Florida Medicaid Program

The AHCA is responsible for the administration of the Florida Medicaid program, authorized under Title XIX of the Social Security Act.[1] This authority includes establishing and maintaining a Medicaid state plan approved by the Centers for Medicare & Medicaid Services (CMS) and

[1] Section 409.902, F.S.

maintaining any Medicaid waivers needed to operate the Florida Medicaid program as directed by the Legislature.[2]

Florida Medicaid enrollees generally receive benefits through one of two service-delivery systems: fee-for-service (FFS) or managed care. Under FFS, health care providers are paid by the state Medicaid program for each service provided to a Medicaid enrollee. In Florida, the majority of Medicaid recipients receive their services through a managed care plan contracted with the AHCA under the SMMC program. The state pays the managed care plans a capitation payment, or fixed monthly payment, per recipient enrolled in the managed care plan.

Managed Care Plan Performance Measure Reporting

The AHCA monitors contracted manage care plan performance through a combination of performance measures developed by the National Committee for Quality Assurance (NCQA), the federal CMS, and the AHCA itself.[3]

The NCQA develops the HEDIS as a standardized tool to measure the performance of health plans. More than 90 percent of health plans in America use the HEDIS tool to measure performance on important dimensions of care and service, making it convenient to compare plan performance.[4] Current law requires managed care plans participating in the SMMC program to collect and report HEDIS measures specified by the AHCA on an annual basis and to post the information its website in a manner that allows recipients to reliably compare the performance of available plans.[5]

For calendar year 2020, the managed care plans were required to report 27 HEDIS measures related to medical care and nine Child and Adult Core Set measures, a total of 36 measures.[6] Many of these measures include sub-measures. The total number of performance measure rates, or lines of data that must currently be reported for the measures and sub-measures is 192.[7]

Each managed care plan operates in at least one region of the state and several managed care plans operate in all 11 regions. For calendar year 2020 performance measure reporting (which occurred in 2021), the AHCA required managed care plans to provide regional breakouts in addition to the statewide rates for most of the HEDIS and Child and Adult Core Set measures that it currently requires plans to report.[8] The AHCA required the regional stratifications to identify potential differences in plan performance by region and to better target areas where improvement may be needed.[9]

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[2] Medicaid.gov, *Medicaid State Plan Amendments, available at* https://www.medicaid.gov/medicaid/medicaid-state-plan-amendments/index.html (last visited Jan. 22, 2022).
[3] Agency for Health Care Administration, Performance Measure Data Submissions for Medicaid, https://ahca.myflorida.com/medicaid/quality_mc/submission.shtml (last visited January 22, 2022).
[4] U.S. Department of Health and Human Services, Healthcare Effectiveness Data and Information Set, https://www.healthypeople.gov/2020/data-source/healthcare-effectiveness-data-and-information-set (last visited January 22, 2022).
[5] Section 409.967(2)(f)2., F.S.
[6] Agency for Health Care Administration, Agency Analysis of HB 855, Dec. 16, 2021 (on file with Committee on Health Policy).
[7] *Id.*
[8] *Id.*
[9] *Id.*

- For plans operating in only one region, the base number of 192 performance measure rates, or lines of data, were required to be reported since the plan's statewide and regional results are the same.
- For a plan operating in two regions of the state, the base number of 192 performance measure rates is multiplied by three, as the plan will be reporting a statewide rate and separate rates for each of the two regions. In this case, 576 performance measure rates were required to be reported.
- For a plan operating in all 11 regions of the state, the base number of 192 performance measure rates is multiplied by 12, as the plan will be reporting a statewide rate and separate rates for each of the 11 regions. In this case, 2,304 performance measure rates were required to be reported.[10]

The AHCA reports that managed care plans have indicated that the addition of the regional stratifications they reported for calendar year 2020 combined with the race and ethnicity stratifications added a substantial workload for them and their software vendors and auditors.[11] The AHCA requires the plans to have their performance measures audited and certified by NCQA-certified HEDIS auditors, which includes any stratifications required by the AHCA.[12]

III. Effect of Proposed Changes:

The bill amends s. 409.967(2)(f), F.S., to require managed care plans to collect and annually report HEDIS measures, the federal Core Set of Children's Health Care Quality measures, and the federal Core Set of Adult Health Care Quality performance measures, as specified by the AHCA. Section 409.967(2)(f), F.S., currently requires managed care plans to collect and annually report HEDIS measures. The AHCA currently requires plans participating in the MMA program to report a selection of measures from both the Adult and Child Core Sets in its contracts with those plans.[13]

Under the bill, each plan must collect and report the Adult Core Set behavioral health measures, which are not currently required by statute to be reported, beginning with data reports for the 2025 calendar year. Each plan must stratify reported measures by age, sex, race, ethnicity, primary language, and whether the enrollee received a Social Security Administration determination of disability for purposes of Supplemental Security Income, beginning with data reports for the 2026 calendar year. The bill requires each managed care plan to post all these measures, and the corresponding stratified data, to the plan's website.

Although the managed care plans have recently added regional and race and ethnicity stratifications to several of the measures they reported on this year, this bill will require them to add race and ethnicity stratifications to all measures, and add stratifications in four additional areas (age, sex, primary language, and disability status) to all AHCA-required measures.[14]

[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] *Id.*

The bill updates a reference to the "HEDIS" data set which was formerly referred to as "Health Plan Employer Data and Information Set" but is now referred to by the NCQA as the "Healthcare Effectiveness Data and Information Set."

The bill also corrects a grammatical error in current law by changing "s." to its plural form "ss."

The bill provides an effective date of July 1, 2022.

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:

The bill increases the stratifications and the volume of performance measure rates to be calculated, audited, and reported. The AHCA reports that this will result in increased operational and administrative costs for the managed care plans due to increased workload for the plans and increased costs for the plans' contracted NCQA-certified auditors and NCQA-certified HEDIS software vendors.[15]

[15] *Id.*

C. Government Sector Impact[16]:

The changes required by this bill would not need to be implemented until calendar year 2025. As such, the current Statewide Medicaid Managed Care (SMMC) contracts would not be affected and would not require an amendment. However, these requirements and expectations would need to be included in the next procurement and in the rates for the next contracts. The exact fiscal impact to the plans and thus, to the rates, is unknown at this time.

SB 1258 poses a moderate operational and fiscal impact on the Florida Medicaid Program. The AHCA reports that the increase in the volume of rates being reported to the AHCA under the bill will increase staff workload and will require one additional FTE. The total cost to the AHCA for the additional FTE is $79,930. This amount includes non-recurring expenditures, salary, and benefits for the position. The cost of the additional FTE is funded by the Medical Care Trust Fund. The state's portion of the total cost is $39,965.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 409.967 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.

[16] *Id.*

By Senator Jones

35-01313A-22 20221258__

A bill to be entitled

An act relating to managed care plan performance; amending s. 409.967, F.S.; requiring managed care plans to collect and report specified measures beginning with a certain data reporting period; requiring plans to stratify reported measures by specified categories beginning with a certain data reporting period; requiring a plan's performance to be published on its website in a specified manner; requiring the Agency for Health Care Administration to use the measures to monitor plan performance; providing an effective date.

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

Section 1. Paragraph (f) of subsection (2) of section 409.967, Florida Statutes, is amended to read:

409.967 Managed care plan accountability.—

(2) The agency shall establish such contract requirements as are necessary for the operation of the statewide managed care program. In addition to any other provisions the agency may deem necessary, the contract must require:

(f) *Continuous improvement.*—The agency shall establish specific performance standards and expected milestones or timelines for improving performance over the term of the contract.

1. Each managed care plan shall establish an internal health care quality improvement system, including enrollee satisfaction and disenrollment surveys. The quality improvement

35-01313A-22 20221258__

system must include incentives and disincentives for network providers.

2. Each managed care plan must collect and report the Healthcare Effectiveness ~~Health Plan Employer~~ Data and Information Set (HEDIS) measures, the federal Core Set of Children's Health Care Quality Measures, and the federal Core Set of Adult Health Care Quality Measures, as specified by the agency. Each plan must collect and report the Adult Core Set behavioral health measures beginning with data reports for the 2025 calendar year. Each plan must stratify reported measures by age, sex, race, ethnicity, primary language, and whether the enrollee received a Social Security Administration determination of disability for purposes of Supplemental Security Income beginning with data reports for the 2026 calendar year. A plan's performance on these measures must be published on the plan's website in a manner that allows recipients to reliably compare the performance of plans. The agency shall use the ~~HEDIS~~ measures as a tool to monitor plan performance.

3. Each managed care plan must be accredited by the National Committee for Quality Assurance, the Joint Commission, or another nationally recognized accrediting body, or have initiated the accreditation process, within 1 year after the contract is executed. For any plan not accredited within 18 months after executing the contract, the agency shall suspend automatic assignment under ss. 409.977 and 409.984 ~~s. 409.977 and 409.984~~.

4. By the end of the fourth year of the first contract term, the agency shall issue a request for information to determine whether cost savings could be achieved by contracting

for plan oversight and monitoring, including analysis of encounter data, assessment of performance measures, and compliance with other contractual requirements.

Section 2. This act shall take effect July 1, 2022.

The Florida Senate

Committee Agenda Request

Senator Shevrin D. “Shev” Jones
214 Senate Building
404 South Monroe Street
Tallahassee, FL 32399-1100

To: Chair Manny Diaz, Jr.
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 13, 2022

I respectfully request that **Senate Bill 1258: Managed Care Plan Performance**, be placed on the:

☒ Committee agenda at your earliest possible convenience.

☐ Next committee agenda.

Senator Shevrin Jones
Florida Senate, District 35

File signed original with committee office

2022 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

BILL INFORMATION	
BILL NUMBER:	HB 855
BILL TITLE:	Managed Care Plan Performance
BILL SPONSOR:	Bartleman
EFFECTIVE DATE:	07/01/2022

COMMITTEES OF REFERENCE
1) Finance and Facilities Subcommittee
2) Health and Human Services Subcommittee
3)
4)
5)

CURRENT COMMITTEE
Finance and Facilities Subcommittee

SIMILAR BILLS	
BILL NUMBER:	
SPONSOR:	

PREVIOUS LEGISLATION	
BILL NUMBER:	HB 899
SPONSOR:	Finance & Facilities Subcommittee and Bartleman
YEAR:	2021
LAST ACTION:	Died in S Appropriations 04/30/2021

IDENTICAL BILLS	
BILL NUMBER:	SB 1258
SPONSOR:	Jones

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

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	December 16, 2021
LEAD AGENCY ANALYST:	Clarke, Stephanie L.
ADDITIONAL ANALYST(S):	Eagle, Brooke; LaCroix, Rachel
LEGAL ANALYST:	
FISCAL ANALYST:	

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

The bill amends ss. 409.967(2)(f), F.S., to require that managed care plans collect and report specified Healthcare Effectiveness Data and Information Set (HEDIS) measures, the federal Core Set of Children's Health Care Quality measures, and the federal Core Set of Adult Health Care Quality measures, as specified by the Agency, beginning with data reports for calendar year 2025. In addition to the aforementioned data, the plans must also collect and report Adult Core Set behavioral health measures beginning with data reports for the calendar year 2026, stratifying reported measures by age, sex, race, ethnicity, primary language, and whether the enrollee received a Social Security Administration (SSA) determination of disability for the purposes of Supplemental Security Income (SSI).

The bill requires that managed care plans collect and annually report on Healthcare Effectiveness Data and Information Set (HEDIS) measures by specified categories (stratification by race, ethnicity, primary language, sex, and disability status); as well as the federal Core Set of Children's Health Care Quality measures (Child Core Set) and the federal Core Set of Adult Health Care Quality performance measures, including behavioral health measures, by the same specified categories. The increase in the volume of rates being reported to the Agency due to the number of stratification areas will increase staff workload and require one additional FTE due to the increase in measures needing to be reviewed and monitored. The total cost to the Agency for the additional FTE is $79,930. This amount includes non-recurring expenditures, salary, and benefits for the position. The cost of the additional FTE is funded by the Medical Care Trust Fund. The State's portion of the total cost is $39,965.

The bill has an effective date of July 1, 2022.

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) and maintaining any Medicaid waivers needed to operate the Florida Medicaid program as directed by the Florida Legislature. In Florida, the majority of Medicaid recipients receive their services through a managed care plan contracted with the Agency under the Statewide Medicaid Managed Care (SMMC) program.

Under the SMMC program, participating health plans are required to report measures annually to the Agency. By July 1 of each Contract year, the plans are required to report to the Agency on performance measure data and a certification by a National Committee for Quality Assurance (NCQA)-certified HEDIS auditor that the performance measure data reported for the previous year are fairly and accurately presented. For calendar year 2020, the managed care plans were required to report on 27 HEDIS measures related to medical care and nine Child and Adult Core Set measures, a total of 36 measures. Many of these measures include sub-measures. For example, the Prenatal and Postpartum Care measure has two sub-measures: Timeliness of Prenatal Care and Postpartum Care; the Asthma Medication Ratio measure has five sub-measures: four age breakouts plus a total. The total number of performance measure rates, or lines of data, that must be reported for the measures and sub-measures is 192. Each line of data for a performance measure rate includes up to 33 fields (e.g., measure abbreviation, measurement year, data collection methodology, region, eligible population, and others) that must be reported. Managed Medical Assistance Specialty plans each report on two to four additional measures that are relevant to their specialty population.

For calendar year 2020 performance measure reporting (which occurred in CY 2021), the Agency required managed care plans to provide regional breakouts in addition to the statewide rates for most of the HEDIS and Child and Adult Core Set measures that it currently requires plans to report. The Agency required the regional stratifications to identify potential differences in plan performance by region and to better target areas where improvement may be needed. Each managed care plan operates in at least one region of the state; several managed care plans operate in all 11 regions.

- For plans operating in only one region, the base number of 192 performance measure rates, or lines of data, will be reported since the plan's statewide and regional results are the same.
- For a plan operating in two regions of the state, the base number of 192 performance measure rates is multiplied by three, as the plan will be reporting a statewide rate and separate rates for each of the two regions. In this case, the total number of performance measure rates to be reported is 576.
- For a plan operating in all 11 regions of the state, the base number of 192 performance measure rates is multiplied by 12, as the plan will be reporting a statewide rate and separate rates for each of the 11 regions. The total number of performance measure rates to be reported is 2,304.

The managed care plans indicated that with the addition of the regional stratifications they reported this year and the race/ethnicity stratifications several of the measures added substantial workload for them and their software vendors and auditors.

Currently, the Agency requires the plans to have their performance measures audited and certified by NCQA-certified HEDIS auditors, which includes any stratifications required by the Agency.

2. EFFECT OF THE BILL:

The bill requires that managed care plans collect and annually report on Healthcare Effectiveness Data and Information Set (HEDIS) measures by specified categories (stratification by race, ethnicity, primary language, sex, and disability status); as well as the federal Core Set of Children's Health Care Quality measures (Child Core Set) and the federal Core Set of Adult Health Care Quality performance measures, including behavioral health measures, by the same specified categories. Although the managed care plans have recently added regional and race/ethnicity stratifications to several of the measures they reported on this year, this bill will require them to add race/ethnicity stratifications to all measures, and add stratifications in four additional areas (age, sex, primary language, and whether the enrollee received an SSA determination of disability for purposes of SSI) to all Agency required measures. The number of categories within each area of stratification will determine the number of additional performance measure rates to be reported by plans. For example, using the base number of 192 performance measure rates:

- If sex is stratified into two categories, the base number of 192 is multiplied by two for a total number of 384 performance measure rates.
- If primary language is stratified into four categories (e.g., English, Spanish, Haitian Creole, Other), the base number of 192 is multiplied by four for a total of 768 performance measure rates.
- If disability determination is stratified into two categories, a total of 384 performance measure rates will be reported by a plan.

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:	N/A
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 **_X_** N ____

If yes, provide a description:	Each managed care plan must collect and report the Healthcare Effectiveness Data and Information Set (HEDIS) measures, the federal Core Set of Children's

	Health Care Quality measures, and the federal Core Set of Adult Health Care Quality Measures, as specified by the agency.
Date Due:	No due date is specified in the bill; however, the bill states that reporting for the related measures must begin with data reports for the 2025 and 2026 calendar years.
Bill Section Number(s):	Section 1

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 ___ N _X__

Revenues:	N/A
Expenditures:	N/A
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 _X__ N ___

Revenues:	N/A
Expenditures:	HB 855 poses a moderate operational and fiscal impact on the Florida Medicaid Program. The increase in the volume of rates being reported to the Agency will increase staff workload and will require one additional FTE. The total cost to the Agency for the additional FTE is $79,930. This amount includes non-recurring expenditures, salary, and benefits for the position.

FISCAL IMPACT:	Year 1 (FY 2022-23)	Year 2 (FY 2023-24)	Year 3 (FY 2024-25)
Non-Recurring Impact:			
Expenditures:			
Expense (Agency Standard Expense Package)			
Professional Staff (1.00 @ $ 4,492)	$ 4,492		
Support Staff (0.00 @ 4,143)	-		
Total Non-Recurring Expense (1.00)	**$ 4,492**		
Total Non-Recurring Expenditures	**$ 4,492**		
Recurring Impact:			
Expenditures:			
Salaries (Class Code / FTEs / Pay Grade / Rate)			
Government Analyst II (2225 / 1.00 / 26 / 46,560)	$ 68,762	$ 68,762	$ 68,762
-	-	-	-
-	-	-	-
Total Salary and Benefits (1.00 / 46,560)	**$ 68,762**	**$ 68,762**	**$ 68,762**
OPS (FTEs)			
- (0.00)	$ -	$ -	$ -
- (0.00)	-	-	-
Total OPS (0.00)	**$ -**	**$ -**	**$ -**
Expenses			
Professional Staff (1.00 @ $ 6,370)	$ 6,370	$ 6,370	$ 6,370
Support Staff (0.00 @ 5,258)	-	-	-
Total Expenses	**$ 6,370**	**$ 6,370**	$ 6,370
Human Resources Services			
FTE Positions (1.00 @ $ 306)	$ 306	$ 306	$ 306
OPS Positions (0.00 @ 96)	-	-	-
Total Human Resources Services	**$ 306**	**$ 306**	**$ 306**
Special Categories/Contracted Services			
-	$ -	$ -	$ -
-	-	-	-
-	-	-	-
Total Special Categories/Contracted Services	**$ -**	**$ -**	**$ -**
Total Recurring Expenditures	**$ 75,438**	**$ 75,438**	**$ 75,438**
Total Revenues and Expenditures:			
Sub-Total Recurring Revenues	$ -	$ -	$ -
Total Revenues	**$ -**	**$ -**	**$ -**
Sub-Total Non-Recurring Expenditures	$ 4,492	$ -	$ -
Sub-Total Recurring Expenditures	75,438	75,438	75,438
Total Expenditures	**$ 79,930**	**$ 75,438**	**$ 75,438**
Net Impact (Total Revenues minus Total Expenditures)	**$ (79,930)**	**$ (75,438)**	**$ (75,438)**
Net Impact (By Fund)			
Medical Care Trust Fund (2474)	$ (79,930)	$ (75,438)	$ (75,438)
-	-	-	-
-	-	-	-
-	-	-	-
Net Impact (By Fund)	**$ (79,930)**	**$ (75,438)**	**$ (75,438)**

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:	N/A
Expenditures:	N/A
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.	

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

This increase in the volume of performance measure rates to be calculated, audited, and reported will result in increased operational and administrative costs for the managed care plans due to increased workload for the plans and increased costs for the plans' contracted NCQA-certified auditors and NCQA-certified HEDIS software vendors.

The changes required by this bill would not need to be implemented until calendar year 2025, as such, the current Statewide Medicaid Managed Care (SMMC) contracts would not be affected and would not require an amendment. However, these requirements and expectations would need to be included in the next procurement and in the rates for the next contracts. The exact fiscal impact to the plans and thus, to the rates, is unknown at this time.

LEGAL – GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

01.26.2022
Meeting Date

Health Policy
Committee

1258
Bill Number or Topic

Amendment Barcode (if applicable)

Name David Mica, Jr.

Phone 352-222-8700

Address 306 E College Ave
Street

Email DavidM@fha.org

Tallahassee FL 32312
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** **Waive Speaking:** ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
Florida Hospital Association

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

1/26/2022
Meeting Date

Health Policy
Committee

1258
Bill Number or Topic

Amendment Barcode (if applicable)

Name Zayne Smith – AARP

Phone 850.228.4243

Address 215 S. Monroe St.
Street

Email zsmith@aarp.org

Tallahassee FL 32301
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
AARP

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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

S-001 (08/10/2021)

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 Commerce and Tourism

BILL:	CS/SB 842
INTRODUCER:	Health Policy Committee and Senator Brodeur
SUBJECT:	Invalid Restrictive Covenants in Health Care
DATE:	January 26, 2022
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	McMillan	McKay	CM	**Favorable**
2.	Smith	Brown	HP	**Fav/CS**
3.			RC	

Please see Section IX. for Additional Information:

PLEASE MAKE SELECTION

I. Summary:

CS/SB 842 amends Florida's non-compete statute, which allows for the enforcement of contracts that restrict or prohibit competition as long as such contracts are reasonable in time, area, and line of business. Under current law, a person seeking enforcement of a non-compete agreement must prove the existence of one or more "legitimate business interests," which include trade secrets; valuable confidential business or professional information; substantial relationships with specific prospective or existing customers, patients, or clients; customer goodwill associated with an ongoing business by way of trade name, specific geographic location, or specific marketing or trade area; or extraordinary or specialized training.

The bill provides that a restrictive covenant in an employment agreement between a physician and a hospital is not supported by a legitimate business interest if it does not include an option for the physician to buy out of the restrictive covenant. If such an option is not provided, the bill provides a legislative finding that the restrictive covenant is void and unenforceable as it limits patient access to physicians and increases costs. These provisions apply only to restrictive covenants entered into on or after July 1, 2022.

The bill provides an effective date of July 1, 2022.

II. Present Situation:

Federal Antitrust Laws

In 1890, Congress passed the first antitrust law, the Sherman Act, as a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade. Congress subsequently passed two additional antitrust laws in 1914: the Federal Trade Commission Act, which created the Federal Trade Commission (FTC), and the Clayton Act. Currently, these are the three core federal antitrust laws.[1]

The Sherman Act

The Sherman Act outlaws every contract, combination, or conspiracy in restraint of trade, and any monopolization, attempted monopolization, or conspiracy or combination to monopolize. The Sherman Act does not prohibit every restraint of trade, only those that are unreasonable. For example, an agreement between two individuals to form a partnership may restrain trade, but may not do so unreasonably, and thus may be lawful under the antitrust laws. In contrast, certain acts are considered "per se" violations of the Sherman Act because they are so harmful to competition. These include plain arrangements among competing individuals or businesses to fix prices, divide markets, or rig bids.[2]

The penalties for violating the Sherman Act can be severe. Although most enforcement actions are civil, the Sherman Act is also a criminal law, and individuals and businesses that violate it may be prosecuted by the U.S. Department of Justice (DOJ). Criminal prosecutions are typically limited to intentional and clear violations. The Sherman Act imposes criminal penalties of up to $100 million for a corporation and $1 million for an individual, along with up to 10 years in prison.[3] Under some circumstances, the maximum fines can reach twice the gain or loss involved.[4]

The Federal Trade Commission Act

The Federal Trade Commission Act prohibits unfair methods of competition and unfair or deceptive acts or practices. The U.S. Supreme Court has said that all violations of the Sherman Act also violate the FTC Act. Therefore, the FTC can bring cases under the FTC Act against the same kinds of activities that violate the Sherman Act. The FTC Act also reaches other practices that harm competition but may not fit neatly into categories of conduct formally prohibited by the Sherman Act. Only the FTC brings cases under the FTC Act.[5]

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[1] *See The Antitrust Laws*, Federal Trade Commission, *available at* https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws (last visited Jan. 12, 2022).
[2] *Id.*
[3] *See Antitrust Enforcement and the Consumer*, U.S. Department of Justice, *available at* https://www.justice.gov/atr/file/800691/download (last visited Jan. 12, 2022).
[4] *Id.*
[5] *See The Antitrust Laws*, Federal Trade Commission, *available at* https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws (last visited Jan. 12, 2022).

The Clayton Act

The Clayton Act addresses specific practices that the Sherman Act does not clearly prohibit, such as mergers and interlocking directorates.[6] It also bans mergers and acquisitions where the effect may substantially lessen competition or create a monopoly. As amended by the Robinson-Patman Act of 1936, the Clayton Act also prohibits certain discriminatory prices, services, and allowances in dealings between merchants. The Clayton Act was amended again in 1976 by the Hart-Scott-Rodino Antitrust Improvements Act to require companies planning large mergers or acquisitions to notify the government of their plans in advance. Additionally, private parties are authorized to sue for triple damages when they have been harmed by conduct that violates either the Sherman or Clayton Act and to obtain a court order prohibiting the anticompetitive practice in the future.[7]

Florida Antitrust Laws

Florida law also provides protections against anticompetitive practices. Chapter 542, F.S., the Florida Antitrust Act of 1980, has a stated purpose to complement the body of federal law prohibiting restraints of trade or commerce in order to foster effective competition.[8] It outlaws every contract, combination, or conspiracy in restraint of trade or commerce in Florida[9] and any person from monopolizing or attempting or conspiring to monopolize any part of trade.[10]

Contracts in Restraint of Trade or Commerce

Generally, a contract in restraint of trade or commerce in Florida is unlawful.[11] However, non-competition restrictive covenants[12] contained in employment agreements that are reasonable in time, area, and line of business are not prohibited.[13] In any action concerning enforcement of a restrictive covenant, a court may not enforce a restrictive covenant unless it is set forth in a writing signed by the person against whom enforcement is sought, and the person seeking enforcement of a restrictive covenant must prove the existence of one or more legitimate business interests justifying the restrictive covenant.[14] The term "legitimate business interest" includes, but is not limited to:

- Trade secrets;[15]
- Valuable confidential business or professional information that does not otherwise qualify as trade secrets;

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[6] "Interlocking directorates" means the same person making business decisions for competing companies. *See also Id*.
[7] *Id*.
[8] Section 542.16, F.S.
[9] Section 542.18, F.S.
[10] Section 542.19, F.S.
[11] Section 542.18, F.S.
[12] Section 542.335, F.S. employs the term "restrictive covenants" and includes all contractual restrictions such as noncompetition/nonsolicitation agreements, confidentiality agreements, exclusive dealing agreements, and all other contractual restraints of trade. *See Henao v. Prof'l Shoe Repair, Inc.*, 929 So.2d 723, 726 (Fla. 5th DCA 2006).
[13] Section 542.335(1), F.S.
[14] *Id*.
[15] Section 688.002(4), F.S., defines a trade secret as information, including a formula, pattern, compilation, program, device, method, technique, or process that derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

- Substantial relationships with specific prospective or existing customers, patients, or clients;
- Customer, patient, or client goodwill associated with:
  - An ongoing business or professional practice, by way of trade name, trademark, service mark, or "trade dress;"
  - A specific geographic location; or
  - A specific marketing or trade area; or
- Extraordinary or specialized training.[16]

Any restrictive covenant not supported by a legitimate business interest is unlawful and is void and unenforceable.[17] A person seeking enforcement of a restrictive covenant must prove that the contractually specified restraint is reasonably necessary to protect the legitimate business interest or interests justifying the restriction.[18]

Restrictive Covenants in Florida Health Care

Pursuant to s. 542.336, F.S., a restrictive covenant entered into with a physician who practices a medical specialty in a county where one entity employs or contracts with all physicians who practice that specialty in that county, is not supported by a legitimate business interest and is void and unenforceable.[19] The restrictive covenant remains void and unenforceable until three years after the date on which a second entity that employs or contracts with one or more physicians who practice that specialty begins serving patients in that county.[20]

21st Century Oncology, Inc., sought a preliminary injunction to enjoin the application and enforcement of this statute. In August of 2019, the U.S. District Court for the Northern District of Florida denied the injunction. While s. 542.336, F.S., was found to impair Plaintiff's employment contracts within the meaning of the Contracts Clause, the court held that the degree of impairment does not outweigh the statute's significant, legitimate public purpose.[21]

III. Effect of Proposed Changes:

The bill amends s. 542.336, F.S., to provide that a restrictive covenant in an employment agreement between a physician and a hospital is not supported by a legitimate business interest if it does not include an option for the physician to buy out of the restrictive covenant.[22] If such an option is not provided, the bill provides a legislative finding that the restrictive covenant is void and unenforceable as it limits patient access to physicians and increases costs. These provisions apply only to restrictive covenants entered into on or after July 1, 2022.

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[16] Section 542.335(1)(b), F.S.
[17] *Id*.
[18] Section 542.335(1)(c), F.S.
[19] Section 542.336, F.S.
[20] *Id*.
[21] "The ostensible public purpose of section 542.336 is to reduce healthcare costs and improve patients' access to physicians. See § 542.336, Fla. Stat. (2019); ECF No. 64 at 8 (Attorney General's post-hearing brief, stating "section 542.336 explicitly sets forth its own rational basis in declaring that the restrictive covenants addressed by it are not supported by a legitimate business interest, restrict patient access to physicians, and increase costs"). It is well settled that access to affordable healthcare is a legitimate state interest." 21st Century Oncology, Inc. v. Moody, 402 F. Supp. 3d 1351, 1359 (N.D. Fla. 2019).
[22] The bill does not define the term "reasonable price," which may lead to differing interpretations of the meaning of the term.

The bill establishes the following definitions:

- "Hospital" means a hospital as defined in s. 395.002(13), F.S.,[23] which is licensed under ch. 395, F.S., and part II of ch. 408, F.S.; and
- "Physician" means a person licensed to practice medicine under ch. 458, F.S., or osteopathic medicine under ch. 459, F.S.

The bill provides an effective date of July 1, 2022.

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:

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The impact of this bill to the private sector overall is indeterminate.

C. Government Sector Impact:

The impact of this bill to the public sector is also indeterminate.

[23] Section 395.002(13), F.S., defines "hospital" as any establishment that offers services more intensive than those required for room, board, personal services, and general nursing care, and offers facilities and beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care for illness, injury, deformity, infirmity, abnormality, disease, or pregnancy, and regularly makes available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment of similar extent, except that a critical access hospital, as defined in s. 408.07, F.S., must not be required to make available treatment facilities for surgery, obstetrical care, or similar services as long as it maintains its critical access hospital designation and must be required to make such facilities available only if it ceases to be designated as a critical access hospital.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 542.336 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 January 26, 2022:
The CS deletes provisions from the underlying bill that would enable a physician or a hospital that has voluntarily entered into a restrictive covenant that includes a buyout clause to allege that the price of the buyout is not reasonable, thereby triggering a binding arbitration process to determine a reasonable price for the buyout. The CS deletes the requirement that such a buyout clause be reasonable.

B. Amendments:

None.

720062

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/26/2022	.	
	.	
	.	
	.	

The Committee on Health Policy (Brodeur) recommended the following:

Senate Amendment (with title amendment)

Delete lines 42 - 47

and insert:

for the physician to buy out of the restrictive covenant. The Legislature

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

And the title is amended as follows:

Delete lines 7 - 10

720062

and insert:

legitimate business interest; providing a legislative finding;

By Senator Brodeur

9-00540-22 2022842__

A bill to be entitled

An act relating to invalid restrictive covenants in health care; amending s. 542.336, F.S.; defining the terms "hospital" and "physician"; specifying that certain restrictive covenants in employment agreements between physicians and hospitals do not support a legitimate business interest; authorizing a party to an employment agreement to elect to have a mutually agreed upon arbitrator make a specified binding determination; providing a legislative finding; providing applicability; providing an effective date.

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

Section 1. Section 542.336, Florida Statutes, is amended to read:

542.336 Invalid restrictive covenants.—

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

(a) "Hospital" means a hospital as defined in s. 395.002(13) which is licensed under chapter 395 and part II of chapter 408.

(b) "Physician" means a person licensed to practice medicine under chapter 458 or osteopathic medicine under chapter 459.

(2) A restrictive covenant entered into with a physician ~~who is licensed under chapter 458 or chapter 459 and~~ who practices a medical specialty in a county wherein one entity employs or contracts with, either directly or through related or affiliated entities, all physicians who practice such specialty

9-00540-22 2022842__

in that county is not supported by a legitimate business interest. The Legislature finds that such covenants restrict patient access to physicians, increase costs, and are void and unenforceable under current law. Such restrictive covenants ~~shall~~ remain void and unenforceable for 3 years after the date on which a second entity that employs or contracts with, either directly or through related or affiliated entities, one or more physicians who practice such specialty begins offering such specialty services in that county.

(3) A restrictive covenant in an employment agreement between a physician and a hospital is not supported by a legitimate business interest if it does not include an option for the physician to buy out of the restrictive covenant at a reasonable price. Any party to an employment agreement which believes that the price to buy out of the restrictive covenant in the agreement is unreasonable may elect to have a mutually agreed upon arbitrator determine a reasonable price, and such arbitrator's decision is binding on the parties. The Legislature finds that a restrictive covenant without this option limits patient access to physicians and increases costs and is void and unenforceable. This subsection applies to restrictive covenants entered into on or after July 1, 2022.

Section 2. This act shall take effect July 1, 2022.

The Florida Senate

Committee Agenda Request

To: Senator Manny Diaz, Jr., Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 11, 2022

I respectfully request that **Senate Bill 842**, relating to **Invalid Restrictive Covenants in Health Care**, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Jason Brodeur

Senator Jason Brodeur
Florida Senate, District 9

File signed original with committee office

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 1950
INTRODUCER:	Health Policy Committee and Senator Brodeur
SUBJECT:	Statewide Medicaid Managed Care Program
DATE:	January 26, 2022
REVISED:	

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

Please see Section IX. for Additional Information:

PLEASE MAKE SELECTION

I. Summary:

CS/SB 1950 makes revisions to the Florida Medicaid program. In Florida, the majority of Medicaid recipients receive their services through a managed care plan contracted with the Agency for Health Care Administration (AHCA) under the Statewide Medicaid Managed Care (SMMC) program. The SMMC program has two components, the Managed Medical Assistance (MMA) program and the Long-term Care (LTC) program. The SMMC program was fully implemented in August 2014 and was re-procured for a period beginning December 2018 and ending in December 2023. In 2020, the Legislature extended the allowable term of the SMMC contracts from five to six years. As a result, the current contracts will end in December 2024. The AHCA will conduct its next procurement in 2022-2023 with the new contracts beginning at the end of 2024.

The bill amends Part IV of ch. 409, F.S., relating to the SMMC program, and affects the recurring competitive procurement of program contracts with Medicaid managed care plans. The bill also makes conforming changes to Part III. CS/SB 1950:

- Requires provider service networks (PSNs) to be reimbursed on a prepaid basis.
- Authorizes the AHCA to select eligible managed care plans to provide services through a single statewide procurement and deletes the requirement that the AHCA conduct separate and simultaneous procurements for each Medicaid region.
- Authorizes the AHCA to award contracts to managed care plans on a regional or statewide basis.

- Outlines a new regional structure for plan selection under the MMA and LTC programs with a minimum and maximum number of plans designated for each region. The bill provides for eight regions named by letters (Regions A-H), rather than the 11 regions named by numbers (Regions 1-11) in current law.
- Requires the AHCA to award a contract to at least one PSN in each of the eight regions under the MMA program and under the LTC program.
- Amends the Achieved Savings Rebates (ASR) structure to change thresholds relating to profit-sharing for managed care plans.
- Requires managed care plans to include Florida cancer hospitals that meet specified federal criteria in their networks as essential providers.
- Revises MMA plan healthy behaviors program requirements to include tobacco cessation programs, rather than smoking cessation programs, and to clarify that substance abuse programs must include opioid abuse recovery.
- Authorizes an MMA child welfare specialty plan to serve a child in a permanent guardianship situation whose parents receiving payments through the Guardianship Assistance Program.
- Deletes obsolete language.

CS/SB 1950 has an indeterminate fiscal impact.

The bill provides an effective date of July 1, 2022.

II. Present Situation:

Florida Medicaid Program

The Medicaid program is a joint federal-state program that finances health coverage for individuals, including eligible low-income adults, children, pregnant women, elderly adults, and persons with disabilities.[1] The Centers for Medicare & Medicaid Services (CMS) within the U.S. Department of Health and Human Services (HHS) is responsible for administering the federal Medicaid program. Florida Medicaid is the health care safety net for low-income Floridians. Florida's program is administered by the AHCA and financed through state and federal funds.[2]

A Medicaid state plan is an agreement between a state and the federal government describing how the state administers its Medicaid programs. The state plan 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 states the flexibility to cover other population groups (optional eligibility groups). States set individual eligibility criteria within federal minimum standards. The AHCA may seek an amendment to the state plan as necessary to comply with

[1] Medicaid.gov, *Medicaid*, *available at* https://www.medicaid.gov/medicaid/index.html (last visited Jan. 23, 2022).
[2] Section 20.42, F.S.

federal or state laws or to implement program changes. States send state plan amendments to the federal CMS for review and approval.[3]

Medicaid enrollees generally receive benefits through one of two service-delivery systems: fee-for-service or managed care. Under fee-for-service, health care providers are paid by the state Medicaid program for each service provided to a Medicaid enrollee. Under managed care, the state contracts with private managed care plans for the coordination and payment of services for Medicaid enrollees. The state pays the managed care plans a capitation payment, or fixed monthly payment, per recipient enrolled in the managed care plan.

Statewide Medicaid Managed Care (SMMC) Program

In Florida, the majority of Medicaid recipients receive their services through a managed care plan contracted with the AHCA under the SMMC program. The SMMC program has three components, the MMA program that provides primary care, acute care, and behavioral health care services; LTC program that provides long-term care services, including nursing facility and home and community-based services; and the dental component. The SMMC minimum benefits are authorized by federal authority and are specifically required in ss. 409.973 for MMA plans and 409.98, F.S. for LTC plans.

In 2011, the Florida Legislature created Part IV of ch. 409, F.S., directing the AHCA to create the SMMC program and contract with managed care plans on a regional basis to provide services to eligible recipients.[4] Part VI of ch. 409 addresses program eligibility and enrollment, plan selection, covered benefits, plan accountability, and plan payment:

- Sections 409.965 through 409.969, F.S., apply to the SMMC program as a whole (including the LTC and MMA components);
- Sections 409.971 through 409.977, F.S., apply to the MMA program; and
- Sections 409.978 through 409.985, F.S., apply to the LTC program.

Sections 409.966, 409.974, and 409.981, F.S., outline the requirements for selecting eligible plans to participate in the SMMC program.

***Eligible Plan Selection*[5]**

The SMMC program was fully implemented in August 2014. During the initial SMMC procurement, the AHCA awarded contracts to 18 plans, including seven provider service networks (PSNs). By the end of the first contract period, due to various mergers, acquisitions, and conversions to HMO status, only one PSN remained (South Florida Community Care Network, DBA Community Care Plan).

During the second procurement for a period beginning December 2018 and ending in December 2023, the AHCA awarded contracts to 16 plans, including five PSNs, (Community Care Plan,

[3] Medicaid.gov, *Medicaid State Plan Amendments, available at* https://www.medicaid.gov/medicaid/medicaid-state-plan-amendments/index.html (last visited Jan. 23, 2022).
[4] Chapter 2011-134, Laws of Fla.
[5] Agency for Health Care Administration, 2022 Agency Legislative Bill Analysis for SB 1950, Jan. 19, 2022 (on file with the Senate Committee on Health Policy).

Florida Community Care, Lighthouse, Miami Children's, and Vivida) but only three of the PSNs currently remain in the program due to mergers and acquisitions with a total of 10 health plans. In 2020, the Legislature extended the allowable term of the SMMC contracts from five to six years. As a result, the AHCA the current contracts will end in December 2024. The AHCA will conduct its next procurement in 2022-2023 with the new contracts beginning at the end of 2024.

Various mergers and acquisitions have occurred during the lifecycle of each SMMC contract, resulting in a situation where a majority of enrollees are receiving services from statewide plans that operate in all 11 regions. As of October 1, 2021, 40 percent of the SMMC population, including those enrolled in a specialty plan, were enrolled in a plan operating statewide and 79 percent were enrolled in a plan that operates in a least eight of the 11 regions. Based on the 2017-2018 procurement, as impacted by various mergers, acquisitions, and name changes that have occurred since the procurement, the following charts reflect the currently operational SMMC plans as of October 1, 2021[6]:

STATEWIDE MEDICAID MANAGED CARE (SMMC) HEALTH PLANS
(2018-2024)

REGIONAL ROLLOUT SCHEDULE	REGION	AETNA BETTER HEALTH (COV)	COMMUNITY CARE PLAN (CCP)	FLORIDA COMMUNITY CARE (FCC)	HUMANA MEDICAL PLAN (HUM)	MOLINA HEALTHCARE (MOL)	AMERIHEALTH (PRS)	SIMPLY HEALTHCARE (SHP)	SUNSHINE HEALTH (SUN)	UNITED-HEALTHCARE (URA)	VIVIDA HEALTH (BST)
PHASE 3 2/1/2019	1			FCC LTC+	HUM COMP			SHP MMA	SUN COMP		
	2			FCC LTC+	HUM COMP			SHP MMA	SUN COMP		
	3			FCC LTC+	HUM COMP				SUN COMP	URA COMP	
	4			FCC LTC+	HUM COMP				SUN COMP	URA COMP	
PHASE 2 1/1/2019	5			FCC LTC+	HUM COMP			SHP COMP	SUN COMP		
	6	COV COMP		FCC LTC+	HUM COMP			SHP COMP	SUN COMP	URA COMP	
	7	COV COMP		FCC LTC+	HUM COMP			SHP COMP	SUN COMP		
	8			FCC LTC+	HUM COMP	MOL COMP			SUN COMP		BST MMA
PHASE 1 12/1/2018	9			FCC LTC+	HUM COMP		PRS MMA	SHP MMA	SUN COMP		
	10		CCP MMA	FCC LTC+	HUM COMP			SHP COMP	SUN COMP		
	11	COV COMP		FCC LTC+	HUM COMP	MOL COMP	PRS MMA	SHP COMP	SUN COMP	URA COMP	

COMP = Comprehensive Plan MMA = Managed Medical Assistance Plan LTC+ = Long-Term Care Plus Plan

As of 10-01-2021

[6] *Id.*

SMMC SPECIALTY PLANS
(2018-2024)

REGIONAL ROLLOUT SCHEDULE		REGION	CHILDREN'S MEDICAL SERVICES PLAN - CHILDREN WITH CHRONIC CONDITIONS	CLEAR HEALTH ALLIANCE HIV/AIDS	MOLINA HEALTHCARE SERIOUS MENTAL ILLNESS (SMI)	SUNSHINE SERIOUS MENTAL ILLNESS (SMI)	SUNSHINE HEALTH CHILD WELFARE (CW)
PHASE 3	2/1/2019	1	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
		2	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
		3	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
		4	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC	MOLINA HEALTHCARE SPEC	SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
PHASE 2	1/1/2019	5	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC	MOLINA HEALTHCARE SPEC	SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
		6	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
		7	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC	MOLINA HEALTHCARE SPEC	SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
		8	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
PHASE 1	12/1/2018	9	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
		10	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
		11	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC

Provider Service Networks (PSNs)

A PSN in the Medicaid program is a managed care plan established or organized and operated by a health care provider, or group of affiliated health care providers, which provides a substantial proportion of the health care items and services under a contract directly through the provider or affiliated group of providers and may make arrangements with physicians or other health care professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health

services by the physicians, by other health professionals, or through the institutions.[7] The health care providers must have a controlling interest in the governing body of the PSN. The AHCA is authorized to contract with PSNs under s. 409.912(1), F.S., and may currently reimburse PSNs on a fee-for-service basis with a shared savings settlement or on a prepaid basis with per-member, per-month payments. A PSN may be reimbursed on a fee-for-service basis for only the first two years of the plan's operation.[8]

Specialty Plans[9]

An MMA managed care plan can participate in the MMA program as a standard plan or as a specialty plan. A specialty plan is a managed care plan that serves Medicaid recipients who meet specified criteria based on age, medical condition, or diagnosis.[10] Under federal Medicaid law and the SMMC waiver, each recipient has a choice of plans and may select any available plan unless that plan is restricted by contract to a specific population that does not include the recipient.[11] If a specialty plan is available to accommodate a specific condition or diagnosis of a Medicaid recipient, the AHCA must automatically enroll the recipient in that plan unless the recipient chooses a different plan.[12] MMA specialty plans cover the same health care services as the standard MMA plans, and in addition, they must maintain a care coordination program tailored to the special needs of the plan's enrollees.

When a recipient is eligible for more than one MMA specialty plan, the AHCA uses a ranking to determine which MMA specialty plan to assign. Unless the recipient chooses to enroll in another MMA specialty plan for which he or she is eligible, or in a standard MMA plan offered in his or her region, the recipient is automatically assigned to the specialty plan listed highest on the ranking. The AHCA has awarded specialty plan contracts to serve enrollees with specialty conditions including severe mental illness, HIV/AIDS, as well as children with special health care needs, and those involved with Florida's child welfare system.

Achieved Savings Rebates (ASR) Program

Section 409.967(3), F.S., creates the ASR program, which requires all Medicaid prepaid plans to provide the AHCA with unaudited quarterly and annual reports that detail managed care plan financial operations and performance for the applicable reporting period. If a plan reports that its profits exceed a certain percent of revenue (thereby achieving savings for the overall program), the plan must return a portion of the profits (a rebate) to the state.

Under s. 409.967(3)(f), F.S., all profit up to five percent of revenue is retained by the plan. Half of the profit above that threshold and up to 10 percent of revenue is retained by the plan and the other half refunded to the state. All profit above 10 percent of revenue is refunded to the state. Under s. 409.967(3)(g), F.S., plans may retain an additional one percent of revenue as an incentive to meet agency-defined quality measures, including plan performance for managing

[7] Section 409.912(1)(b), F.S.
[8] *Id.*
[9] Agency for Health Care Administration, *Medicaid Managed Medical Assistance Specialty Plans available at* https://ahca.myflorida.com/medicaid/statewide_mc/pdf/mma/Specialty_Plans_110316.pdf (last visited Jan. 23, 2022).
[10] Section 409.962(18), F.S.
[11] Section 409.969(1), F.S.
[12] Section 409.977(1), F.S.

complex, chronic conditions that are associated with an elevated likelihood of recurring high-cost medical treatments.

The following charts reflect the total amount of rebates the plans were required to pay to the AHCA and the number of plans who made a payment, by year.

MMA/LTC Plans[13]:

ASR Year	Total Rebate	Number of plans
2015	$ 2,373,946	2
2106	$ 30,440,542	4
2017/2018	$ 13,140,788	1
2019	$ 127,889,844	1
2020	$ 218,431,920	8

Dental[14]:

ASR Year	Total Rebate	Number of plans
2019	$ 1,409,012	1
2020	$ 55,796,119	3

III. Effect of Proposed Changes:

Section 1 of the bill amends s. 409.912(1), F.S., to eliminate fee-for-service (FFS) reimbursement of provider service networks (PSNs) in conjunction with changes made to s. 409.968(2), F.S., in section 6 of the bill. Under these changes, PSNs must be reimbursed on a prepaid basis, receiving a per-member, per-month payment. This section of the bill prohibits the AHCA from contracting with a PSN outside of the procurement process in s. 409.966, F.S., as amended by section 4 of the bill.

Changes to this subsection relocate, but do not substantively change, language exempting PSNs from parts I and III of ch. 643, F.S.

Section 2 of the bill repeals obsolete language in s. 409.9124, F.S., relating to managed care plan reimbursement.

Section 3 of the bill amends s. 409.964, F.S., to eliminate an obsolete requirement that the AHCA provide public notice and the opportunity for public comment before seeking a waiver to implement the SMMC program. This language is obsolete as the public notice and public meeting requirements were met prior to the AHCA seeking federal authority to implement the SMMC program in 2011 and 2012.

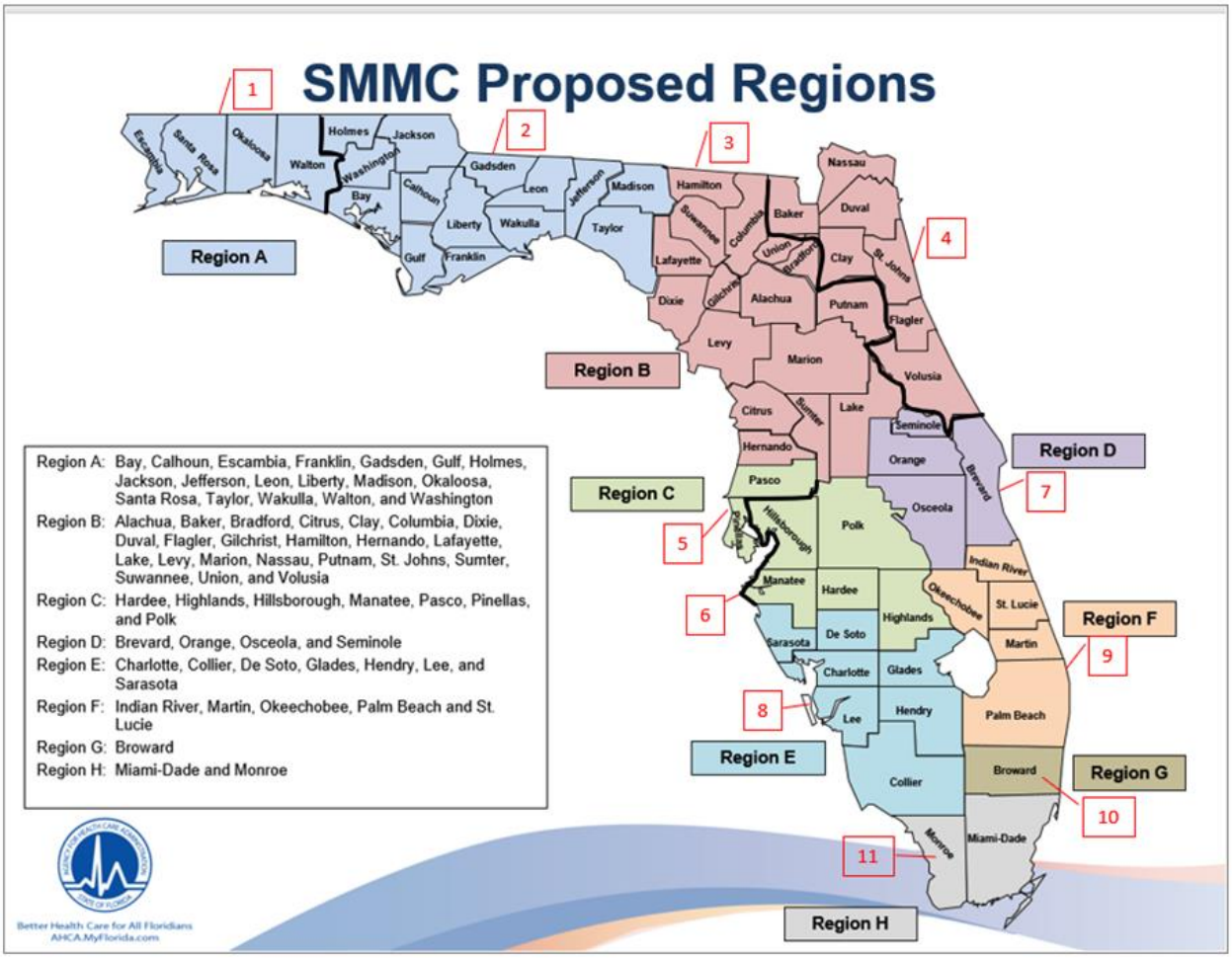
Section 4 of the bill amends s. 409.966(2), F.S., to require the AHCA's databook consisting of Medicaid utilization and spending data (which must be published 90 days before issuing an

[13] Supra note 5.
[14] *Id.*

invitation to negotiate) to include at least the 24 most recent months of data from the Medicaid Encounter Data System. This removes the requirement that the databook consist of data for the three most recent contract years, include historic fee-for-service claims, and delineate utilization by age, gender, eligibility group, geographic area, and aggregate clinical risk score.

This section of the bill deletes the requirement for the AHCA to conduct separate and simultaneous procurements for each Medicaid region and outlines a new structure for regional awards. The new structure includes eight regions named by letters (Regions A-H), rather than the 11 regions named by numbers (Regions 1-11) included in the original statute.

The following map and chart outline the eight regions proposed in the bill:[15]



Current Regions	Counties	Proposed Regions
Region 1	ESCAMBIA, OKALOOSA, SANTA ROSA, WALTON	**Region A**
Region 2	BAY, CALHOUN, FRANKLIN, GADSDEN, GULF, HOLMES, JACKSON, JEFFERSON, LEON, LIBERTY, MADISON, TAYLOR, WAKULLA, WASHINGTON	

[15] *Id.*

Region 3	ALACHUA, BRADFORD, CITRUS, COLUMBIA, DIXIE, GILCHRIST, HAMILTON, HERNANDO, LAFAYETTE, LAKE, LEVY, MARION, PUTNAM, SUMTER, SUWANNEE, UNION	**Region B**
Region 4	BAKER, CLAY, DUVAL, FLAGLER, NASSAU, ST JOHNS, VOLUSIA	
Region 5	PASCO & PINELLAS	**Region C**
Region 6	HARDEE, HIGHLANDS, HILLSBOROUGH, MANATEE, POLK	
Region 7	BREVARD, ORANGE, OSCEOLA, SEMINOLE	**Region D**
Region 8	CHARLOTTE, COLLIER, DESOTO, GLADES, HENDRY, LEE, SARASOTA	**Region E**
Region 9	INDIAN RIVER, MARTIN, OKEECHOBEE, PALM BEACH, ST LUCIE	**Region F**
Region 10	BROWARD	**Region G**
Region 11	MIAMI-DADE & MONROE	**Region H**

This section of the bill deletes obsolete language in s. 409.966(3)(d), F.S., which required AHCA to negotiate capitation rates for the first year of the first contract term. It also deletes s. 409.966(3)(e), F.S., which awarded additional contracts to plans who are awarded contracts in Regions 1 and 2. The AHCA indicates that because the bill merges Regions 1 and 2 into a single Region A, and because the bill provides for the award of statewide contracts, this provision is no longer needed.[16]

Section 5 of the bill amends s. 409.967, F.S., to delete obsolete language in paragraphs (2)(c) relating to plans contracting with hospital facilities that became licensed and operational before January 1, 2013. This section of the bill also deletes obsolete language in subparagraph (2)(f)4., requiring the AHCA to issue a request for information to determine whether cost savings could be achieved through oversight and management by the end of the fourth year of the first contract term.

Currently under s. 409.967(3)(f), F.S., all profit up to five percent of revenue is retained by the plan. Half of the profit above that threshold and up to 10 percent of revenue is retained by the plan and the other half refunded to the state. All profit above 10 percent of revenue is refunded to the state. Under current s. 409.967(3)(g), F.S., plans may retain an additional one percent of revenue as an incentive to meet agency-defined quality measures, including plan performance for managing complex, chronic conditions that are associated with an elevated likelihood of recurring high-cost medical treatments.

[16] *Id.*

Current Statute	**3%**	**4%**	**5%**	**6%**	**7%**	**8%**	**9%**	**10 %**	**11 %**
Profit retained without meeting agency-defined quality measures	100%	100%	100%	50%	50%	50%	50 %	50%	0%
Profit retained meeting agency-defined quality measures	100%	100%	100%	100 %	50%	50%	50 %	50%	0%

The bill changes the threshold at which profit-sharing begins from five percent to three percent of revenue. The bill authorizes the plans to retain up to an additional two percent of revenue, rather than the additional one percent. The bill specifies that AHCA's quality measures must include two tiers, with tier one exceeding quality measures and tier two more-so exceeding those quality measures. A plan meeting tier one quality or performance targets would retain all profit up to four percent of revenue. A plan meeting tier two quality or performance targets would retain all profit to five percent of revenue. Half of the profit above such final threshold, up to 10 percent of revenue, would be retained by the plan and the other half refunded to the state. All profit above 10 percent of revenue would continue to be refunded to the state.

Under the bill	**3%**	**4%**	**5%**	**6%**	**7%**	**8%**	**9%**	**10%**	**11%**
Profit retained without meeting any quality benchmarks	100%	50%	50%	50%	50%	50%	50%	50%	0%
Profit retained once new tier one benchmarks are met	100%	100%	50%	50%	50%	50%	50%	50%	0%
Profit retained once new tier two benchmarks are met	100%	100%	100%	50%	50%	50%	50%	50%	0%

Section 6 of the bill amends s. 409.968(2), F.S., to delete language allowing PSNs to receive fee-for-service rates with a shared savings settlement. In conjunction with changes made to s. 409.912. F.S., in section 1 of this bill, the bill requires all PSNs to be prepaid plans, receiving a per-member, per-month payment, and negotiated pursuant to the procurement process in s. 409.966, F.S.

Section 7 of the bill amends s. 409.973, F.S., to revise language related to Healthy Behaviors programs which MMA plans are required to establish to encourage and reward healthy behaviors. The bill requires each plan to establish a "tobacco cessation program" rather than a "smoking cessation program" to ensure that each program also includes smokeless tobacco products. It also requires an MMA plan's substance abuse recovery program to include opioid abuse recovery.

This section of the bill also deletes obsolete language in 409.97(4)(b), F.S., relating to the Primary Care Initiative, which requires the plans to schedule an appointment with a primary care

provider for enrollees who became eligible for Medicaid between January 1, 2014 and December 31, 2015, within 6 months of enrollment in the plan.

Section 8 of the bill amends s. 409.974(1), F.S., to outline the structure for plan selection under the MMA program. This section authorizes the AHCA to select eligible plans to provide services through a single statewide procurement and to award contracts to plans on a regional or statewide basis. It requires the AHCA to award a contract to at least one PSN in each of the 8 regions and to procure:

- 3-4 plans for Region A
- 3-6 plans for Region B
- 5-10 plans for Region C
- 3-6 plans for Region D
- 3-4 plans for Region E
- 3-5 plans for Region F
- 3-5 plans for Region G
- 5-10 plans for Region H

This section of the bill also amends s. 409.974(2), F.S., to eliminate the requirement that the AHCA exercise a preference for plans with a provider network in which over 10 percent of the providers use electronic health records. It is estimated that 80 percent of providers currently use electronic health records.[17]

Section 9 of the bill amends s. 409.975(1)(b), F.S., to expand the list of statewide essential providers to include Florida cancer hospitals that meet the criteria in 42 U.S.C. s. 1395ww(d)(1)(B)(v). Currently, Moffitt Cancer Center in Tampa and Sylvester Comprehensive Cancer Center in Miami meet this criteria. Under the bill, managed care plans would be required to include these cancer hospitals in their networks as essential providers.

Section 10 of the bill amends s. 409.977, F.S., to revise and relocate the requirement for the AHCA to maintain a recipient's enrollment in a plan if a recipient was enrolled in a plan immediately before the recipient's choice period and that plan is still available in the region, unless an applicable specialty plan is available from subsection (1) to subsection (2).

This section of the bill deletes the obsolete requirement in s. 409.977(4), F.S., for the AHCA to seek federal approval develop and implement a process to enable a Medicaid recipient with access to employer-sponsored health care coverage to opt out of all managed care plans and to use Medicaid financial assistance to pay for the recipient's share of the cost in such employer-sponsored coverage. The AHCA has already obtained federal approval for what has come to be known as their Health Insurance Premium Payment (HIPP) program[18] and continues to

[17] Email from Legislative Affairs Director, Agency for Health Care Administration, to Senate Committee on Health Policy Staff (Jan. 24, 2022) (on file with the Senate Committee on Health Policy).
[18] *See* Rule 59G-7.007, F.A.C.

implement this program.[19] As of August 2021, 53 recipients were participating in the HIPP program.[20]

This section of the bill also amends s. 409.977(5), F.S., to authorize a child welfare specialty managed care plan under contract with the MMA program to serve a child in a permanent guardianship situation.[21] Specifically, such a child must continue to be eligible for Medicaid and must receive guardianship assistance payments under the Guardianship Assistance Program. Currently, only children in foster care, extended foster care, or subsidized adoption are eligible for the child welfare specialty plan.

Section 11 of the bill amends s. 409.981, F.S., to outline the structure for plan selection under the LTC program. Tracking the structure for MMA plan selection above in section 8 of this bill, except as noted, this section authorizes the AHCA to select eligible plans to provide services through a single statewide procurement and to award contracts to plans on a regional or statewide basis. It requires the AHCA to award a contract to at least one PSN in each of the eight regions and to procure:

- 3-4 plans for Region A
- 3-6 plans for Region B
- 5-10 plans for Region C
- 3-6 plans for Region D
- 3-4 plans for Region E
- 3-5 plans for Region F
- 3-4 plans for Region G[22]
- 5-10 plans for region H

Section 12 of the bill amends s. 409.8132, F.S., to conform a cross-reference to changes made in bill section 2 which repeals s. 409.9124, F.S.

Section 13 of the bill reenacts s. 409.962, F.S., to incorporate changes made by this act to s. 409.912, F.S., in bill section 1.

Section 14 of the bill reenacts s. 641.19, F.S., to incorporate changes made by this act to s. 409.912, F.S., in bill section 1.

Section 15 of the bill reenacts s. 430.2053, F.S., to incorporate changes made by this act to s. 409.981, F.S., in bill section 11.

Section 16 of the bill provides an effective date of July 1, 2022.

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[19] The AHCA reports that for the 2020 calendar year, $95,388.79 was spent on premium reimbursements through the HIPP program. From January to August of 2021, $912,363.87 was spent on premium reimbursements through the program. *Supra* note 5.

[20] *Supra* note 17.

[21] For more information on the Sunshine Health Child Welfare Specialty Plan and the Guardianship Assistance Program, *see* Florida Senate Bill Analysis and Fiscal Impact Statement for CS/SB 1080, Jan. 19, 2022 *available* at https://www.flsenate.gov/Session/Bill/2022/1080/Analyses/2022s01080.hp.PDF (last visited Jan. 23, 2022). The provisions of CS/SB 1080 are identical to the changes made to s. 409.977(5), F.S., in this bill.

[22] Note that the AHCA must award 3-5 MMA plans for Region G under bill section 8.

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:

Changes made by the bill to the Achieved Savings Rebate program could result in cost savings. The bill tasks the AHCA with specifying two tiers of quality measures on which profit-sharing would be based. Without additional information as to what those quality measures are, it is impossible to estimate whether the AHCA would receive revenue (and at what percent) from the plans, and a fiscal impact is indeterminate.

The capitation rate for children in the child welfare specialty plan is higher than the rates for most children in other plans. If children become eligible and receive services through the child welfare specialty plan as authorized in the bill, the bill will have an indeterminate negative fiscal impact. The AHCA estimates a maximum fiscal impact of $12.2 million annually ($4.7 million General Revenue) based on rate year 2020-21 based

on an estimate of 4,120 children who currently would be eligible for the change in plans.[23]

The precise fiscal impact of children becoming newly eligible for the child welfare specialty plans cannot be calculated without knowing the Medicaid region in which an eligible child resides and the capitation rate category in which the child is currently categorized. This is because Medicaid capitation rates vary by region and children could be in different rate cells based on age, gender, Medicaid eligibility category, and other characteristics.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.912, 409.964, 409.966, 409.967, 409.968, 409.973, 409.974, 409.975, 409.977, 409.981, and 409.8132.

This bill repeals section 409.9124 of the Florida Statutes.

This bill reenacts the following sections of the Florida Statutes: 409.962, 641.19, and 430.2053.

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 January 26, 2022:
The CS corrects a drafting error in the underlying bill that would have inadvertently deleted the AHCA's existing authority to implement the HIPP program. The amendment keeps the HIPP program intact and removes obsolete language from statute regarding already-obtained federal approval to implement the program.

B. Amendments:

None.

[23] *Id.*

591072

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/26/2022	.	
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	.	

The Committee on Health Policy (Brodeur) recommended the following:

Senate Amendment (with title amendment)

Delete lines 856 - 876

and insert:

(4) The agency shall develop a process to enable a recipient with access to employer-sponsored health care coverage to opt out of all managed care plans and to use Medicaid financial assistance to pay for the recipient's share of the cost in such employer-sponsored coverage. ~~Contingent upon federal approval,~~ The agency shall also enable recipients with

591072

access to other insurance or related products providing access to health care services created pursuant to state law, including any product available under the Florida Health Choices Program, or any health exchange, to opt out. The amount of financial assistance provided for each recipient may not exceed the amount of the Medicaid premium that would have been paid to a managed care plan for that recipient. The agency shall ~~seek federal approval to~~ require Medicaid recipients with access to employer-sponsored health care coverage to enroll in that coverage and use Medicaid financial assistance to pay for the recipient's share of the cost for such coverage. The amount of financial assistance provided for each recipient may not exceed the amount of the Medicaid premium that would have been paid to a managed care plan for that recipient.

(5) Specialty plans serving children in the care and

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

And the title is amended as follows:

Delete lines 50 - 54

and insert:

deleting obsolete language; authorizing specialty plans to serve certain children who receive guardianship assistance payments under the Guardianship Assistance Program; amending s. 409.981, F.S.; requiring the

By Senator Brodeur

9-01655-22 20221950__

A bill to be entitled

An act relating to the statewide Medicaid managed care program; amending s. 409.912, F.S.; requiring, rather than authorizing, that the reimbursement method for provider service networks be on a prepaid basis; deleting the authority to reimburse provider service networks on a fee-for-service basis; conforming provisions to changes made by the act; providing that provider service networks are subject to and exempt from certain requirements; providing construction; repealing s. 409.9124, F.S., relating to managed care reimbursement; amending s. 409.964, F.S.; deleting a requirement that the Agency for Health Care Administration provide the opportunity for public feedback on a certain waiver application; amending s. 409.966, F.S.; revising requirements relating to the databook published by the agency consisting of Medicaid utilization and spending data; reallocating regions within the statewide managed care program; deleting a requirement that the agency negotiate plan rates or payments to guarantee a certain savings amount; deleting a requirement for the agency to award additional contracts to plans in specified regions for certain purposes; revising a limitation on when plans may begin serving Medicaid recipients to apply to any eligible plan that participates in an invitation to negotiate, rather than plans participating in certain regions; making technical changes; amending s. 409.967, F.S.; deleting obsolete provisions; revising

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provisions relating to agency-defined quality measures under the achieved savings rebate program for Medicaid prepaid plans; amending s. 409.968, F.S.; conforming provisions to changes made by the act; amending s. 409.973, F.S.; revising requirements for healthy behaviors programs established by plans; deleting an obsolete provision; amending s. 409.974, F.S.; requiring the agency to select plans for the managed medical assistance program through a single statewide procurement; authorizing the agency to award contracts to plans on a regional or statewide basis; specifying requirements for minimum numbers of plans which the agency must procure for each specified region; conforming provisions to changes made by the act; deleting a requirement for the agency to exercise a preference for certain plans; amending s. 409.975, F.S.; providing that cancer hospitals meeting certain criteria are statewide essential providers; amending s. 409.977, F.S.; revising the circumstances for maintaining a recipient's enrollment in a plan; deleting a requirement for the agency to develop a process for certain recipients to opt out of managed care plans; conforming provisions to changes made by the act; authorizing specialty plans to serve certain children; amending s. 409.981, F.S.; requiring the agency to select plans for the long-term care managed medical assistance program through a single statewide procurement; authorizing the agency to award contracts to plans on a regional or statewide basis; specifying

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

requirements for minimum numbers of plans which the agency must procure for each specified region; conforming provisions to changes made by the act; amending s. 409.8132, F.S.; conforming a cross-reference; reenacting ss. 409.962(1), (7), (13), and (14) and 641.19(22) relating to definitions, to incorporate the amendments made by this act to s. 409.912, F.S., in references thereto; reenacting s. 430.2053(3)(h), (i), and (j) and (11), relating to aging resource centers, to incorporate the amendments made by this act to s. 409.981, F.S., in references thereto; providing an effective date.

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

Section 1. Subsection (1) of section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.—The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician's opinion of the correct diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. s. 438.114. Such confirmation or second opinion shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid

aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider's professional peers or the national guidelines of a provider's professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services

results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers are not entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(1) The agency may contract with a provider service network, which must ~~may~~ be reimbursed on a ~~fee-for-service or~~ prepaid basis. ~~Prepaid~~ Provider service networks shall receive per-member, per-month payments. ~~A provider service network that does not choose to be a prepaid plan shall receive fee-for-service rates with a shared savings settlement. The fee-for-service option shall be available to a provider service network only for the first 2 years of the plan's operation or until the~~

~~contract year beginning September 1, 2014, whichever is later. The agency shall annually conduct cost reconciliations to determine the amount of cost savings achieved by fee-for-service provider service networks for the dates of service in the period being reconciled. Only payments for covered services for dates of service within the reconciliation period and paid within 6 months after the last date of service in the reconciliation period shall be included. The agency shall perform the necessary adjustments for the inclusion of claims incurred but not reported within the reconciliation for claims that could be received and paid by the agency after the 6-month claims processing time lag. The agency shall provide the results of the reconciliations to the fee-for-service provider service networks within 45 days after the end of the reconciliation period. The fee-for-service provider service networks shall review and provide written comments or a letter of concurrence to the agency within 45 days after receipt of the reconciliation results. This reconciliation shall be considered final.~~

~~(a) A provider service network which is reimbursed by the agency on a prepaid basis shall be exempt from parts I and III of chapter 641 but must comply with the solvency requirements in s. 641.2261(2) and meet appropriate financial reserve, quality assurance, and patient rights requirements as established by the agency.~~

~~(b)~~ A provider service network is a network established or organized and operated by a health care provider, or group of affiliated health care providers, which provides a substantial proportion of the health care items and services under a contract directly through the provider or affiliated group of

providers and may make arrangements with physicians or other health care professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians, by other health professionals, or through the institutions. The health care providers must have a controlling interest in the governing body of the provider service network organization.

(a) A provider service network is exempt from parts I and III of chapter 641 but must comply with the solvency requirements in s. 641.2261(2) and meet appropriate financial reserve, quality assurance, and patient rights requirements as established by the agency.

(b) This subsection does not authorize the agency to contract with a provider service network outside of the procurement process described in s. 409.966.

Section 2. Section 409.9124, Florida Statutes, is repealed.

Section 3. Section 409.964, Florida Statutes, is amended to read:

409.964 Managed care program; state plan; waivers.—The Medicaid program is established as a statewide, integrated managed care program for all covered services, including long-term care services. The agency shall apply for and implement state plan amendments or waivers of applicable federal laws and regulations necessary to implement the program. ~~Before seeking a waiver, the agency shall provide public notice and the opportunity for public comment and include public feedback in the waiver application. The agency shall hold one public meeting in each of the regions described in s. 409.966(2), and the time~~

~~period for public comment for each region shall end no sooner than 30 days after the completion of the public meeting in that region.~~

Section 4. Subsections (2), (3), and (4) of section 409.966, Florida Statutes, are amended to read:

409.966 Eligible plans; selection.—

(2) ELIGIBLE PLAN SELECTION.—The agency shall select a limited number of eligible plans to participate in the Medicaid program using invitations to negotiate in accordance with s. 287.057(1)(c). At least 90 days before issuing an invitation to negotiate, the agency shall compile and publish a databook consisting of a comprehensive set of utilization and spending data consistent with actuarial rate-setting practices and standards ~~for the 3 most recent contract years consistent with the rate-setting periods for all Medicaid recipients by region or county~~. The source of the data in the databook ~~report~~ must include, at a minimum, the 24 most recent months of ~~both historic fee-for-service claims and~~ validated data from the Medicaid Encounter Data System. The statewide managed care program includes ~~report must be available in electronic form and delineate utilization use by age, gender, eligibility group, geographic area, and aggregate clinical risk score. Separate and simultaneous procurements shall be conducted in each of~~ the following regions:

(a) Region A ~~1~~, which consists of Bay, Calhoun, Escambia, ~~Okaloosa, Santa Rosa, and Walton Counties.~~

~~(b) Region 2, which consists of Bay, Calhoun,~~ Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Okaloosa, Santa Rosa, Taylor, Wakulla, Walton, and

Washington Counties.

(b) ~~(c)~~ Region B ~~3~~, which consists of Alachua, Baker, Bradford, Citrus, Clay, Columbia, Dixie, Duval, Flagler, Gilchrist, Hamilton, Hernando, Lafayette, Lake, Levy, Marion, Nassau, Putnam, St. Johns, Sumter, Suwannee, ~~and~~ Union ~~Counties.~~

~~(d) Region 4, which consists of Baker, Clay, Duval, Flagler, Nassau, St. Johns~~, and Volusia Counties.

(c) ~~(e)~~ Region C ~~5~~, which consists of ~~Pasco and Pinellas Counties.~~

~~(f) Region 6, which consists of~~ Hardee, Highlands, Hillsborough, Manatee, Pasco, Pinellas, and Polk Counties.

(d) ~~(g)~~ Region D ~~7~~, which consists of Brevard, Orange, Osceola, and Seminole Counties.

(e) ~~(h)~~ Region E ~~8~~, which consists of Charlotte, Collier, DeSoto, Glades, Hendry, Lee, and Sarasota Counties.

(f) ~~(i)~~ Region F ~~9~~, which consists of Indian River, Martin, Okeechobee, Palm Beach, and St. Lucie Counties.

(g) ~~(j)~~ Region G ~~10~~, which consists of Broward County.

(h) ~~(k)~~ Region H ~~11~~, which consists of Miami-Dade and Monroe Counties.

(3) QUALITY SELECTION CRITERIA.—

(a) The invitation to negotiate must specify the criteria and the relative weight of the criteria that will be used for determining the acceptability of the reply and guiding the selection of the organizations with which the agency negotiates. In addition to criteria established by the agency, the agency shall consider the following factors in the selection of eligible plans:

1. Accreditation by the National Committee for Quality

Assurance, the Joint Commission, or another nationally recognized accrediting body.

2. Experience serving similar populations, including the organization's record in achieving specific quality standards with similar populations.

3. Availability and accessibility of primary care and specialty physicians in the provider network.

4. Establishment of community partnerships with providers that create opportunities for reinvestment in community-based services.

5. Organization commitment to quality improvement and documentation of achievements in specific quality improvement projects, including active involvement by organization leadership.

6. Provision of additional benefits, particularly dental care and disease management, and other initiatives that improve health outcomes.

7. Evidence that an eligible plan has obtained signed contracts or written agreements or ~~signed contracts or~~ has made substantial progress in establishing relationships with providers before the plan submits ~~submitting~~ a response.

8. Comments submitted in writing by any enrolled Medicaid provider relating to a specifically identified plan participating in the procurement in the same region as the submitting provider.

9. Documentation of policies and procedures for preventing fraud and abuse.

10. The business relationship an eligible plan has with any other eligible plan that responds to the invitation to

negotiate.

(b) An eligible plan must disclose any business relationship it has with any other eligible plan that responds to the invitation to negotiate. The agency may not select plans in the same region for the same managed care program that have a business relationship with each other. Failure to disclose any business relationship shall result in disqualification from participation in any region for the first full contract period after the discovery of the business relationship by the agency. For the purpose of this section, "business relationship" means an ownership or controlling interest, an affiliate or subsidiary relationship, a common parent, or any mutual interest in any limited partnership, limited liability partnership, limited liability company, or other entity or business association, including all wholly or partially owned subsidiaries, majority-owned subsidiaries, parent companies, or affiliates of such entities, business associations, or other enterprises, that exists for the purpose of making a profit.

(c) After negotiations are conducted, the agency shall select the eligible plans that are determined to be responsive and provide the best value to the state. Preference shall be given to plans that:

1. Have signed contracts with primary and specialty physicians in sufficient numbers to meet the specific standards established pursuant to s. 409.967(2)(c).

2. Have well-defined programs for recognizing patient-centered medical homes and providing for increased compensation for recognized medical homes, as defined by the plan.

3. Are organizations that are based in and perform

operational functions in this state, in-house or through contractual arrangements, by staff located in this state. Using a tiered approach, the highest number of points shall be awarded to a plan that has all or substantially all of its operational functions performed in the state. The second highest number of points shall be awarded to a plan that has a majority of its operational functions performed in the state. The agency may establish a third tier; however, preference points may not be awarded to plans that perform only community outreach, medical director functions, and state administrative functions in the state. For purposes of this subparagraph, operational functions include corporate headquarters, claims processing, member services, provider relations, utilization and prior authorization, case management, disease and quality functions, and finance and administration. For purposes of this subparagraph, the term "corporate headquarters" means the principal office of the organization, which may not be a subsidiary, directly or indirectly through one or more subsidiaries of, or a joint venture with, any other entity whose principal office is not located in the state.

4. Have contracts or other arrangements for cancer disease management programs that have a proven record of clinical efficiencies and cost savings.

5. Have contracts or other arrangements for diabetes disease management programs that have a proven record of clinical efficiencies and cost savings.

6. Have a claims payment process that ensures that claims that are not contested or denied will be promptly paid pursuant to s. 641.3155.

~~(d) For the first year of the first contract term, the agency shall negotiate capitation rates or fee for service payments with each plan in order to guarantee aggregate savings of at least 5 percent.~~

~~1. For prepaid plans, determination of the amount of savings shall be calculated by comparison to the Medicaid rates that the agency paid managed care plans for similar populations in the same areas in the prior year. In regions containing no prepaid plans in the prior year, determination of the amount of savings shall be calculated by comparison to the Medicaid rates established and certified for those regions in the prior year.~~

~~2. For provider service networks operating on a fee-for-service basis, determination of the amount of savings shall be calculated by comparison to the Medicaid rates that the agency paid on a fee-for-service basis for the same services in the prior year.~~

~~(e) To ensure managed care plan participation in Regions 1 and 2, the agency shall award an additional contract to each plan with a contract award in Region 1 or Region 2. Such contract shall be in any other region in which the plan submitted a responsive bid and negotiates a rate acceptable to the agency. If a plan that is awarded an additional contract pursuant to this paragraph is subject to penalties pursuant to s. 409.967(2)(i) for activities in Region 1 or Region 2, the additional contract is automatically terminated 180 days after the imposition of the penalties. The plan must reimburse the agency for the cost of enrollment changes and other transition activities.~~

(d) ~~(f)~~ The agency may not execute contracts with managed

care plans at payment rates not supported by the General Appropriations Act.

(4) ADMINISTRATIVE CHALLENGE.—Any eligible plan that participates in an invitation to negotiate ~~in more than one region and is selected in at least one region~~ may not begin serving Medicaid recipients ~~in any region for which it was selected~~ until all administrative challenges to procurements required by this section to which the eligible plan is a party have been finalized. If the number of plans selected is less than the maximum amount of plans permitted in the region, the agency may contract with other selected plans in the region not participating in the administrative challenge before resolution of the administrative challenge. For purposes of this subsection, an administrative challenge is finalized if an order granting voluntary dismissal with prejudice has been entered by any court established under Article V of the State Constitution or by the Division of Administrative Hearings, a final order has been entered into by the agency and the deadline for appeal has expired, a final order has been entered by the First District Court of Appeal and the time to seek any available review by the Florida Supreme Court has expired, or a final order has been entered by the Florida Supreme Court and a warrant has been issued.

Section 5. Paragraphs (c) and (f) of subsection (2) and subsection (3) of section 409.967, Florida Statutes, are amended to read:

409.967 Managed care plan accountability.—

(2) The agency shall establish such contract requirements as are necessary for the operation of the statewide managed care

program. In addition to any other provisions the agency may deem necessary, the contract must require:

(c) *Access.*—

1. The agency shall establish specific standards for the number, type, and regional distribution of providers in managed care plan networks to ensure access to care for both adults and children. Each plan must maintain a regionwide network of providers in sufficient numbers to meet the access standards for specific medical services for all recipients enrolled in the plan. The exclusive use of mail-order pharmacies may not be sufficient to meet network access standards. Consistent with the standards established by the agency, provider networks may include providers located outside the region. ~~A plan may contract with a new hospital facility before the date the hospital becomes operational if the hospital has commenced construction, will be licensed and operational by January 1, 2013, and a final order has issued in any civil or administrative challenge.~~ Each plan shall establish and maintain an accurate and complete electronic database of contracted providers, including information about licensure or registration, locations and hours of operation, specialty credentials and other certifications, specific performance indicators, and such other information as the agency deems necessary. The database must be available online to both the agency and the public and have the capability to compare the availability of providers to network adequacy standards and to accept and display feedback from each provider's patients. Each plan shall submit quarterly reports to the agency identifying the number of enrollees assigned to each primary care provider.

The agency shall conduct, or contract for, systematic and continuous testing of the provider network databases maintained by each plan to confirm accuracy, confirm that behavioral health providers are accepting enrollees, and confirm that enrollees have access to behavioral health services.

2. Each managed care plan must publish any prescribed drug formulary or preferred drug list on the plan's website in a manner that is accessible to and searchable by enrollees and providers. The plan must update the list within 24 hours after making a change. Each plan must ensure that the prior authorization process for prescribed drugs is readily accessible to health care providers, including posting appropriate contact information on its website and providing timely responses to providers. For Medicaid recipients diagnosed with hemophilia who have been prescribed anti-hemophilic-factor replacement products, the agency shall provide for those products and hemophilia overlay services through the agency's hemophilia disease management program.

3. Managed care plans, and their fiscal agents or intermediaries, must accept prior authorization requests for any service electronically.

4. Managed care plans serving children in the care and custody of the Department of Children and Families must maintain complete medical, dental, and behavioral health encounter information and participate in making such information available to the department or the applicable contracted community-based care lead agency for use in providing comprehensive and coordinated case management. The agency and the department shall establish an interagency agreement to provide guidance for the

format, confidentiality, recipient, scope, and method of information to be made available and the deadlines for submission of the data. The scope of information available to the department shall be the data that managed care plans are required to submit to the agency. The agency shall determine the plan's compliance with standards for access to medical, dental, and behavioral health services; the use of medications; and followup on all medically necessary services recommended as a result of early and periodic screening, diagnosis, and treatment.

(f) *Continuous improvement.*—The agency shall establish specific performance standards and expected milestones or timelines for improving performance over the term of the contract.

1. Each managed care plan shall establish an internal health care quality improvement system, including enrollee satisfaction and disenrollment surveys. The quality improvement system must include incentives and disincentives for network providers.

2. Each plan must collect and report the Health Plan Employer Data and Information Set (HEDIS) measures, as specified by the agency. These measures must be published on the plan's website in a manner that allows recipients to reliably compare the performance of plans. The agency shall use the HEDIS measures as a tool to monitor plan performance.

3. Each managed care plan must be accredited by the National Committee for Quality Assurance, the Joint Commission, or another nationally recognized accrediting body, or have initiated the accreditation process, within 1 year after the

contract is executed. For any plan not accredited within 18 months after executing the contract, the agency shall suspend automatic assignment under s. 409.977 and 409.984.

~~4. By the end of the fourth year of the first contract term, the agency shall issue a request for information to determine whether cost savings could be achieved by contracting for plan oversight and monitoring, including analysis of encounter data, assessment of performance measures, and compliance with other contractual requirements.~~

(3) ACHIEVED SAVINGS REBATE.—

(a) The agency is responsible for verifying the achieved savings rebate for all Medicaid prepaid plans. To assist the agency, a prepaid plan shall:

1. Submit an annual financial audit conducted by an independent certified public accountant in accordance with generally accepted auditing standards to the agency on or before June 1 for the preceding year; and

2. Submit an annual statement prepared in accordance with statutory accounting principles on or before March 1 pursuant to s. 624.424 if the plan is regulated by the Office of Insurance Regulation.

(b) The agency shall contract with independent certified public accountants to conduct compliance audits for the purpose of auditing financial information, including but not limited to: annual premium revenue, medical and administrative costs, and income or losses reported by each prepaid plan, in order to determine and validate the achieved savings rebate.

(c) Any audit required under this subsection must be conducted by an independent certified public accountant who

meets criteria specified by rule. The rules must also provide that:

1. The entity selected by the agency to conduct the audit may not have a conflict of interest that might affect its ability to perform its responsibilities with respect to an examination.

2. The rates charged to the prepaid plan being audited are consistent with rates charged by other certified public accountants and are comparable with the rates charged for comparable examinations.

3. Each prepaid plan audited shall pay to the agency the expenses of the audit at the rates established by the agency by rule. Such expenses include actual travel expenses, reasonable living expense allowances, compensation of the certified public accountant, and necessary attendant administrative costs of the agency directly related to the examination. Travel expense and living expense allowances are limited to those expenses incurred on account of the audit and must be paid by the examined prepaid plan together with compensation upon presentation by the agency to the prepaid plan of a detailed account of the charges and expenses after a detailed statement has been filed by the auditor and approved by the agency.

4. All moneys collected from prepaid plans for such audits shall be deposited into the Grants and Donations Trust Fund, and the agency may make deposits into such fund from moneys appropriated for the operation of the agency.

(d) At a location in this state, the prepaid plan shall make available to the agency and the agency's contracted certified public accountant all books, accounts, documents,

files, and information that relate to the prepaid plan's Medicaid transactions. Records not in the prepaid plan's immediate possession must be made available to the agency or the certified public accountant in this state within 3 days after a request is made by the agency or certified public accountant engaged by the agency. A prepaid plan has an obligation to cooperate in good faith with the agency and the certified public accountant. Failure to comply to such record requests shall be deemed a breach of contract.

(e) Once the certified public accountant completes the audit, the certified public accountant shall submit an audit report to the agency attesting to the achieved savings of the plan. The results of the audit report are dispositive.

(f) Achieved savings rebates validated by the certified public accountant are due within 30 days after the report is submitted. Except as provided in paragraph (h), the achieved savings rebate is established by determining pretax income as a percentage of revenues and applying the following income sharing ratios:

1. One hundred percent of income up to and including 3 ~~5~~ percent of revenue shall be retained by the plan.

2. Fifty percent of income above 3 ~~5~~ percent and up to 10 percent shall be retained by the plan, and the other 50 percent refunded to the state and transferred to the General Revenue Fund, unallocated.

3. One hundred percent of income above 10 percent of revenue shall be refunded to the state and transferred to the General Revenue Fund, unallocated.

(g) A plan that exceeds agency-defined quality measures in

the reporting period may retain up to an additional 2 ~~1~~ percent of revenue. For the purpose of this paragraph, the quality measures must include two tiers and must include plan performance for preventing or managing complex, chronic conditions that are associated with an elevated likelihood of requiring high-cost medical treatments.

1. If the agency-defined quality or performance targets identified in tier one are met, the plan may retain up to 4 percent of revenue. Fifty percent of income above 4 percent and up to 10 percent must be retained by the plan, and the other 50 percent refunded to the state and transferred to the General Revenue Fund, unallocated.

2. If the agency-defined quality or performance targets identified in tier two are met, the plan may retain up to 5 percent of revenue. Fifty percent of income above 5 percent and up to 10 percent must be retained by the plan, and the other 50 percent refunded to the state and transferred to the General Revenue Fund, unallocated.

(h) The following may not be included as allowable expenses in calculating income for determining the achieved savings rebate:

1. Payment of achieved savings rebates.

2. Any financial incentive payments made to the plan outside of the capitation rate.

3. Any financial disincentive payments levied by the state or federal government.

4. Expenses associated with any lobbying or political activities.

5. The cash value or equivalent cash value of bonuses of

any type paid or awarded to the plan's executive staff, other than base salary.

6. Reserves and reserve accounts.

7. Administrative costs, including, but not limited to, reinsurance expenses, interest payments, depreciation expenses, bad debt expenses, and outstanding claims expenses in excess of actuarially sound maximum amounts set by the agency.

The agency shall consider these and other factors in developing contracts that establish shared savings arrangements.

(i) Prepaid plans that incur a loss in the first contract year may apply the full amount of the loss as an offset to income in the second contract year.

(j) If, after an audit, the agency determines that a prepaid plan owes an additional rebate, the plan has 30 days after notification to make the payment. Upon failure to timely pay the rebate, the agency shall withhold future payments to the plan until the entire amount is recouped. If the agency determines that a prepaid plan has made an overpayment, the agency shall return the overpayment within 30 days.

Section 6. Subsection (2) of section 409.968, Florida Statutes, is amended to read:

409.968 Managed care plan payments.—

(2) Provider service networks must ~~may~~ be prepaid plans and receive per-member, per-month payments negotiated pursuant to the procurement process described in s. 409.966. ~~Provider service networks that choose not to be prepaid plans shall receive fee-for-service rates with a shared savings settlement. The fee-for-service option shall be available to a provider~~

~~service network only for the first 2 years of its operation. The agency shall annually conduct cost reconciliations to determine the amount of cost savings achieved by fee-for-service provider service networks for the dates of service within the period being reconciled. Only payments for covered services for dates of service within the reconciliation period and paid within 6 months after the last date of service in the reconciliation period must be included. The agency shall perform the necessary adjustments for the inclusion of claims incurred but not reported within the reconciliation period for claims that could be received and paid by the agency after the 6 month claims processing time lag. The agency shall provide the results of the reconciliations to the fee-for-service provider service networks within 45 days after the end of the reconciliation period. The fee-for-service provider service networks shall review and provide written comments or a letter of concurrence to the agency within 45 days after receipt of the reconciliation results. This reconciliation is considered final.~~

Section 7. Subsections (3) and (4) of section 409.973, Florida Statutes, are amended to read:

409.973 Benefits.—

(3) HEALTHY BEHAVIORS.—Each plan operating in the managed medical assistance program shall establish a program to encourage and reward healthy behaviors. At a minimum, each plan must establish a medically approved tobacco ~~smoking~~ cessation program, a medically directed weight loss program, and a medically approved alcohol recovery program or substance abuse recovery program that must include, but may not be limited to, opioid abuse recovery. Each plan must identify enrollees who

smoke, are morbidly obese, or are diagnosed with alcohol or substance abuse in order to establish written agreements to secure the enrollees' commitment to participation in these programs.

(4) PRIMARY CARE INITIATIVE.—Each plan operating in the managed medical assistance program shall establish a program to encourage enrollees to establish a relationship with their primary care provider. Each plan shall:

(a) Provide information to each enrollee on the importance of and procedure for selecting a primary care provider, and thereafter automatically assign to a primary care provider any enrollee who fails to choose a primary care provider.

(b) If the enrollee was not a Medicaid recipient before enrollment in the plan, assist the enrollee in scheduling an appointment with the primary care provider. If possible the appointment should be made within 30 days after enrollment in the plan. ~~For enrollees who become eligible for Medicaid between January 1, 2014, and December 31, 2015, the appointment should be scheduled within 6 months after enrollment in the plan.~~

(c) Report to the agency the number of enrollees assigned to each primary care provider within the plan's network.

(d) Report to the agency the number of enrollees who have not had an appointment with their primary care provider within their first year of enrollment.

(e) Report to the agency the number of emergency room visits by enrollees who have not had at least one appointment with their primary care provider.

Section 8. Subsections (1) and (2) of section 409.974, Florida Statutes, are amended to read:

409.974 Eligible plans.—

(1) ELIGIBLE PLAN SELECTION.—The agency shall select eligible plans for the managed medical assistance program through the procurement process described in s. 409.966 through a single statewide procurement. The agency may award contracts to plans selected through the procurement process either on a regional or statewide basis. The awards must include at least one provider service network in each of the eight regions outlined in this subsection. The agency shall procure:

(a) At least 3 plans and up to 4 plans for Region A.

(b) At least 3 plans and up to 6 plans for Region B.

(c) At least 5 plans and up to 10 plans for Region C.

(d) At least 3 plans and up to 6 plans for Region D.

(e) At least 3 plans and up to 4 plans for Region E.

(f) At least 3 plans and up to 5 plans for Region F.

(g) At least 3 plans and up to 5 plans for Region G.

(h) At least 5 plans and up to 10 plans for Region H. ~~The agency shall notice invitations to negotiate no later than January 1, 2013.~~

~~(a) The agency shall procure two plans for Region 1. At least one plan shall be a provider service network if any provider service networks submit a responsive bid.~~

~~(b) The agency shall procure two plans for Region 2. At least one plan shall be a provider service network if any provider service networks submit a responsive bid.~~

~~(c) The agency shall procure at least three plans and up to five plans for Region 3. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(d) The agency shall procure at least three plans and up to five plans for Region 4. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(e) The agency shall procure at least two plans and up to four plans for Region 5. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(f) The agency shall procure at least four plans and up to seven plans for Region 6. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(g) The agency shall procure at least three plans and up to six plans for Region 7. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(h) The agency shall procure at least two plans and up to four plans for Region 8. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(i) The agency shall procure at least two plans and up to four plans for Region 9. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(j) The agency shall procure at least two plans and up to four plans for Region 10. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(k) The agency shall procure at least five plans and up to~~

~~10 plans for Region 11. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

If no provider service network submits a responsive bid, the agency shall procure no more than one less than the maximum number of eligible plans permitted in that region. Within 12 months after the initial invitation to negotiate, the agency shall attempt to procure a provider service network. The agency shall notice another invitation to negotiate only with provider service networks in those regions where no provider service network has been selected.

(2) QUALITY SELECTION CRITERIA.—In addition to the criteria established in s. 409.966, the agency shall consider evidence that an eligible plan has written agreements or signed contracts or has made substantial progress in establishing relationships with providers before the plan submitting a response. The agency shall evaluate and give special weight to evidence of signed contracts with essential providers as defined by the agency pursuant to s. 409.975(1). ~~The agency shall exercise a preference for plans with a provider network in which over 10 percent of the providers use electronic health records, as defined in s. 408.051.~~ When all other factors are equal, the agency shall consider whether the organization has a contract to provide managed long-term care services in the same region and shall exercise a preference for such plans.

Section 9. Paragraph (b) of subsection (1) of section 409.975, Florida Statutes, is amended to read:

409.975 Managed care plan accountability.—In addition to

the requirements of s. 409.967, plans and providers participating in the managed medical assistance program shall comply with the requirements of this section.

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

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

1. Faculty plans of Florida medical schools.

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

3. Hospitals licensed as specialty children's hospitals as defined in s. 395.002(28).

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

5. Florida cancer hospitals that meet the criteria in 42 U.S.C. s. 1395ww(d)(1)(B)(v).

Managed care plans that have not contracted with all statewide essential providers in all regions as of the first date of

recipient enrollment must continue to negotiate in good faith. Payments to physicians on the faculty of nonparticipating Florida medical schools shall be made at the applicable Medicaid rate. Payments for services rendered by regional perinatal intensive care centers shall be made at the applicable Medicaid rate as of the first day of the contract between the agency and the plan. Except for payments for emergency services, payments to nonparticipating specialty children's hospitals shall equal the highest rate established by contract between that provider and any other Medicaid managed care plan.

Section 10. Subsections (1), (2), (4), and (5) of section 409.977, Florida Statutes, are amended to read:

409.977 Enrollment.—

(1) The agency shall automatically enroll into a managed care plan those Medicaid recipients who do not voluntarily choose a plan pursuant to s. 409.969. The agency shall automatically enroll recipients in plans that meet or exceed the performance or quality standards established pursuant to s. 409.967 and may not automatically enroll recipients in a plan that is deficient in those performance or quality standards. When a specialty plan is available to accommodate a specific condition or diagnosis of a recipient, the agency shall assign the recipient to that plan. ~~In the first year of the first contract term only, if a recipient was previously enrolled in a plan that is still available in the region, the agency shall automatically enroll the recipient in that plan unless an applicable specialty plan is available.~~ Except as otherwise provided in this part, the agency may not engage in practices that are designed to favor one managed care plan over another.

(2) When automatically enrolling recipients in managed care plans, if a recipient was enrolled in a plan immediately before the recipient's choice period and that plan is still available in the region, the agency must maintain the recipient's enrollment in that plan unless an applicable specialty plan is available. Otherwise, the agency shall automatically enroll based on the following criteria:

(a) Whether the plan has sufficient network capacity to meet the needs of the recipients.

(b) Whether the recipient has previously received services from one of the plan's primary care providers.

(c) Whether primary care providers in one plan are more geographically accessible to the recipient's residence than those in other plans.

~~(4) The agency shall develop a process to enable a recipient with access to employer-sponsored health care coverage to opt out of all managed care plans and to use Medicaid financial assistance to pay for the recipient's share of the cost in such employer-sponsored coverage. Contingent upon federal approval, the agency shall also enable recipients with access to other insurance or related products providing access to health care services created pursuant to state law, including any product available under the Florida Health Choices Program, or any health exchange, to opt out. The amount of financial assistance provided for each recipient may not exceed the amount of the Medicaid premium that would have been paid to a managed care plan for that recipient. The agency shall seek federal approval to require Medicaid recipients with access to employer-sponsored health care coverage to enroll in that coverage and~~

~~use Medicaid financial assistance to pay for the recipient's share of the cost for such coverage. The amount of financial assistance provided for each recipient may not exceed the amount of the Medicaid premium that would have been paid to a managed care plan for that recipient.~~

(4)~~(5)~~ Specialty plans serving children in the care and custody of the department may serve such children as long as they remain in care, including those remaining in extended foster care pursuant to s. 39.6251, or are in subsidized adoption and continue to be eligible for Medicaid pursuant to s. 409.903, or are receiving guardianship assistance payments and continue to be eligible for Medicaid pursuant to s. 409.903.

Section 11. Subsection (2) of section 409.981, Florida Statutes, is amended to read:

409.981 Eligible long-term care plans.—

(2) ELIGIBLE PLAN SELECTION.—The agency shall select eligible plans for the long-term care managed care program through the procurement process described in s. 409.966 through a single statewide procurement. The agency may award contracts to plans selected through the procurement process on a regional or statewide basis. The awards must include at least one provider service network in each of the eight regions outlined in this subsection. The agency shall procure:

(a) At least 3 plans and up to 4 plans for Region A.

(b) At least 3 plans and up to 6 plans for Region B.

(c) At least 5 plans and up to 10 plans for Region C.

(d) At least 3 plans and up to 6 plans for Region D.

(e) At least 3 plans and up to 4 plans for Region E.

(f) At least 3 plans and up to 5 plans for Region F.

(g) At least 3 plans and up to 4 plans for Region G.

(h) At least 5 plans and up to 10 plans for Region H.

~~Two plans for Region 1. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(b) Two plans for Region 2. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(c) At least three plans and up to five plans for Region 3. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(d) At least three plans and up to five plans for Region 4. At least one plan must be a provider service network if any provider service network submits a responsive bid.~~

~~(e) At least two plans and up to four plans for Region 5. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(f) At least four plans and up to seven plans for Region 6. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(g) At least three plans and up to six plans for Region 7. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(h) At least two plans and up to four plans for Region 8. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(i) At least two plans and up to four plans for Region 9. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(j) At least two plans and up to four plans for Region 10. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(k) At least five plans and up to 10 plans for Region 11. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

If no provider service network submits a responsive bid ~~in a region other than Region 1 or Region 2~~, the agency shall procure no more than one less than the maximum number of eligible plans permitted in that region. Within 12 months after the initial invitation to negotiate, the agency shall attempt to procure a provider service network. The agency shall notice another invitation to negotiate only with provider service networks in regions where no provider service network has been selected.

Section 12. Subsection (4) of section 409.8132, Florida Statutes, is amended to read:

409.8132 Medikids program component.—

(4) APPLICABILITY OF LAWS RELATING TO MEDICAID.—The provisions of ss. 409.902, 409.905, 409.906, 409.907, 409.908, 409.912, 409.9121, 409.9122, 409.9123, ~~409.9124,~~ 409.9127, 409.9128, 409.913, 409.916, 409.919, 409.920, and 409.9205 apply to the administration of the Medikids program component of the Florida Kidcare program, except that s. 409.9122 applies to Medikids as modified by the provisions of subsection (7).

Section 13. For the purpose of incorporating the amendment made by this act to section 409.912, Florida Statutes, in references thereto, subsections (1), (7), (13), and (14) of section 409.962, Florida Statutes, are reenacted to read:

409.962 Definitions.—As used in this part, except as otherwise specifically provided, the term:

(1) "Accountable care organization" means an entity qualified as an accountable care organization in accordance with federal regulations, and which meets the requirements of a provider service network as described in s. 409.912(1).

(7) "Eligible plan" means a health insurer authorized under chapter 624, an exclusive provider organization authorized under chapter 627, a health maintenance organization authorized under chapter 641, or a provider service network authorized under s. 409.912(1) or an accountable care organization authorized under federal law. For purposes of the managed medical assistance program, the term also includes the Children's Medical Services Network authorized under chapter 391 and entities qualified under 42 C.F.R. part 422 as Medicare Advantage Preferred Provider Organizations, Medicare Advantage Provider-sponsored Organizations, Medicare Advantage Health Maintenance Organizations, Medicare Advantage Coordinated Care Plans, and Medicare Advantage Special Needs Plans, and the Program of All-inclusive Care for the Elderly.

(13) "Prepaid plan" means a managed care plan that is licensed or certified as a risk-bearing entity, or qualified pursuant to s. 409.912(1), in the state and is paid a prospective per-member, per-month payment by the agency.

(14) "Provider service network" means an entity qualified pursuant to s. 409.912(1) of which a controlling interest is owned by a health care provider, or group of affiliated providers, or a public agency or entity that delivers health services. Health care providers include Florida-licensed health

care professionals or licensed health care facilities, federally qualified health care centers, and home health care agencies.

Section 14. For the purpose of incorporating the amendment made by this act to section 409.912, Florida Statutes, in a reference thereto, subsection (22) of section 641.19, Florida Statutes, is reenacted to read:

641.19 Definitions.—As used in this part, the term:

(22) "Provider service network" means a network authorized under s. 409.912(1), reimbursed on a prepaid basis, operated by a health care provider or group of affiliated health care providers, and which directly provides health care services under a Medicare, Medicaid, or Healthy Kids contract.

Section 15. For the purpose of incorporating the amendments made by this act to section 409.981, Florida Statutes, in references thereto, paragraphs (h), (i), and (j) of subsection (3) and subsection (11) of section 430.2053, Florida Statutes, are reenacted to read:

430.2053 Aging resource centers.—

(3) The duties of an aging resource center are to:

(h) Assist clients who request long-term care services in being evaluated for eligibility for enrollment in the Medicaid long-term care managed care program as eligible plans become available in each of the regions pursuant to s. 409.981(2).

(i) Provide enrollment and coverage information to Medicaid managed long-term care enrollees as qualified plans become available in each of the regions pursuant to s. 409.981(2).

(j) Assist Medicaid recipients enrolled in the Medicaid long-term care managed care program with informally resolving grievances with a managed care network and assist Medicaid

recipients in accessing the managed care network's formal grievance process as eligible plans become available in each of the regions defined in s. 409.981(2).

(11) In an area in which the department has designated an area agency on aging as an aging resource center, the department and the agency shall not make payments for the services listed in subsection (9) and the Long-Term Care Community Diversion Project for such persons who were not screened and enrolled through the aging resource center. The department shall cease making payments for recipients in eligible plans as eligible plans become available in each of the regions defined in s. 409.981(2).

Section 16. This act shall take effect July 1, 2022.

The Florida Senate

Committee Agenda Request

To: Senator Manny Diaz, Jr., Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 12, 2022

I respectfully request that **Senate Bill 1950**, relating to **Statewide Medicaid Managed Care Program**, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Jason Brodeur

Senator Jason Brodeur
Florida Senate, District 9

File signed original with committee office

S-009 (01/2021)

2022 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

BILL INFORMATION	
BILL NUMBER:	SB 1950
BILL TITLE:	Statewide Medicaid Managed Care Program
BILL SPONSOR:	Senator Brodeur
EFFECTIVE DATE:	July 1, 2022

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

CURRENT COMMITTEE
Health Policy

SIMILAR BILLS	
BILL NUMBER:	
SPONSOR:	

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

IDENTICAL BILLS	
BILL NUMBER:	
SPONSOR:	

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

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	1/19/22
LEAD AGENCY ANALYST:	Kristin Sokoloski, Medicaid Program Coordination
ADDITIONAL ANALYST(S):	For any questions, please contact Patrick Steele at (850) 412-3615
LEGAL ANALYST:	
FISCAL ANALYST:	

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

The proposed legislation amends Part IV of Chapter 409, relating to the Statewide Medicaid Managed Care (SMMC) program, as it relates to the recurring competitive procurement of the program contracts to better align procurement and award structure to support the current Medicaid delivery system and market.

In addition to several technical changes to remove obsolete provisions which are no longer applicable given the full implementation of SMMC.

Specifically, the bill makes several substantive changes to improve the quality of care received by Medicaid enrollees and the procurement process for participating SMMC health plans:

- Realigns Florida counties from 11 to 8 SMMC regions, to ensure regions more accurately distribute the Medicaid population and improve access to care.
- Improves the competitive procurement process to align with current operations and increase efficiency for both regional and statewide awards for respondents, evaluators, and negotiators.
- Adds Florida's comprehensive cancer hospitals to essential provider provisions.
- Implements new incentive driven quality measures for plans to ensure Medicaid members are receiving the highest level of care.
- Adds new healthy behaviors program focuses for tobacco and opioid use.
- Clarifies statute to ensure children in permanent guardianship are eligible for enrollment in the child welfare specialty plan.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

Overview of Part IV, Chapter 409, Florida Statutes:

In 2011, the Florida Legislature created Part IV of Chapter 409, Florida Statutes, directing the Agency to create the Statewide Medicaid Managed Care (SMMC) program. In Florida, the majority of Medicaid recipients receive their services through a managed care plan contracted with the Agency under the SMMC program. The SMMC program has three components: the integrated Managed Medical Assistance (MMA) program that provides primary care, acute care and behavioral health care services; Long-Term Care (LTC) program that provides long-term care services, including nursing facility and home and community-based services; and the dental component.

Part IV of Chapter 409 contains numerous specific provisions relating to the requirement that the SMMC plan contracts be competitively procured. The initial structure of the procurement was designed to integrate the fractured system of care for Florida Medicaid enrollees that existed in 2011. This included 15 different waiver programs, a primary case management program (MediPass), and various levels of managed care penetration depending on regional areas, including the Medicaid Reform Pilot in the Jacksonville and Broward areas, limited prepaid health plans providing dental and behavioral health services, as well as child welfare services, and a series of managed care plans providing non-reform services in scattered areas of the state.

Part VI of Chapter 409 is constructed such that: (1) Sections 409.965 through 409.969, F.S., apply to the SMMC program as a whole (including the LTC and MMA components); (2) Sections 409.971 through 409.77, F.S., apply to the MMA program, and (3) Sections 409.978 through 409.985, F.S., apply to the LTC program. Each of these three sections includes parameters relating to program eligibility and enrollment, plan selection, covered benefits, plan accountability, and plan payment, sometimes overlapping and sometimes unique.

During the initial SMMC procurement, the Agency awarded contracts to 18 plans, including seven PSNs. By the end of the first contract period, due to various mergers, acquisitions, and HMO conversions, only one PSN remained (South Florida Community Care Network, DBA Community Care Plan). During the second procurement, the Agency awarded contracts to 16 plans, including five PSNs, (Community Care Plan, Florida Community Care, Lighthouse, Miami Children's, and Vivida) but only three of the PSNs currently remain in the program due to mergers and acquisitions with a total of 10 health plans.

During both procurement cycles, the Agency has awarded specialty plan contracts designed to serve enrollees with specialty conditions including severe mental illness, HIV/AIDS, as well as children with special health care needs, and those involved with Florida's child welfare system. While enrollees entering the program are automatically enrolled in a specialty plan, per statutory requirements, if one is available to accommodate a specific

condition or diagnosis of a recipient, they may also choose to enroll in another MMA plan. Experience has shown that a significant portion of those enrollees choose another plan for their healthcare services. An enhanced capitated rate is paid for people with a specialty condition regardless of whether they are enrolled in a specialty plan.

While plans are awarded contracts on a regional basis, as required by Part IV of 409, a majority of enrollees are served by statewide plans. Experience has shown that regardless of contract awards made initially following procurement, during the lifecycle of each SMMC contract, the market forces have led to various mergers and acquisitions resulting in a reality where a majority of enrollees are receiving services from statewide plans. As of October 1, 2021, 40 percent of the SMMC population, including those enrolled in a specialty plan, were enrolled in a plan operating statewide (i.e., in all 11 regions); 79 percent were enrolled in a plan that operates in a least eight of the 11 regions.

The SMMC program began operation in 2013-2014 under the initial five-year contracts procured by the Agency and the contracts were reprocured by the Agency in 2017-2018 with the new contracts beginning in 2018-2019. In 2020, the Florida legislature extended the time period of the SMMC contracts from five years to six years. As a result, the Agency will conduct the next procurement in 2022-2023 with the new contracts beginning in 2024, which will be the 11th year of operation for the program. Statutory changes are needed to modernize the structure of the procurements use to secure health plan contracts prior to the release of the competitive procurements in late 2022.

Program Established (409.963 and 409.964):

As adopted in 2011, sections 409.963 and 409.964, F.S., designated the Agency as the single state Agency authorized to manage, operate, and make payments for medical assistance and related services under Title XIX of the Social Security Act. Statute also established the SMMC program as a statewide, integrated managed care program for all covered services, including long-term care services.

In 2016, the Florida Legislature passed legislation to carve dental services out of the MMA component of the SMMC program and directed the Agency, by March 2019, to competitively procure dental plans to implement a separate statewide Medicaid prepaid dental health program for children and adults. The Agency awarded contracts to three plans to provide dentals services statewide. The dental plans provide comprehensive dental services to children, state plan dental services to adults, and expanded benefits to adults. All Medicaid recipients whose benefit package includes dental services must enroll in the prepaid dental program to receive those services, including those enrolled in the iBudget and the Medically Needy program.

In 2020, the Florida legislature extended the allowable term of the SMMC contracts, including the dental contracts, from five to six years. As a result, the Agency will conduct the next procurement in 2022-2023 with the new contracts beginning in 2024, which will be the 11th year of operation for the program.

Program Eligibility (409.965, 409.972, 409.979):

These sections outline which Florida Medicaid enrollees are required to enroll in the SMMC program (“mandatory”), which may choose whether to enroll in the SMMC program (voluntary), and which are precluded from enrolling in the SMMC program (“excluded").

Managed Medical Assistance:

Currently, section 409.965 F.S. states that all Medicaid recipients shall receive covered services through the statewide managed care program, except as provided by statute pursuant to an approved federal waiver. The following Medicaid recipients are exempt (or “excluded”) from participation in the statewide managed care program, and continue to receive their medical services through the fee-for-service system:

(1) Women who are eligible only for family planning services.
(2) Women who are eligible only for breast and cervical cancer services (through eligibility for the Florida Department of Health’s Breast and Cervical Cancer program).
(3) Persons who are eligible for emergency Medicaid for aliens.
   i. These are individuals who would be eligible for Medicaid based on being in a group, i.e. a child, pregnant woman, parent or caretaker, etc., and meeting the financial requirements, but they do not meet the technical requirement of being a Florida Resident, a U.S. citizen, and having or applying for a SSN.

Currently section 409.972 states that the following Medicaid-eligible persons are exempt from mandatory managed care enrollment required by s. 409.965, and may voluntarily choose to participate in the managed medical assistance program ("voluntary" population"):
(a) Medicaid recipients who have other creditable health care coverage, excluding Medicare.
(b) Medicaid recipients residing in residential commitment facilities operated through the Department of Juvenile Justice or a treatment facility as defined in s. 394.455(48).
(c) Persons eligible for refugee assistance.
(d) Medicaid recipients who are residents of a developmental disability center, including Sunland Center in Marianna and Tacachale in Gainesville.
(e) Medicaid recipients enrolled in the home and community-based services waiver pursuant to chapter 393, and Medicaid recipients waiting for waiver services.
(f) Medicaid recipients residing in a group home facility licensed under chapter 393.
(g) Children receiving services in a prescribed pediatric extended care center.
(2) Persons eligible for Medicaid but exempt from mandatory participation who do not choose to enroll in managed care shall be served in the Medicaid fee-for-service program as provided under part III of this chapter.

All recipients who are not exempt, pursuant to ss. 409.965 and 409.9722, F.S., from mandatory enrollment must enroll in the MMA component of the SMMC program.

Long-Term Care:

Section 409.979 currently states that Medicaid recipients who meet all of the following criteria are eligible to receive LTC services and must receive these services by participating in the LTC managed care program. There is no fee-for-service delivery system option to receive these LTC services. The recipient must be:
(a) 65 years of age or older, or age 18 or older and eligible for Medicaid by reason of a disability.
(b) Determined by the Comprehensive Assessment Review and Evaluation for Long-Term Care Services (CARES) preadmission screening program to require:
1. Nursing facility care as defined in s. 409.985(3); or
2. Hospital level of care, for individuals diagnosed with cystic fibrosis.

Section 409.979 also outlines the process that the Department of Elder Affairs shall use to offer individuals the opportunity to enroll in the LTC program if it is determined that sufficient funds exist to support additional enrollment while outlining the wait list process. The statute also specifies that individuals who were previously enrolled in one of the following waivers are eligible for participation in the LTC program:
1. Traumatic Brain and Spinal Cord Injury Waiver.
2. Adult Cystic Fibrosis Waiver.
3. Project AIDS Care Waiver.

Individuals excluded from enrolling in the LTC program include:
- Individuals enrolled in the iBudget waiver
- Individuals enrolled in the Program of All-inclusive Care for the Elderly (PACE)
- Individuals residing in a Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID)
- Individuals residing in a State mental hospital

An individual can only enroll in one waiver program under Florida Medicaid. For the groups listed above, if they qualify for enrollment into the LTC program that can choose to disenroll from their current waiver program and enroll in the LTC program.

Eligible Plan Selection (409.966, 409.974, 409.981):

Sections 409.966, 409.974, and 409.981, F.S., outline the requirements for selecting eligible plans to participate in the SMMC program. Section 409.966, F.S., specifies that services shall be provided by eligible plans and that provider service networks must be capable of providing all mandatory SMMC services or may limit the services to a specific target population based on the age, chronic disease state, or medical condition of the enrollee to whom the network will provide services. Section 409.966, F.S. also includes the general quality selection criteria for selecting health plans under the SMMC program and information on administrative challenges to the procurements of the health plans.

Section 409.974, F.S., outlines the structure for the plan selection under the MMA component, including additional quality selection criteria including a requirement that the Agency exercise a preference for plans with a provider network in which over 10 percent of the providers use electronic health records. The section also includes an exemption from procurement for the Children's Medical Services plan and certain Medicare plans.

Section 409.981, F.S., outlines the structure for the plan selection under the LTC component, including additional quality selection criteria and an exemption from procurement for the PACE program and certain Medicare plans.

Currently, section 409.966, F.S, requires the Agency to select a limited number of eligible plans to participate in the Medicaid program using invitations to negotiate in accordance with s. 287.057(1)(c). The Agency is required to conduct separate and simultaneous procurements in the 11 regions specified in statute. Sections 409.974 and 409.981, F.S., currently outline the minimum and maximum number of plans that the Agency must contract with in each region. The current regional structure and information on the statutory minimum and maximum number of plans per region is outlined in the chart below:

REGION	COUNTIES	Min Plans	Max Plans
Region 1	Escambia, Okaloosa, Santa Rosa and Walton	2	2
Region 2	Bay, Calhoun, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Taylor, Wakulla, and Washington	2	2
Region 3	Alachua, Bradford, Citrus, Columbia, Dixie, Gilchrist, Hamilton, Hernando, Lafayette, Lake, Levy, Marion, Putnam, Sumter, Suwannee, and Union	3	5
Region 4	Baker, Clay, Duval, Flagler, Nassau, St. Johns, and Volusia	3	5
Region 5	Pasco and Pinellas	2	4
Region 6	Hardee, Highlands, Hillsborough, Manatee and Polk	4	7
Region 7	Brevard, Orange, Osceola and Seminole	3	6
Region 8	Charlotte, Collier, DeSoto, Glades, Hendry, Lee, and Sarasota	2	4
Region 9	Indian River, Martin, Okeechobee, Palm Beach and St. Lucie	2	4
Region 10	Broward	2	4
Region 11	Miami-Dade and Monroe	5	10

Statute also requires that at least one plan in each region shall be a provider service network if any provider service networks submit a responsive bid. During the initial SMMC procurement, the Agency awarded contracts to 18 plans, including seven PSNs. By the end of the first contract period, due to various mergers, acquisitions, and HMO conversions, only one PSN remained (South Florida Community Care Network, DBA Community Care Plan). During the second procurement, the Agency awarded contracts to 16 plans, including five PSNs, (Community Care Plan, Florida Community Care, Lighthouse, Miami Children's, and Vivida) but only three of the PSNs currently remain in the program due to mergers and acquisitions with a total of 10 health plans.

The table below details the five current types of plans:

Managed Medical Assistance Plan	Long-Term Care Plus Plan	Comprehensive Plan	Specialty Plan	Dental Plan
Provides Managed Medical Assistance services to eligible recipients. This plan type cannot provide services to recipients who are eligible for Long-term Care services.	Provides Managed Medical Assistance (MMA) services and Long-Term Care services to recipients enrolled in the Long-Term Care program. This plan type cannot provide services to recipients who are only eligible for MMA services.	Provides Managed Medical Assistance services and Long-Term Care services to eligible recipients.	Provides Managed Medical Assistance services to eligible recipients who are defined as a specialty population.	Provides preventive and therapeutic dental services to all recipients in managed care and all fully eligible fee-for-service individuals.

Based on the 2017-2018 procurement, as impacted by various mergers, acquisitions and name changes that have occurred since the procurement, the following reflects the currently operational SMMC plans as of October 1, 2021:

STATEWIDE MEDICAID MANAGED CARE (SMMC) HEALTH PLANS
(2018-2024)

REGIONAL ROLLOUT SCHEDULE	REGION	AETNA BETTER HEALTH (COV)	COMMUNITY CARE PLAN (CCP)	FLORIDA COMMUNITY CARE (FCC)	HUMANA MEDICAL PLAN (HUM)	MOLINA HEALTHCARE (MOL)	AMERIHEALTH (PRS)	SIMPLY HEALTHCARE (SHP)	SUNSHINE HEALTH (SUN)	UNITED-HEALTHCARE (URA)	VIVIDA HEALTH (BST)
PHASE 3 2/1/2019	1			FCC LTC+	HUM COMP			SHP MMA	SUN COMP		
	2			FCC LTC+	HUM COMP			SHP MMA	SUN COMP		
	3			FCC LTC+	HUM COMP				SUN COMP	URA COMP	
	4			FCC LTC+	HUM COMP				SUN COMP	URA COMP	
PHASE 2 1/1/2019	5			FCC LTC+	HUM COMP			SHP COMP	SUN COMP		
	6	COV COMP		FCC LTC+	HUM COMP			SHP COMP	SUN COMP	URA COMP	
	7	COV COMP		FCC LTC+	HUM COMP			SHP COMP	SUN COMP		
	8			FCC LTC+	HUM COMP	MOL COMP			SUN COMP		BST MMA
PHASE 1 12/1/2018	9			FCC LTC+	HUM COMP		PRS MMA	SHP MMA	SUN COMP		
	10		CCP MMA	FCC LTC+	HUM COMP			SHP COMP	SUN COMP		
	11	COV COMP		FCC LTC+	HUM COMP	MOL COMP	PRS MMA	SHP COMP	SUN COMP	URA COMP	

COMP = Comprehensive Plan MMA = Managed Medical Assistance Plan LTC+ = Long-Term Care Plus Plan

As of 10-01-2021

SMMC SPECIALTY PLANS
(2018-2024)

REGIONAL ROLLOUT SCHEDULE	REGION	CHILDREN'S MEDICAL SERVICES PLAN - CHILDREN WITH CHRONIC CONDITIONS	CLEAR HEALTH ALLIANCE HIV/AIDS	MOLINA HEALTHCARE SERIOUS MENTAL ILLNESS (SMI)	SUNSHINE SERIOUS MENTAL ILLNESS (SMI)	SUNSHINE HEALTH CHILD WELFARE (CW)
PHASE 3 2/1/2019	1	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
	2	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
	3	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
	4	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC	MOLINA HEALTHCARE SPEC	SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
PHASE 2 1/1/2019	5	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC	MOLINA HEALTHCARE SPEC	SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
	6	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
	7	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC	MOLINA HEALTHCARE SPEC	SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
	8	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
PHASE 1 12/1/2018	9	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
	10	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC
	11	CHILDREN'S MEDICAL SERVICES PLAN SPEC	CLEAR HEALTH ALLIANCE SPEC		SUNSHINE HEALTH SPEC	SUNSHINE HEALTH SPEC

Plan Accountability (409.967. 409.975 and 409.982):

Section 409.967, F.S., outlines the general accountability requirements for the SMMC program including the length of the contracts. The section includes direction that the Agency establish contract requirements necessary to operate the program including requirements related to:

- Physician compensation
- Payment of emergency services
- Provider networks
- Preferred drug lists
- Prior Authorizations
- Coordination of services for children in the care and custody of the Department of Children and Families
- Care coordination for behavior health care services
- Encounter data reporting
- Performance standards for improving performance
- Program integrity
- Grievance resolution
- Penalties
- Electronic claims
- Achieved Saving Rebate
- Medical Loss Ratio

Section 409.967 (3) outlines provisions relating to the Achieved Savings Rebate (ASR). With the implementation of the SMMC program came a move towards greater accountability and transparency. One part of that effort was the inclusion of new financial reporting requirements as part of the authorizing statute. Specifically, Section 409.967 (3) created the ASR program, which requires plans to specific financial data, audited by an independent certified public accountant.

The purpose of the ASR report is to provide the Agency with unaudited quarterly and annual ASR Financial Reports that detail Health Plan financials operations and performance for the applicable reporting period. Based on the ASR, if a plan exceeds a certain percent of revenue, the plan must return a portion of the profits to the state.

The following charts shows the historical final ASR numbers, the total amount of any rebate the plans were required to pay, and the number of plans who had to make a payment:

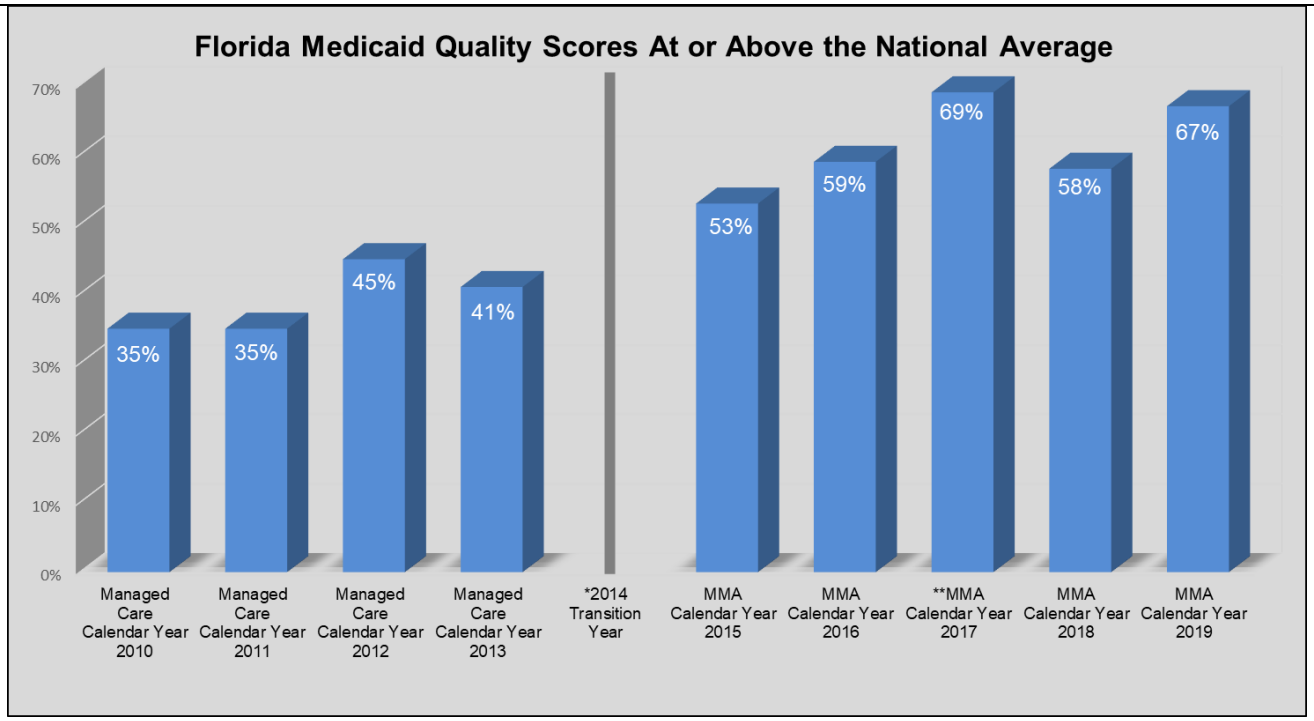
MMA/LTC:

ASR Year	5% current Amount	# of plans
2015	$ 2,373,946	2
2106	$ 30,440,542	4
2017/2018	$ 13,140,788	1
2019	$ 127,889,844	1
2020	$ 218,431,920	8

Dental:

ASR Year	5% current Amount	# of plans
2019	$ 1,409,012	1
2020	$ 55,796,119	3

Section 409.967, F.S., states that each plan must collect and report the Health Plan Employer Data and Information Set (HEDIS) measures, as specified by the Agency. Under the SMMC program, the Florida Medicaid program has seen continual increases in overall performance. The chart below reflects the percent of HEDIS measures that were at or above the national average historically from calendar year 2010 to calendar year 2019.



*Calendar Year 2014 was a transition year between Florida's prior managed care delivery system and the SMMC program implementation. **The HEDIS specifications for the Follow-up After Hospitalization for Mental Illness measure changed for the CY 2017 measurement period. Follow-up visits with a mental health practitioner that occur on the date of discharge are no longer included in the numerator as previously required in the CY 2016 specifications. Florida Medicaid plan rates and statewide weighted means are compared to national means that are calculated using the previous year's service data. Since the CY 2016 and CY 2017 measure specifications do not align, results are not comparable and the measure was excluded.

Section 409.975, F.S., outlines the accountability requirements specifically for the MMA component of the SMMC program including requirements that the plans and participating providers must comply with including requirements related to:

- Provider networks
- Essential and statewide essential providers
- Payment of emergency services
- Florida Medical Schools Quality Network
- Performance measurement
- Momcare network
- Early and Periodic Screening, Diagnosis, and Treatment Service (EPSDT) screening rate
- Provider payment

Section 409.975 (1) outlines requirements relating to essential and statewide essential providers, including that the plans participating in the SMMC program are required to include all providers identified as essential providers by the Agency. The section further specifies that certain providers are statewide resources and essential providers for all managed care plans in all regions. All plans are required to include these essential providers in their networks. Statewide essential providers include:

1. Faculty plans of Florida medical schools.

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

3. Hospitals licensed as specialty children's hospitals as defined in s. 395.002(28).

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

Section 409.982, F.S., outlines the accountability requirements specifically for the LTC component of the SMMC program including requirements that the plans and participating providers must comply with including requirements related to:

- Provider networks
    - Including requirement that Medicaid enrolled nursing homes and hospices must contract with all plans in the region the provider is located
- Performance measurement
- Specific provider network standards
- Provider payment

Managed Care Plan Payments (409.968, 409.976, 409.983):

There are currently three sections of statute, sections 409.968, 409.976, and 409.983, F.S., outlining payment provisions for the SMMC program, including establishing the payment of a capitated rate, requiring that services provided in Prescribed Pediatric Extended Care facilities be reimbursed through the fee-for-service system, requiring that health plans pay the reimbursement rate established by the Agency for the fee-for-service system for SIPP, Nursing facility and hospice services, and establishing the housing assistance pilot program.

Program Enrollment (409.969, 409.977, 409.984):

Florida Statute provides direction to the Agency on how to enroll people into the health plans participating in the program. Statute provides for a 30-day period before plan enrollment for a recipient to choose a plan, and a 90-day period following enrollment during which a recipient can change their plan for any reason. In addition, recipients are allowed to change plans during their open enrollment period or with a state-approved "For Cause" reason at any time following their initial choice period.

Sections 409.977, F.S. and 409.984, F.S., direct the Agency to "automatically enroll into a managed care plan those Medicaid recipients who do not voluntarily choose a plan pursuant to s. 409.969." Enrollees are guaranteed a choice of plans and, if no choice is made, are assigned based on an algorithm which takes into consideration statutory requirements for a preference for Specialty plans and Medicare plans.

SMMC enrollment and assignment consists of the following processes. The enrollment system looks at each of these in this order:

- **Reinstatement**: Reinstatement is applicable to recipients enrolled in managed care who lose Medicaid eligibility for less than 180 days and then regain it. Recipients eligible for reinstatement are enrolled in the last plan in which they were enrolled. (Specialty plans have specific eligibility requirements such as age; if recipients no longer meet those requirements, they will not be enrolled in their prior plan.)
- **Recipient Choice**: If the recipient is not eligible for reinstatement, the system evaluates if the recipient has made a choice of plans. If the recipient chose a plan, they are enrolled with that plan.
- **Auto Assignment**: If the recipient is not eligible for reinstatement and did not make a choice of plan, the recipient is assigned to a plan by the auto-assignment process. Enrollment occurs after each step of the auto assignment process in which the recipient meets the criteria of that step. If auto assignment occurs, the recipient will receive a letter outlining their plan assignment and how to choose a different plan, if they wish.
    - **Newborn**: Parents who are enrolled in Medicaid may select a plan for a newborn prior to the child being born. Recipients who are born without a plan choice on file are assigned to their mother's plan if they are eligible to enroll in that plan. If not, they are assigned based on the auto-assignment algorithm.

The Agency received approval via an amendment to the 1115 MMA waiver in 2015 to implement a process known as Express Enrollment. The Agency submitted this amendment to federal CMS for review after a 30-day public comment period from March 27 through April 26, 2015. The Agency also held two public meetings on April 7 and April 14, 2015. Express enrollment was implemented in January 2016.

Express enrollment removes the 30-day period between eligibility determination and managed care plan enrollment. This allows individuals to be enrolled in a plan immediately upon becoming eligible for Medicaid coverage. Following the implementation of Express Enrollment, instead of the 30-day initial choice period and the following 90-day change period, the process allows individuals to change their plan during the first 120 days of their enrollment. After 120 days, recipients are allowed to change plans during their open enrollment period or with a state-approved "For Cause" reason. Under Express Enrollment, individuals have the option of choosing a managed care plan at the time they submit their Medicaid eligibility application. If an individual does not choose a plan during the application process the Agency will auto-assign them into a plan based on the algorithm described above.

The table below details the number of individuals who changed plans during the calendar year (CY) prior to implementation of express enrollment, the first year of express enrollment, and the most recent full CY. The table further breaks down the number of Medicaid members who changed plans during their 90- or 120-day change period after initial enrollment in a plan, those who changed plans after their 90- or 120-day change periods, and the average monthly enrollment for those time periods. The number of individuals who changed plans after the 90- or 120-day period dropped significantly in CY 2020 due to the alignment with the federal Medicaid Managed Care rule removing the "good cause" reasons for changing plans.

Time Period	Members who Changed Plans During 90 or 120 Day Change Period		Members who Changed Plans After the 90 or 120 Day Change Period		Average Monthly Enrollment
Prior to Express Enrollment (CY 2015)	60,071	2.00%	266,403	8.87%	3,002,799
First Year of Express Enrollment (CY 2016)	157,111	4.93%	245,472	7.71%	3,185,013
Most Recent Year (CY 2020)	102,743	3.19%	125,961	3.91%	3,222,076

Section 409.977 (4), F.S., directed the Agency to develop a process to enable a recipient with access to employer-sponsored health care coverage to opt-out of the SMMC program plans and use Medicaid financial assistance to pay for their employer sponsored health plan premium. On September 20, 2011, the Agency received approval for a State Plan Amendment from federal CMS with an effective date July 1, 2011, to implement this provision as the Health Insurance Premium Payment (HIPP) Program. The state plan was amended in 2013 to make participation in the program a condition of Medicaid eligibility (meaning participation is mandatory for those who qualify). The HIPP program rule was promulgated with an effective date of March 30, 2015, and the first individuals were enrolled in the HIPP program beginning in December 2015. The table below reflects the HIPP program expenditures since implementation through August 2021.

Health Insurance Premium Payment (HIPP) Program Expenditures

Calendar Year	Premium Reimbursements	Premium Reimbursements with Vendor Fee
2017	$76,028.15	$85,513.15
2018	$89,565.29	$98,665.29
2019	$94,742.96	$118,258.37
2020	$95,388.79	$104,908.79
2021 Through August	$91,2363.87	$99,663.87

Medicaid paid the TPL Vendor $60,020.41 to manage the HIPP Program (during the above date span).

Minimum Benefits (409.973 and 409.98):

Currently, Florida statute includes two separate sections, 409.973 and 409.98, F.S., outlining the minimum covered benefits under the MMA and LTC programs. This includes preventive, acute, behavioral, therapeutics services including pharmacy and transportation services under the MMA program and nursing facility, assisted living, and home-based services under the LTC program. Certain services, including Prescribed Pediatric Extended Care and Dental services are specifically excluded by statute. As specified above, in 2016 the Florida Legislature passed legislation to carve dental services out of the Statewide Medicaid Managed Care program and directed the Agency to select dental plans to implement a statewide prepaid dental health program.

Section 409.973, F.S., also outlines the Healthy Behaviors program and states "Each plan operating in the managed medical assistance program shall establish a program to encourage and reward healthy behaviors. At a minimum, each plan must establish a medically approved smoking cessation program, a medically directed weight loss program, and a medically approved alcohol or substance abuse recovery program. Each plan must identify enrollees who smoke, are morbidly obese, or are diagnosed with alcohol or substance abuse in order to establish written agreements to secure the enrollees' commitment to participation in these programs."

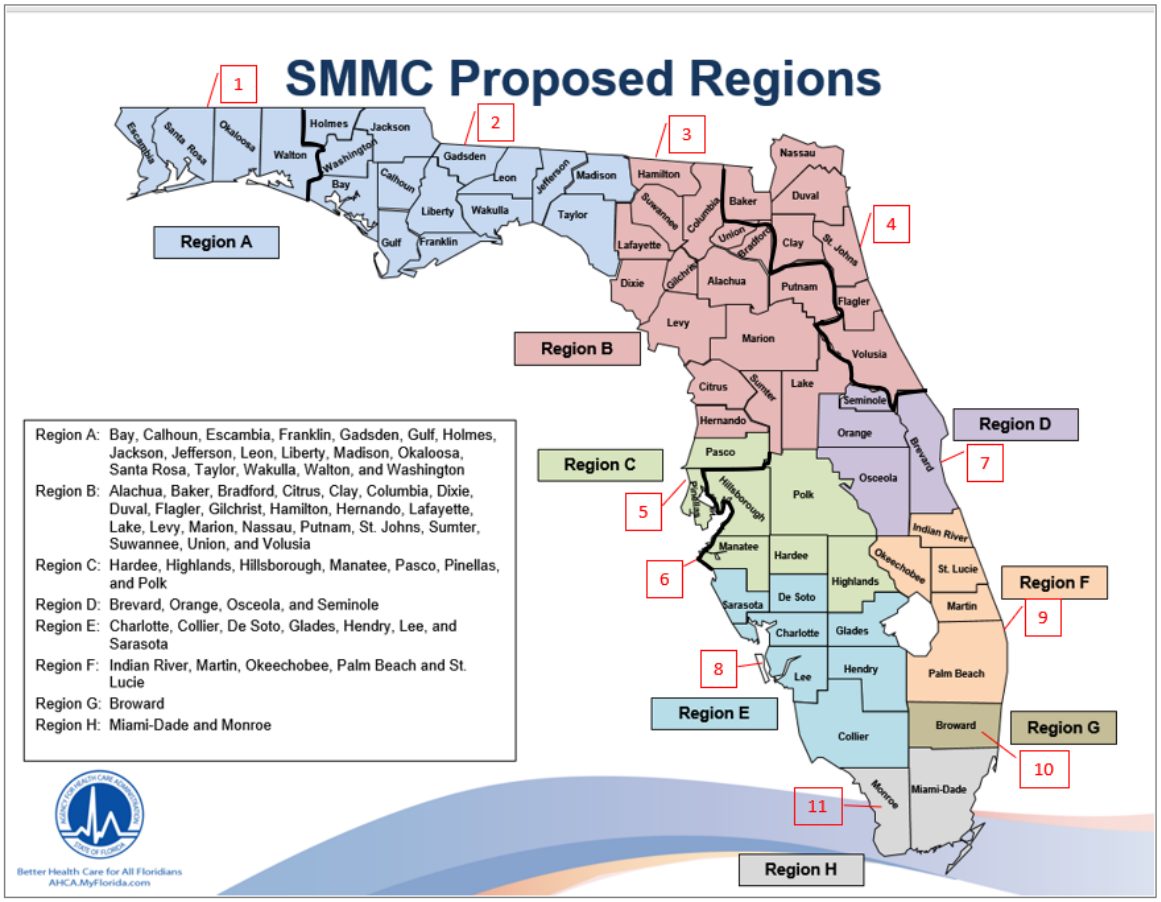
2. EFFECT OF THE BILL:

The proposed legislation amends multiple parts of Part IV of Chapter 409, relating to the SMMC program, as it relates to the recurring competitive procurement of the program contracts, to better align procurement and award structure to support the current Medicaid delivery system and market.

Eligible Plan Selection:

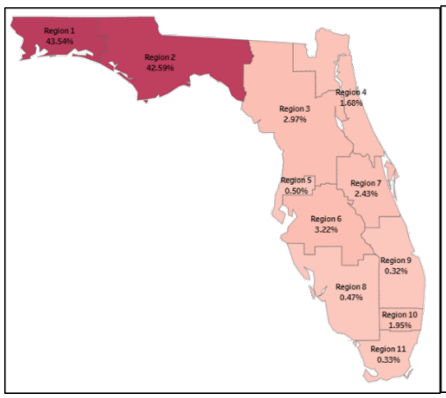
This proposal amends s. 409.966, 409.974, and 409.981 F.S. relating to the selection of participating plans through procurement to allow the Agency to select eligible plans to provide services through a single statewide procurement.

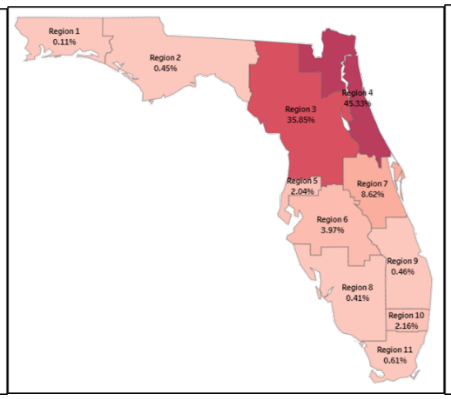
- The Agency would be allowed to award contracts to plans selected through the procurement process either on a regional or statewide basis.
- This means that the Agency would likely award a combination of statewide and regional contracts, based on where regional or statewide awards are deemed to be the best value to the state.
- The proposal outlines a new regional structure for those regional awards, with a minimum and maximum number of plans in each region, which includes eight regions rather than the 11 included in the original statute. The new regional structure combines regions 1 and 2, regions 3 and 4, and regions 5 and 6. The following map and chart outlines the eight regions being proposed:

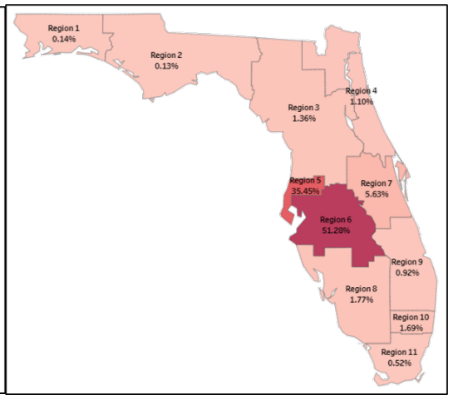


The below referral patterns support the proposed regional structure by looking at the counties where the most services are provided to the enrollees:

Current Regions	Counties	Proposed Regions
Region 1	ESCAMBIA, OKALOOSA, SANTA ROSA, WALTON	**Region A**
Region 2	BAY, CALHOUN, FRANKLIN, GADSDEN, GULF, HOLMES, JACKSON, JEFFERSON, LEON, LIBERTY, MADISON, TAYLOR, WAKULLA, WASHINGTON	
Region 3	ALACHUA, BRADFORD, CITRUS, COLUMBIA, DIXIE, GILCHRIST, HAMILTON, HERNANDO, LAFAYETTE, LAKE, LEVY, MARION, PUTNAM, SUMTER, SUWANNEE, UNION	**Region B**
Region 4	BAKER, CLAY, DUVAL, FLAGLER, NASSAU, ST JOHNS, VOLUSIA	
Region 5	PASCO & PINELLAS	**Region C**
Region 6	HARDEE, HIGHLANDS, HILLSBOROUGH, MANATEE, POLK	
Region 7	BREVARD, ORANGE, OSCEOLA, SEMINOLE	**Region D**
Region 8	CHARLOTTE, COLLIER, DESOTO, GLADES, HENDRY, LEE, SARASOTA	**Region E**
Region 9	INDIAN RIVER, MARTIN, OKEECHOBEE, PALM BEACH, ST LUCIE	**Region F**
Region 10	BROWARD	**Region G**
Region 11	MIAMI-DADE & MONROE	**Region H**







*(County, Region)	Counties where the most services are rendered to members (Changes by selecting county or all from Table Member County)				
Total Amount Paid	Rank: 1	Rank: 2	Rank: 3	Rank: 4	Rank: 5
*All, Region 1 & Region 2 $991.54M	Escambia $273.87M	Leon $164.26M	Bay $96.80M	Okaloosa $82.95M	Santa Rosa $47.45M

*(County, Region)	Counties where the most services are rendered to members (Changes by selecting county or all from Table Member County)				
Total Amount Paid	Rank: 1	Rank: 2	Rank: 3	Rank: 4	Rank: 5
*All, Region 3 & Region 4 $2,805.71M	Duval $744.98M	Alachua $311.89M	Volusia $304.23M	Marion $176.62M	Orange $167.78M

*(County, Region)	Counties where the most services are rendered to members (Changes by selecting county or all from Table Member County)				
Total Amount Paid	Rank: 1	Rank: 2	Rank: 3	Rank: 4	Rank: 5
*All, Region 5 & Region 6 $3,045.90M	Hillsborough $1,025.96M	Pinellas $837.19M	Polk $346.67M	Pasco $242.61M	Orange $127.46M

The proposal amends section 409.966(8), F.S., relating to quality selection criteria, to be used in selecting plans pursuant to the Invitation to Negotiate (ITN), to add a requirement that the Agency exercise a preference for plans with a provider network in which 50 percent of the providers use electronic health records, as defined in s. 408.051 rather than the 10 percent currently specified in statute. This requirement is being added to existing statutory criteria that includes:

- Accreditation by a nationally recognized accrediting body
- Experience serving similar populations
- Availability and accessibility of primary care and specialty physicians in the provider network.
- Establishment of community partnerships that create opportunities for reinvestment in community-based services.
- Organizational commitment to quality improvement
- Provision of additional benefits and other initiatives that improve health outcomes
- Evidence that an eligible plan has written agreements or signed contracts or has made substantial progress in establishing relationships with providers before the plan submitted a response to the ITN.
- Comments submitted in writing by any enrolled Medicaid provider relating to a specifically identified plan participating in the procurement in the same region as the submitting provider
- Documentation of policies and procedures for preventing fraud and abuse
- The business relationship an eligible plan has with any other eligible plan that responds to the ITN
- Evidence of the employment of executive managers with expertise and experience in serving aged and disabled persons who require long-term care.

The proposal also amends s. 409.974, F.S. to specify that the Agency will evaluate and give special weight to plans during the procurement process who have evidence of signed contracts with dentists with hospital privileges for network hospitals.

The proposal also deletes obsolete language related to:

- Negotiating the capitation rates for the first year of the first contract term
- Awarding additional contracts to plans who are awarded contracts in the current regions one and two; the need for this provision is negated by the proposed change to regional structure which mergers current regions 1 and 2 and allows for the award of statewide contracts where appropriate
- Administrative challenges to the invitation to negotiate to reflect the proposed change to a statewide procurement rather than regional procurements.
- Requirement that the Agency includes three years of FFS data in the Databook that must be published 90 days before issuing an invitation to negotiate
    - The Agency does not have three years of FFS data that can be utilized for the Databook.

Plan Accountability:

This proposal amends s. 409.967, F.S. relating to managed care plan accountability to delete obsolete language requiring the Agency to contract, by the end of the fourth year of the first contract term, relating to whether the cost savings could be achieved by contracting for plan oversight and monitoring, as the contract requirement has already been met.

The proposal amends the Achieved Savings Rebate (ASR) provision to change the thresholds relating to profit sharing. The goal of these changes is two-fold: to ensure plans have access to appropriate revenues while returning excess profit to the state and to provide quality performance targets that are sufficiently attainable to

incentivize plans to invest in the program and operational changes that will help them achieve the targets. Under the current structure, the profit threshold at which the plans profit retention changes from the retention of `00% of profits to 50% of profit (e.g., the threshold at which profit sharing begins) is 5%. Under this proposal we would change that threshold to an incremental profit-sharing threshold which would begin at 3%. It should be noted that capitated rates established by the Agency's actuary for the health plans include an element establishing the assumption of a 2% profit margin for participating plans. The chart below displays the proposed changed and its impact on profit retention and profit sharing.

Current Statute	**3%**	**4%**	**5%**	**6%**	**7%**	**8%**	**9%**	**10%**	**11%**
Profit retained with-out meeting original quality benchmarks	**100%**	**100%**	**100%**	**50%**	50%	50%	50%	50%	0%
Profit retained once meet original quality benchmark	**100%**	**100%**	**100%**	**100%**	50%	50%	50%	50%	0%
Proposed Statute	**3%**	**4%**	**5%**	**6%**	**7%**	**8%**	**9%**	**10%**	**11%**
Profit retained without meeting any quality benchmarks	**100%**	50%	50%	50%	50%	50%	50%	50%	0%
Profit retained once new tier one benchmarks are met	**100%**	**100%**	50%	50%	50%	50%	50%	50%	0%
Profit retained once new tier two benchmarks are met	**100%**	**100%**	**100%**	50%	50%	50%	50%	50%	0%

Previously the plans were allowed to retain 50% of income above 5% and up to 10% regardless of if they met the performance measures defined by the Agency while the other 50% was returned to the state. Under the proposed revision, plans could retain an additional 2% of revenue, from 3%-4%, and then again from 4%-5%, for meeting Agency-defined quality or performance targets. If a plan met targets for the 3%-4% threshold and then again for the 4%-5% threshold, plans would ultimately be able to retain the same amount of revenue (5%) before profit sharing as before. The targets for 3%-4% threshold would be lower/easier to attain than that of the 4%-5% threshold. Targets for both thresholds would be set such that they are attainable in order to provide a financial incentive to meet the targets. This language specifies that if a plan fails to meet the quality or performance defined by the Agency that they must return 50% of the income beyond 3% while the other 50% is returned to the state.

The following charts shows the historical final ASR numbers and what the total amount of any rebate the plans would have been required to pay if the threshold was changed to 4% or 3%:

MMA/ LTC

ASR Year	5% current Amount	# of plans	4% Amount	# of plans	3% Amount	# of plans
2015	$ 2,373,946	2	$ 6,013,585	2	$ 13,970,458	3
2106	$ 30,440,542	4	$ 61,993,849	4	$ 81,823,880	5
2017/2018	$ 13,140,788	1	$ 185,811,142	2	$ 251,765,859	5
2019	$ 127,889,844	1	$ 127,944,809	2	$ 128,595,419	3
2020	$ 219,060,774	8	$ 276,389,755	11	$ 355,782,284	14

DENTAL

ASR Year	5% current Amount	# of plans	4% Amount	# of plans3	3% Amount	# of plans2
2019	$ 1,409,012	1	$ 1,950,846	1	$ 2,492,679	1
2020	$ 55,796,119	3	$ 55,796,119	3	$ 55,796,119	3

Managed Care Plan Payments:

This proposal amends s. 409.968, F.S. relating manage care plan payments to delete language allowing PSNs to be either prepaid plans and receive a per-member, per-month payments negotiated pursuant to the procurement process described in s. 409.966, F.S. or they can choose not to be prepaid plans and receive fee-for-service rates with a shared savings settlement. This would require all PSNs to be prepaid plans and receive a per-member, per-month payment.

Minimum Benefits:

The proposal amends the current statutory language related to Healthy Behaviors to remove the focus on smoking tobacco to allow the program to be used for any type of tobacco use while adding additional focus on opioid abuse recovery. While the current statutory language includes focus on obesity and alcohol and substance abuse, in the intervening years since original passed of Part IV of Chapter 409, use of tobacco in the form of smoking and CHEW and the opioid epidemic have come to the forefront.

The proposal also eliminates obsolete language related to the Primary Care Initiative that requires the plans to schedule an appointment with a primary care provider within six months of enrollment in the plan for enrollees who became eligible for Medicaid between January 1, 2014, and December 31, 2015.

Managed Care Plan Accountability:

The proposal amends s. 409.975, F.S. relating to statewide essential providers to add Florida cancer hospitals that meet the criteria in 42 U.S.C. s 1195ww (d) (1) (B) (v). This means that plans will be required to include these essential providers in their networks.

Plan Enrollment:

The proposal amends ss. 409.977 (4), F.S., which directs the Agency to develop a process to enable a recipient with access to employer-sponsored health care coverage to opt-out of the SMMC program plans and use Medicaid financial assistance to pay for their employer sponsored health plan premium.

The bill also amends 409.977 to authorize Medicaid managed care specialty plans to continue serving certain children whose guardians receive guardianships assistance payments under the Guardianship Assistance Program. Specifically, the bill allows children who are in a permanent guardianship situation to be eligible for a child welfare specialty plan, which is in line with children in foster care, extended foster care, or in a subsidized adoption. The bill allows children in permanent guardianship situations to be eligible to receive funding/ benefits from the Title IV-E Guardianship Assistance Program (GAP).

Additionally, the bill amends s. 409.977 by requiring the Agency to automatically enroll recipients in plans that they have previously been enrolled in when auto-enrolling recipients in managed care plans. Specifically, if a recipient was enrolled in a plan immediately before the recipient's choice period and that plan is still available in the region, the agency must maintain the recipient's enrollment in that plan unless an applicable specialty plan is available.

Cost-effective Purchasing of Health Care:

This proposal amends s. 409.912, F.S. to align the definition of PSN with the changes being proposed under s. 409.968, F.S. to clarify that PSNs must be prepaid plans and receive a per-member, per-month payment.

Additionally, the bill exempts PSN's from Part 1 and Part 3 of Chapter 641, but requires the PSN must comply with solvency requirements in s. 641.2261(2) and meet appropriate financial reserve, quality assurance, and patients' rights requirements as established by the Agency.

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:	N/A
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 _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.? REQUIRED 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 ___ N _X__

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 _X__ N ___

Revenues:	This proposal may have a potential for cost savings to the Medicaid program. Currently statute allows the plans to retain 100% of income up to and including 5% of revenue. Based on the 2020 Pre-Audit calculation of the Achieved Saving Rebate (ASR), the Agency is receiving $274,856,894 in ASR payments from the Health Plans (18 Plans, which includes Plans that had been merged or acquired in 2021). Using the 2020 Pre-Audits as a proxy, if the ASR threshold was to have been changed to 3%, the Agency would receive approximately $411,578,403 in ASR payments from the Health Plans. Similarly, if the threshold was adjusted to 4%, the Agency would receive approximately $332,185,874 in ASR payment from the Health Plans. There will be a fiscal impact because the Child Welfare Specialty Plan capitation rate category is higher than the rates for most children. The precise fiscal impact of children becoming newly eligible for the specialty plans cannot be calculated without knowing the AHCA region in which an eligible child resides and the capitation rate category in which the child is currently categorized. This is because Medicaid capitation rates vary by region and children could be in a myriad of different rate cells based on age, gender, Medicaid eligibility category, and other characteristics. The Agency has calculated an estimated maximum fiscal impact based on rate year 2020-21 based on an estimate of 4,120 children who currently would be eligible for the change in plans. The maximum impact is slightly over $1,000,000 per month or $12.2 million annually ($4.7 million General Revenue). This estimated fiscal assumes the 3,765 qualified children are in the lowest TANF 0-13 rate cell and 355 children are in the lowest TANF 14+ rate cell and are switching into the Child Welfare rate cell.
Expenditures:	N/A
Does the legislation contain a State Government appropriation?	N/A
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:	N/A
Expenditures:	N/A
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.	

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

The Agency would recommend an amendment beginning on line 856 to remove the proposed deletion of the Health Insurance Premium Payment (HIPP) Program referenced in s. 409.977(4), F.S.

LEGAL – GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	

From: Zander, Lindsey
To: Smith, Kelly
Cc: Steele, Patrick; Sokoloski, Kristin; Brown, Allen; Farrill, Cody
Subject: RE: SB 1950 - Senate Analysis Questions
Date: Monday, January 24, 2022 12:09:17 PM
Attachments: image001.png

Kelly, please see the Agency's responses below:

1. I believe in one of our prior meetings, AHCA indicated that over 80% of providers currently use electronic health records. (In regards to s. 409.974(2), F.S.) Would it be possible to get that number in writing from you all, either in a separate email or a document that I can cite to in the analysis?
   80% is not a definitive number, but one the Agency feels comfortable with at this time.

2. Thank you for providing financial data for the HIPP program! Would it be possible to give us the number of current participants in the program? As with above, something that I can cite to would be wonderful.
   As of August 2021, we had 53 eligible members.

3. On a different note - I'm struggling to wrap my mind around the 2024 transition year. Current contracts now expire 12/31/24, but the new contracts also start in 2024. The actual coverage period is 2025-2030. I know that the transition typically happens in phases and that during the last procurement cycle the phases started in Dec and ended in Feb. Would you be able to give me a call and explain what 2024 will look like? I have the following written in the analysis, but I want to be sure to get it right and to say it clearly.

The SMMC program was fully implemented in August 2014 and was re-procured for a period beginning December 2018 and ending in December 2023. In 2020, the Legislature extended the allowable term of the SMMC contracts from 5 to 6 years. As a result, the AHCA will conduct its next procurement in 2022-2023 with the new contracts beginning in 2024.

The current contacts are effective through December 31, 2024. Our anticipated timeline for the procurement and transition to new plans, which is of course preliminary, is:

- Post procurement: Fall of 2022
- Finalize awards: End of 2023
- Transition to new contracts: End of 2024

Procurement Timeline

This is high level and best case scenario in nature. We've limited this rough draft to quarters of the year rather than landing on a specified Month/Day. This should reinforce the need that the changes occur this session in order to provide adequate time to draft, advertise, evaluate, negotiate, and award new contracts AND provide sufficient lead time for transition during the 2024 calendar year.

SMMC	
Activity	**Date**

Posting Date	LATE FALL 2022
Q&A Posting Date	WINTER 2023
Responses Due	SPRING 2023
Responses Opened	SPRING 2023
Evaluations Begin	LATE SPRING 2023
Evaluations End	LATE SUMMER 2023
Negotiations Begin	FALL 2023
Negotiations End	FALL 2023/WINTER 2024

Lindsey Zander
Legislative Affairs Director
Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, FL 32308
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1/26/22
Meeting Date

Health Policy
Committee

The Florida Senate
APPEARANCE RECORD

Deliver both copies of this form to
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1950
Bill Number or Topic

Amendment Barcode (if applicable)

Name VICTORIA ZEPP

Phone 850 241 6305

Address 310 W. College Ave.
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Email VICTORIA@Team180.com

TLH 32301
City State Zip

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

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing: FL Coalition for Children

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

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01/26/2022
Meeting Date

Health Policy
Committee

SB 1980
Bill Number or Topic

Amendment Barcode (if applicable)

Name Sarah Nemes, Embrace Families Phone 407-592-1732

Address 4001 Pelee Street Email sarah-nemes@embrace.families.org

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City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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S-001 (08/10/2021)

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The Florida Senate

APPEARANCE RECORD

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1/26/22
Meeting Date

Health Policy
Committee

SB 1950
Bill Number or Topic

Amendment Barcode (if applicable)

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City State Zip

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PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

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1-26-21
Meeting Date

SB 1950
Bill Number or Topic

Committee

Amendment Barcode (if applicable)

Name Cody Farrill

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Tallahassee FL 32308
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Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

Agency For Health Care Administration

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

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 1184
INTRODUCER:	Health Policy Committee and Senator Broxson
SUBJECT:	Free Speech of Health Care Practitioners
DATE:	January 26, 2022
REVISED:	

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

Please see Section IX. for Additional Information:

PLEASE MAKE SELECTION

I. Summary:

CS/SB 1184 prohibits regulatory boards within the Department of Health (DOH), or the DOH if there is no applicable board, from reprimanding, sanctioning, revoking or threatening to revoke a license, certificate, or registration of a health care practitioner for exercising his or her constitutional right of free speech, including speech through the use of a social media platform.

The bill requires a regulatory board, or the DOH if there is no applicable board, to prove beyond a reasonable doubt that the use of free speech by a health care practitioner led to the direct physical harm of a person with whom the health care practitioner had a practitioner-patient relationship within the three years immediately preceding the incident of physical harm in order to reprimand, sanction, or revoke or threaten to revoke, a license, certificate, or registration of the health care practitioner for his or her speech. The bill specifies that if the board or the DOH fails to meet such burden of proof and reprimands, sanctions, or revokes or threatens to revoke, a license, certificate, or registration of the health care practitioner for his or her speech, the board or the DOH is liable for a sum of up to $1.5 million per occurrence for direct or indirect damages to the health care practitioner.

The bill requires such regulatory board, or the DOH if there is no applicable board, to provide the health care practitioner with any complaint it has received that may result in revocation of licensure, certification, or registration, within seven days after receiving the complaint. If the board or the DOH fails to provide such a complaint, it must pay the practitioner an administrative penalty of $500 each day the complaint is not provided to the practitioner.

The bill provides an effective date of July 1, 2022.

II. Present Situation:

Department of Health Regulation

The Florida Department of Health (DOH) is responsible to regulate health practitioners for the preservation of the health, safety, and welfare of the public.[1] Chapter 456 of the Florida Statutes governs health professions and occupation regulated by the DOH. For purposes of ch. 456, F.S. the term "health care practitioner" includes any person licensed under:

- Chapter 457 (Acupuncturists);
- Chapter 458 (Physicians);
- Chapter 459 (Osteopathic Physicians);
- Chapter 460 (Chiropractors);
- Chapter 461 (Podiatrists);
- Chapter 462 (Naturopathic Physicians);
- Chapter 463 (Optometrists);
- Chapter 464 (Nurses);
- Chapter 465 (Pharmacists);
- Chapter 466; (Dentists, Dental Hygienists);
- Chapter 467 (Midwives);
- Part I of chapter 468 (Speech Language Pathologists, Audiologists);
- Part II of chapter 468 (Nursing Home Administrators);
- Part III of chapter 468 (Occupational Therapists);
- Part V of chapter 468 (Respiratory Therapists);
- Part X of chapter 468 (Dietitian/nutritionists, Nutrition Counselor);
- Part XIII of chapter 468 (Athletic Trainers);
- Part XIV of chapter 468 (Orthotists, Pedorthists, Prosthetists);
- Chapter 478 (Electrologists);
- Chapter 480 (Massage Therapists);
- Part I of chapter 483 (Clinical Laboratory Personnel);
- Part II of chapter 483 (Medical Physicists);
- Part III of chapter 483 (Genetic Counselors);
- Chapter 484 (Opticians and Hearing Aid Specialists);
- Chapter 486 (Physical Therapists);
- Chapter 490 (Psychologists); and
- Chapter 491 (Psychotherapists, Clinical Social Workers, Marriage and Family Therapists, Mental Health Counselors).

Due to the diverse practices and differences between these health care professions, various licensing Boards exist within the DOH to ensure that health care practitioners are meeting the minimum requirements for safe practice in each practice area. The Division of Medical Quality

[1] Section 20.42(1)(g), F.S.

Assurance within the DOH serves as the principle administrative support unit for the Boards.[2] The Boards are supported by a full-time professional staff based in Tallahassee. Board members are appointed by the governor and are subject to confirmation by the Senate. The following Boards exist within the DOH:

- Board of Acupuncture.
- Board of Occupational Therapy.
- Board of Athletic Trainers.
- Board of Opticianry.
- Board of Chiropractic Medicine.
- Board of Optometry.
- Board of Clinical Laboratory Personnel.
- Board of Orthotists and Prosthetists.
- Board of Clinical Social Work, Marriage & Family Therapy, and Mental Health Counseling.
- Board of Osteopathic Medicine.
- Board of Dentistry.
- Board of Pharmacy.
- Board of Hearing Aid Specialists.
- Board of Physical Therapy.
- Board of Massage.
- Board of Podiatric Medicine.
- Board of Medicine.
- Board of Psychology.
- Board of Nursing.
- Board of Respiratory Care.
- Board of Nursing Home Administrators.
- Board of Speech-Language Pathology and Audiology.[3]

Grounds for Discipline and Penalties

Section 456.072(1), F.S., sets out 45 separate grounds for discipline for health care practitioners. These grounds address criminal activity, fraud, sexual harassment, practicing under the influence, making misleading, deceptive, untrue or fraudulent representations in or related to the practice of the licensee's profession, and many other situations.

When the board, or the department when there is no board, regulating the applicable health care profession, finds a health care practitioner guilty of any of the grounds set forth in the health care practitioner's applicable practice act or rules adopted thereunder, of violating any of the 45 separate grounds for discipline listed in s. 456.072(1), F.S., or of substantially violating the grounds for discipline within that subsection prior to obtaining a license, the board or department may issue an order:

- Refusing to license the individual.
- Suspending or permanently revoking a license.

[2] Florida Department of Health, Boards and Councils *available at* http://www.floridahealth.gov/licensing-and-regulation/boards-and-councils.html (last visited Jan. 24, 2022).
[3] *Id.*

- Restricting the practice or license, including, but not limited to, restricting the licensee from practicing in certain settings, restricting the licensee to work only under designated conditions or in certain settings, restricting the licensee from performing or providing designated clinical and administrative services, restricting the licensee from practicing more than a designated number of hours, or any other restriction found to be necessary for the protection of the public health, safety, and welfare.
- Imposing an administrative fine not to exceed $10,000 for each count or separate offense. If the violation is for fraud or making a false or fraudulent representation, the board, the fine must be $10,000 per count or offense.
- Issuing of a reprimand or letter of concern.
- Putting the licensee on probation, subject to conditions which may include, but are not limited to, requiring the licensee to undergo treatment, attend continuing education courses, submit to be reexamined, work under the supervision of another licensee, or satisfy any terms which are reasonably tailored to the violations found.
- Issuing corrective action.
- When the health care provider fails to make available to patients a summary of their rights, imposing an administrative fine of up to $100 for nonwillful violations and up to $500 for willful violations.[4]
- Requiring the fund fees billed and collected from the patient or a third party on behalf of the patient.
- Requiring remedial education.[5]

In determining what action is appropriate, the board, or the DOH if there is no board, must first consider what sanctions are necessary to protect the public or to compensate the patient. After those sanctions are considered, the board or department may consider rehabilitating the practitioner. The health care practitioner is responsible for all costs associated with the compliance of such orders.[6]

If the ground for disciplinary action is the first-time violation of a practice act for unprofessional conduct and no actual harm to the patient occurred, the board or department, as applicable, shall issue a citation and assess a penalty as determined by rule of the board or department.[7]

Freedom of Speech

The First Amendment of the United States Constitution protects the right to freedom of expression from government interference. The First Amendment is applicable to the states through the Due Process Clause of the Fourteenth Amendment.[8] "The First Amendment assures the broadest tolerable exercise of free speech, free press, and free assembly, not merely for religious purposes, but for political, economic, scientific, news, or informational ends as well."[9]

[4] Section 381.0261(4), F.S.
[5] Section 456.072(2), F.S.
[6] *Id.*
[7] Section 456.072(3)(b), F.S.
[8] *See De Jonge v. Oregon*, 299 U.S. 353, 364–65(1937) (incorporating right of assembly); *Gitlow v. New York*, 268 U.S. 652, 666 (1925) (incorporating right of freedom of speech).
[9] *Douglas v. City of Jeannette (Pennsylvania)*, 319 U.S. 157, 179, (1943) (Jackson, J., concurring in result).

It is well established that a government regulation based on the content of speech is presumptively invalid and will be upheld only if it is necessary to advance a compelling governmental interest, precisely tailored to serve that interest, and is the least restrictive means available for establishing that interest.[10] The government bears the burden of demonstrating the constitutionality of any such content-based regulation.[11] "Falsity alone may not suffice to bring the speech outside the First Amendment; the statement must be a knowing and reckless falsehood."[12]

In regards to speech made on internet platforms, the Supreme Court has clarified, "Online speech is equally protected under the First Amendment as there is 'no basis for qualifying the level of First Amendment scrutiny that should be applied' to online speech."[13]

Professional Speech

In 2018, the U.S. Supreme Court clarified that professional speech of individuals who perform personalized services that require a professional license from the state is not a separate category of speech exempt from the rule that content-based regulations of speech are subject to strict scrutiny.[14] Justice Thomas delivered the opinion of the court, "The dangers associated with content-based regulations of speech are also present in the context of professional speech. As with other kinds of speech, regulating the content of professionals' speech poses the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to suppress unpopular ideas or information."[15] "When the government polices the content of professional speech, it can fail to preserve an uninhibited marketplace of ideas in which truth will ultimately prevail."[16]

III. Effect of Proposed Changes:

The bill creates s. 456.61, F.S., which prohibits regulatory boards within the DOH, or the DOH if there is no applicable board, from reprimanding, sanctioning, revoking or threatening to revoke a license, certificate, or registration of a health care practitioner for exercising his or her constitutional right of free speech, including speech through the use of a social media platform.[17]

The bill requires a regulatory board, or the DOH if there is no applicable board, to prove beyond a reasonable doubt that the use of free speech by a health care practitioner led to the direct physical harm of a person with whom the health care practitioner had a practitioner-patient relationship within the three years immediately preceding the incident of physical harm in order to reprimand, sanction, or revoke or threaten to revoke, a license, certificate, or registration of the health care practitioner for his or her speech. The bill specifies that if the board or the DOH fails to meet such burden of proof and reprimands, sanctions, or revokes or threatens to revoke, a license, certificate, or registration of the health care practitioner for his or her speech, the board

[10] *Ashcroft v. Am. Civil Liberties Union,* 542 U.S. 656, 665-66 (2004).
[11] *Id.* at 660.
[12] See *U.S. v. Alvarez*, 617 F. 3d 1198 (2012) and *New York Times v. Sullivan*, 376 U.S. 254 (1964).
[13] *Reno v. Am. Civil Liberties Union*, 521 U.S. 844, 870 (1997).
[14] Nat'l Inst. of Family & Life Advocates v. Becerra, 138 S. Ct. 2361, 2365 (2018).
[15] *Id.* at 2374.
[16] *Id.* at 2366.
[17] See section 501.2041(1)(g), F.S.

or the DOH is liable for a sum of up to $1.5 million per occurrence for direct or indirect damages to the health care practitioner.

The bill requires such regulatory board, or the DOH if there is no applicable board, to provide the health care practitioner with any complaint it has received that may result in revocation of licensure, certification, or registration, within seven days after receiving the complaint. If the board or the DOH fails to provide such a complaint, it must pay the practitioner an administrative penalty of $500 each day the complaint is not provided to the practitioner.

The bill provides an effective date of July 1, 2022.

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:

Subsection (2) of s. 456.61, F.S., as created in the bill, appears to establish a civil cause of action that authorizes a court to award a sum of up to $1.5 million per occurrence to a health care practitioner when the DOH or a board within its jurisdiction fails to meet the

required burden of proof. It is probable that this bill would have a negative fiscal impact resulting from increased litigation for the DOH and its boards.

VI. Technical Deficiencies:

None.

VII. Related Issues:

It is possible that this bill may be interpreted to conflict with authorizations in s. 456.072(1)(a) and (m), F.S., and other similar grounds for discipline in a health care practitioner's applicable practice act or rules adopted thereunder.

Section 456.072(1)(a), F.S. authorizes discipline for a practitioner making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession.

Section 456.072(1)(m), F.S., authorizes discipline for a practitioner making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or scheme in or related to the practice of a profession.

On July 29, 2021, the Federation of State Medical Boards, issued the following statement:
"Physicians who generate and spread COVID-19 vaccine misinformation or disinformation are risking disciplinary action by state medical boards, including the suspension or revocation of their medical license. Due to their specialized knowledge and training, licensed physicians possess a high degree of public trust and therefore have a powerful platform in society, whether they recognize it or not. They also have an ethical and professional responsibility to practice medicine in the best interests of their patients and must share information that is factual, scientifically grounded and consensus-driven for the betterment of public health. Spreading inaccurate COVID-19 vaccine information contradicts that responsibility, threatens to further erode public trust in the medical profession and puts all patients at risk."[18]

Ultimately, the DOH and the boards established within it are responsible to regulate health practitioners for the preservation of the health, safety, and welfare of the public. This bill does not protect speech that is not already protected under the U.S. and Florida constitutions. Rather, it prohibits the DOH and its boards from administratively penalizing a person exercising free speech unless it meets a specific burden of proof. The $1.5 million liability established in the bill may deter the DOH and the boards from taking action against health care practitioners in their efforts to preserve the health, safety, and welfare of the public.

[18] Federation of State Medical Boards, FSMB: Spreading COVID-19 Vaccine Misinformation May Put Medical License at Risk (July 29, 2021) *available at* https://www.fsmb.org/advocacy/news-releases/fsmb-spreading-covid-19-vaccine-misinformation-may-put-medical-license-at-risk/ (last visited Jan. 24, 2022).

VIII. Statutes Affected:

This bill creates section 456.61 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 January 26, 2022:
The CS clarifies that the provisions of the bill apply to all speech made by a health care practitioner and not solely to speech conveyed through the use of social media. It also clarifies that any cause of action established in the bill must be related to the health care practitioner's speech. The CS deletes the reference to recognizing agencies approved by the Board of Osteopathic Medicine so that the provisions of the bill would no longer apply to those recognizing agencies.

B. Amendments:

None.

646934

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/26/2022	.	
	.	
	.	
	.	

The Committee on Health Policy (Broxson) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 456.61, Florida Statutes, is created to read:

456.61 Use of free speech by a health care practitioner; prohibition.—

(1) A board, or the department if there is no board, may not reprimand, sanction, or revoke or threaten to revoke a

646934

license, certificate, or registration of a health care practitioner for exercising his or her constitutional right of free speech, including, but not limited to, speech through the use of a social media platform as defined in s. 501.2041(1)(g).

(2) To reprimand, sanction, or revoke or threaten to revoke a license, certificate, or registration of a health care practitioner for his or her speech, the board, or the department if there is no board, must prove beyond a reasonable doubt that the health care practitioner's speech led to the direct physical harm of a person with whom the health care practitioner had a practitioner-patient relationship within the 3 years immediately preceding the incident of physical harm. If the board or the department, as applicable, reprimands, sanctions, revokes, or threatens to revoke a license, certificate, or registration of a health care practitioner for his or her speech, and proof beyond a reasonable doubt has not been established under this subsection, the board or the department is liable for a sum of up to $1.5 million per occurrence for any direct or indirect damages to a health care practitioner.

(3) The board, or the department if there is no board, must provide a health care practitioner with any complaints it has received which may result in the revocation of the health care practitioner's license, certification, or registration, within 7 days after receipt of the complaint. The board, or the department if there is no board, must pay the health care practitioner an administrative penalty of $500 for each day the complaint is not provided to the health care practitioner after the specified 7 days.

Section 2. This act shall take effect July 1, 2022.

646934

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to free speech of health care practitioners; creating s. 456.61, F.S.; prohibiting certain regulatory boards and the Department of Health from reprimanding, sanctioning, or revoking or threatening to revoke a license, certificate, or registration of a health care practitioner for specified use of his or her right of free speech without specified proof; providing for liability; requiring the board or department, as applicable, to provide to a health care practitioner certain complaints within a specified timeframe; providing a penalty; providing an effective date.

By Senator Broxson

1-01388-22 20221184__

A bill to be entitled

An act relating to free speech of health care practitioners; creating s. 456.61, F.S.; prohibiting certain entities from reprimanding, sanctioning, or revoking or threatening to revoke a license, certificate, or registration of a health care practitioner for specified use of his or her right of free speech without specified proof; providing for liability; requiring certain entities to provide to a health care practitioner any complaints within a specified timeframe; providing a penalty; providing an effective date.

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

Section 1. Section 456.61, Florida Statutes, is created to read:

456.61 Use of free speech by a health care practitioner; prohibition.—A board within the jurisdiction of the department, the department if there is no board, or a recognizing agency approved by the Board of Osteopathic Medicine under rule 64B15-14.001, Florida Administrative Code:

(1) May not reprimand, sanction, or revoke or threaten to revoke a license, certificate, or registration of a health care practitioner for exercising his or her constitutional right of free speech through the use of a social media platform as defined in s. 501.2041(1)(g).

(2) Must prove beyond a reasonable doubt that the use of free speech by a health care practitioner led to the direct

1-01388-22 20221184__

physical harm of a person with whom the health care practitioner had a practitioner-patient relationship within the 3 years immediately preceding the incident of physical harm to reprimand, sanction, or revoke or threaten to revoke a license, certificate, or registration of a health care practitioner.

(3) Is liable for a sum of up to $1.5 million per occurrence for any direct or indirect damages to a health care practitioner if proof beyond a reasonable doubt has not been established under subsection (2) for reprimanding, sanctioning, or revoking or threatening to revoke a license, certificate, or registration of the health care practitioner.

(4) Must provide to a health care practitioner any complaints received for which revocation actions may be in order within 7 days after receipt of the complaint or, if it fails to provide such complaint, must pay to the health care practitioner an administrative penalty of $500 for each day the complaint is not provided to the health care practitioner.

Section 2. This act shall take effect July 1, 2022.

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

The Florida Senate

Committee Agenda Request

To: Senator Manny Diaz, Jr., Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 10, 2022

I respectfully request that **Senate Bill # 1184**, relating to Free Speech of Health Care Practitioners, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Doug Broxson
Florida Senate, District 1

File signed original with committee office

S-020 (03/2004)

The Florida Senate

APPEARANCE RECORD

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1/26/22
Meeting Date

Senate Health Policy
Committee

SB 1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name William Platt

Phone 850 276 1417

Address 501 N 9th St
Street

Email wgp3@hotmail.com

Lynn Haven FL 32444
City State Zip

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

PLEASE CHECK ONE OF THE FOLLOWING:

☒ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

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Meeting Date

Senate Health Policy
Committee

SB 1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name Dawn Dawn

Phone 321 305-6909

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Street

Email cocoapharmacy@gmail.com

Cocoa FL 32922
City State Zip

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

PLEASE CHECK ONE OF THE FOLLOWING:

☒ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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1/26/2022
Meeting Date

Health Policy
Committee

SB 1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name P.G. Schafer

Phone 352-302-3023

Address 2015 SW 43rd Place
Street

Email pgschafer1@aol.com

Ocala FL 34471
City State Zip

Speaking: [X] For [ ] Against [ ] Information **OR** Waive Speaking: [ ] In Support [ ] Against

PLEASE CHECK ONE OF THE FOLLOWING:

[X] I am appearing without compensation or sponsorship.

[ ] I am a registered lobbyist, representing:

[ ] I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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2/26/22
Meeting Date

Health Policy
Committee

SB1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name Robert Schmidt

Phone 860 367 7320

Address 11488 SW 82nd CT Rd
Street

Email rds bobby@aol.com

Ocala FL 34481
City State Zip

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

PLEASE CHECK ONE OF THE FOLLOWING:

☒ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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S-001 (08/10/2021)

The Florida Senate

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1/26/22
Meeting Date

Health Services
Committee

SB 1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name Brigitte Smith

Phone 727 484 1124

Address 4275 SW 85th ave
Street

Email

Ocala FL 34481
City State Zip

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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S-001 (08/10/2021)

The Florida Senate

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1/26/22
Meeting Date

Health
Committee

SB 1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name ~~DR~~ John Littell MD

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Street

Email jlittellmd@gmail.com

Ocala FL 34482
City State Zip

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

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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The Florida Senate

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Jan. 26. 2022
Meeting Date

Health Policy
Committee

SB 1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name Carmen Soto

Phone -

Address PO Box 1643
Street

Email -

Ocala FL 34478
City State Zip

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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S-001 (08/10/2021)

The Florida Senate

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1/26/22
Meeting Date

Health Policy
Committee

1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name Aaron DiPietro

Phone 904-608-4471

Address 4853 S. Orange Ave
Street

Email aarond@flfamily.org

Orlando FL 32806
City State Zip

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing: Florida Family Policy Council

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

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1/26/22
Meeting Date

Health Policy
Committee

SB 1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name Jon Harris Maurer

Phone

Address 201 E. Park Ave, Ste. 200A
Street

Email jonharris@equalityflorida.org

Tallahassee FL 32301
City State Zip

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

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☒ I am a registered lobbyist, representing: Equality Florida

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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01/26/22
Meeting Date

Health Policy
Committee

SB 1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name Jon Ward

Phone 850-867-7503

Address 247 S Copeland Dr
Street

Email jonward16@yahoo.com

PC FL 32401
City State Zip

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

PLEASE CHECK ONE OF THE FOLLOWING:

☒ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

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1-26-21
Meeting Date

HEALTH POLICY
Committee

1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name BILL BUNKLEY

Phone 813.264.2977

Address PO BOX 341644
Street

Email BILL@FGALC.ORG

TAMPA FL 33694
City State Zip

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

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

FLORIDA ETHICS & RELIGIOUS LIBERTY COMMISSION

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

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1-26-22
Meeting Date

Health Policy
Committee

SB 1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name Devon Graham

Phone

Address
Street

Email

City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☑ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.
volunteer @ American Atheists

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

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1-26-22
Meeting Date

Health Policy
Committee

SB 1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name Stacey Bearden

Phone 352 817-3944

Address P.O. Box 771492
Street

Email sbeardens@aol.com

Ocala FL
City State Zip

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

PLEASE CHECK ONE OF THE FOLLOWING:

☒ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

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1/26/2022
Meeting Date

Health Policy
Committee

SB 1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name Jeff Wiita

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Address 9517 SW 94th Loop
Street

Email jeffwiita@yahoo.com

Ocala FL 34481
City State Zip

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

PLEASE CHECK ONE OF THE FOLLOWING:

☒ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

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Senate professional staff conducting the meeting

1/26/22
Meeting Date

Health Policy
Committee

SB1184
Bill Number or Topic

Amendment Barcode (if applicable)

Name John Berry

Phone 352 598 7355

Address 640 SE 25 PL apt B
Street

Email JCFberry@gmail.com

Ocala FL 34471
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

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01.26.2022
Meeting Date

SB 1184
Bill Number or Topic

Senate Health Policy
Committee

Amendment Barcode (if applicable)

Name Wolfe, Waneda

Phone 850 814-8400

Address 100 Doctors Dr Suite C
Street

Email wanedawolfe@protonmail.com

Panama City FL 32405
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

1/26/2022
Meeting Date

Health Policy
Committee

1184
Bill Number or Topic

646934
Amendment Barcode (if applicable)

Name Ellen W. McKnight, M.D.

Phone 850-380-3672

Address 20 High Point Dr
Street

Email mcknightmd@summitarthritis.com

Gulf Breeze FL ~~32~~ 32561
City State Zip

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

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S-001 (08/10/2021)

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 1260
INTRODUCER:	Senator Gruters
SUBJECT:	Conversion of a Public Health Care System
DATE:	January 25, 2022
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Favorable**
2.			CA	
3.			RC	

I. Summary:

SB 1260 creates s. 155.42, F.S., to allow a public health care system (PHCS) to convert to a nonprofit entity by following the steps that are specified in the bill.

Initially, the governing body of the PHCS must vote by majority plus one to evaluate the potential conversion to a nonprofit entity. After doing so, the PHCS' governing body must allow for public input on a potential conversion and contract with a certified public accounting firm, or other similar firm, to render an independent valuation of the PHCS.

After receiving public input and the valuation from the independent firm, should the PHCS still wish to convert, the PHCS' governing body may negotiate an agreement with the governing authority in the county where the majority of the PHCS is located and its services are rendered. The agreement must specify terms and conditions by which the nonprofit entity that is succeeding the PHCS may acquire title and possession of property rights and other appurtenances owned by the PHCS as well as any other terms governing the conversion. The bill specifies what must be included in such an agreement and that the agreement must be in writing.

Once the agreement is negotiated, the governing bodies of the PHCS and of the county may elect by majority vote plus one to approve the conversion of the PHCS. Prior to doing so, all documents supporting the conversion must be published on the PHCS' website for a period of 20 days. Additionally, the governing bodies may not vote to approve the conversion unless the required valuation was completed within the preceding 18 months, and each member of the governing body of the PHCS must disclose whether he or she intends to serve on the board of the nonprofit entity once converted.

After the assets and liabilities are transferred pursuant to the conversion, the bill specifies that the PHCS and the county's governing authority must jointly submit a notice of completion to the Legislature, at which point the PHCS is deemed dissolved.

The bill provides an effective date of July 1, 2022.

II. Present Situation:

Hospitals

Hospitals are licensed by the Agency for Health Care Administration (AHCA) under ch. 395, F.S., and the general licensure provisions of part II, of ch. 408, F.S. Hospitals offer a range of health care services with beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care.[1] Hospitals must, at a minimum, make clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment, regularly available.[2] Currently, there are 311 hospitals licensed in Florida, of which 153 are for-profit and 158 are nonprofit.[3]

Public Hospitals

In Florida there are currently 42 hospitals that are either government owned or that have been granted sovereign immunity by Legislative act. Several of these hospitals are owned under the same health care system[4,5] Some examples of public hospital systems in Florida include: Halifax Health, Lee Health, Memorial Healthcare System, Sarasota Memorial Health Care System, and Broward Health.[6]

Halifax Health

Halifax Health is located in Daytona Beach, Florida, and is the area's largest healthcare provider. It has 944 licensed beds and over 500 physicians on staff. The hospital provides a number of services including having a Level II trauma center, comprehensive stroke center, neonatal and pediatric intensive care units, child and adolescent behavioral services, and kidney transplant program. It also provides psychiatric services, a regional cancer program with four outreach centers, the area's largest hospice organization, and a preferred provider organization. Halifax Health is a legislatively chartered taxing healthcare organization governed by a Board of Commissioners appointed by the Governor.[7]

Lee Health

Lee Health has been open since 1916 and is one of the top five largest public health systems in the United States and the largest community-owned health system in Southwest Florida. The

[1] Section 395.002(13), F.S.
[2] Id.
[3] Florida Health Finder search, available at https://www.floridahealthfinder.gov/facilitylocator/FacilitySearch.aspx (last visited Jan. 19, 2022).
[4] Financial Data Dashboard – Operations – government controlled, Florida Health Finder, available at https://bi.ahca.myflorida.com/t/ABICC/views/FinancialDataDashboard/FinancialDataDashboard?:embed=y&:showShareOptions=true&:display_count=no&:showVizHome=no (last visited Jan. 20, 2022).
[5] A list of such hospitals is on file with Senate Health Policy Committee staff.
[6] Public Hospitals, Safety Net Hospital Alliance of Florida, available at http://safetynetsflorida.org/public (last visited Jan. 19, 2022).
[7] Id.

health system has 1,423 beds and is made up of four acute-care hospitals and two specialty hospitals, as well as outpatient centers, walk-in medical centers and primary care physician offices. Lee Health provides regional programs, such as the only children's hospital, the only Level II trauma center and the only kidney transplant center between Tampa and Miami. The system has a medical staff of nearly 1,200 Lee County physicians, 4,500 volunteers and 9,300 employees. Lee Health is governed by a 10-member publicly elected board.[8]

Memorial Healthcare System

The Memorial Healthcare System has 1,978 beds and is among the nation's largest public healthcare systems. The system consists of a hospital, a freestanding children's hospital, nine primary care centers, four community hospitals, a nursing home, two urgent care centers, a large freestanding 24/7 care center, and a home health agency.

Memorial Regional Hospital, located in Hollywood, is the flagship of the system and one of the largest hospitals in Florida. It offers extensive and diverse services that include Memorial Transplant Institute, Memorial Cardiac and Vascular Institute, Memorial Cancer Institute and Memorial Neuroscience Institute.

Memorial Regional Hospital South is also located in Hollywood and offers medical and surgical services and houses Memorial Rehabilitation Institute, an 89-bed, inpatient comprehensive rehabilitation hospital.

Joe DiMaggio Children's Hospital is located in Broward and Palm Beach counties with major services in pediatric cardiology, including surgery and transplantation, oncology, orthopedics and neurosciences.

Memorial Hospital Miramar and Memorial Hospital Pembroke serve western Broward County as community hospitals. Additionally, Memorial Hospital West, which houses Memorial Cancer Institute, Moffitt Malignant Hematology & Cellular Therapy at Memorial Healthcare System, Memorial Manor nursing home, and a variety of ancillary healthcare facilities rounds out the system. Memorial Healthcare System is governed by a seven-member Board of Commissioners appointed by the Governor.[9]

Sarasota Memorial Health Care System

Sarasota Memorial Health Care System is an 839-bed medical center with over 6,000 staff and 1,000 physicians. Founded in 1925, Sarasota Memorial provides specialized expertise in cardiac, vascular, oncology, maternity and neuroscience services, as well as a complete continuum of care, with a network of outpatient and urgent care centers, physician practices, rehabilitation and skilled nursing, among other programs.

The region's only public hospital, Sarasota Memorial is governed by the Sarasota County Public Hospital Board, made up of nine unpaid citizens elected by local voters. It is the only hospital in Sarasota County providing trauma services, obstetrical care, pediatrics, neonatal intensive care,

[8] Id.
[9] Id.

and psychiatric services for patients of all ages. Sarasota Memorial also operates a Community Medical Clinic, which provides specialty care for uninsured and underinsured residents.[10]

Broward Health

Broward Health is has been located in South Florida for more than 80 years. Broward Health includes four major hospitals and more than 30 locations and offices overall. The staff of Broward Health includes over 1,800 doctors and 8,000 other healthcare professionals.[11]

Broward Health is governed by a seven-member Board of Commissioners, each appointed by the governor to a four-year term. The terms are staggered to expire in alternate years. Five commissioners represent specific regions within Broward County while the other two are at-large members. The Board exercises budgetary authority, selects the senior executive management, participates in the fiscal management, provides taxing authority, and determines the scope of services to be provided to the community. The President/CEO of the North Broward Hospital District reports to the Board.[12]

III. Effect of Proposed Changes:

SB 1260 creates s. 155.42, F.S., to allow a PHCS to convert to a nonprofit entity by following the steps that are specified in the bill.

The bill defines the terms:

- "Affected community" to mean those persons residing within the geographic boundaries of the PHCS.
- "Local governing authority" to mean the governing authority of the county in which the PHCS is primarily located and provides health care services.
- "Public health care system" to mean a county, district, or municipal hospital or health care system created pursuant to special act.

In order to start the process of converting from a PHCS to a nonprofit entity, the bill requires that the governing body of the PHCS must vote by majority plus one to evaluate the potential conversion to a nonprofit entity. If the governing body votes to evaluate the conversion, the governing body must allow for public input by publishing notice of and conducting at least one public hearing in accordance with s. 189.015, F.S., and making publicly available on the PHCS' website all documents considered by the governing body during its evaluation. Additionally the governing body must contract with a certified public accounting firm or other firm that has substantial expertise in the valuation of the type of activities engaged in by the PHCS to render an independent valuation of the PHCS. The firm must certify its valuation.

Upon completing the evaluation, if the governing body determines that it is in the best interest of the PHCS to convert, the PHCS may negotiate an agreement with the local governing authority which contains terms and conditions by which the nonprofit entity that is succeeding the PHCS

[10] Id.
[11] Broward Health Services, Broward Health, available at https://www.browardhealth.org/services (last visited Jan 20, 2022).
[12] Broward Health Board Information, Broward Health, available at https://www.browardhealth.org/pages/board-calendar-2022 (last visited Jan. 20, 2022).

may acquire title and possession of property rights and other appurtenances owned by the PHCS as well as any other terms governing the conversion. The bill specifies that the agreement must be in writing and must include:

- A description of the terms and conditions of all proposed agreements.
- A description of the assets and liabilities, if any, that will be transferred to the local governing authority upon conversion of the PHCS.
- The estimated total value of the assets and liabilities, if any, that will be transferred to the local governing authority upon conversion of the PHCS.
- A description of the assets and liabilities, if any, that will be transferred to the succeeding nonprofit entity upon conversion of the PHCS.
- The estimated total value of the assets and liabilities, if any, that will be transferred to the succeeding nonprofit entity upon conversion of the PHCS.
- A provision that the remaining assets and liabilities, if any, of the PHCS which are not transferred to the local governing authority or the succeeding nonprofit entity, will be resolved upon conversion of the PHCS.
- An enforceable commitment that programs and services provided by the PHCS will continue to be provided to the affected community in perpetuity so long as the nonprofit entity is in operation or, if otherwise agreed to by the PHCS and the local governing authority, until the nonprofit entity has otherwise met all obligations set forth in the agreement.
- A provision that transfers the rights and obligations agreed to by the PHCS and the local governing authority to the successor nonprofit entity upon conversion of the PHCS.
- A provision that prohibits a board member of the local governing authority from serving on the board of the successor nonprofit entity; however, the agreement may allow for members of the governing body of the PHCS to serve on the board of the successor nonprofit entity.
- Any other terms or conditions mutually agreed upon by the PHCS and the local governing authority.

Once the agreement is negotiated, the governing bodies of the PHCS and of the county may elect, by majority vote plus one, to approve the conversion of the PHCS if the following conditions are met:

- The evaluations, agreements, disclosures, and all other documents supporting the conversion must be published on the websites of the PHCS and the local governing authority and made publicly available for a period of at least 20 days before the governing bodies of the PHCS and the local governing authority may vote to approve the conversion of the PHCS to a nonprofit entity pursuant to the terms and conditions of the agreement.
- The governing bodies of the public health care system and the local governing authority may not vote to approve the conversion of the public health care system unless the required valuation conducted by the certified public accounting firm, or other similar firm, was completed within the preceding 18 months.

The bill requires that a member of the governing body of the PHCS must disclose whether he or she intends to serve on the board of the successor nonprofit entity. After the assets and liabilities are transferred pursuant to the conversion, the bill specifies that the PHCS and the county's governing authority must jointly submit a notice of completion to the Legislature, at which point the PHCS is deemed dissolved.

The bill provides an effective date of July 1, 2022.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 155.42 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 Gruters

23-01356-22 20221260__

A bill to be entitled

An act relating to the conversion of a public health care system; creating s. 155.42, F.S.; defining terms; authorizing the governing body of a public health care system to evaluate the potential conversion of the public health care system to a nonprofit entity; specifying requirements for such evaluation; requiring such governing body to publish notice of its completed evaluation in a specified manner; authorizing a public health care system and local governing authority to negotiate an agreement for such conversion; specifying requirements for such agreement; authorizing the governing body of the public health care system and local governing authority to approve such conversion subject to certain requirements; requiring members of the governing body of the public health care system to disclose whether they intend to serve on the board of the successor nonprofit entity; requiring the public health care system and local governing authority to jointly submit a notice of completion of such conversion to the Legislature after certain requirements are met; providing that the public health care system is dissolved as a matter of law on the date that such notice is submitted to the Legislature; providing an effective date.

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

Section 1. Section 155.42, Florida Statutes, is created to

23-01356-22 20221260__

read:

155.42 Conversion of a public health care system.—

(1) For purposes of this section, the term:

(a) "Affected community" means those persons residing within the geographic boundaries of the public health care system.

(b) "Local governing authority" means the governing authority of the county in which the public health care system is primarily located and provides health care services.

(c) "Public health care system" means a county, district, or municipal hospital or health care system created pursuant to a special act.

(2)(a) The governing body of a public health care system may elect, by a majority vote plus one, to evaluate the potential conversion of the public health care system to a nonprofit entity.

(b) If the governing body of a public health care system elects to evaluate the potential conversion of the public health care system as set forth in paragraph (a), the governing body must evaluate the potential benefits to the affected community of converting the public health care system to a nonprofit entity and must:

1. Publish notice of and conduct a public hearing in accordance with s. 189.015 to provide the affected community the opportunity to publicly testify regarding the conversion of the public health care system.

2. Contract with a certified public accounting firm or other firm that has substantial expertise in the valuation of the type of activities engaged in by the public health care

system to render an independent valuation of the public health care system. The certified public accounting firm or other firm shall certify its valuation of the public health care system.

3. Make publicly available on the public health care system's website all documents considered by the governing body during its evaluation.

(c) After completing its evaluation, the governing body of the public health care system shall publish notice of the evaluation in the same manner as provided in s. 189.015(1).

(3)(a) Upon completing the evaluation of the benefits of the conversion of the public health care system, if the governing body of the public health care system determines that it is in the best interest of the affected community to convert the public health care system to a nonprofit entity, the public health care system may negotiate an agreement with the local governing authority which contains the terms and conditions by which the nonprofit entity that is succeeding the public health care system may acquire title and possession of property, rights, and other appurtenances owned by the public health care system and any other terms or conditions governing the conversion.

(b) An agreement between the public health care system and the local governing authority to convert the public health care system to a nonprofit entity must be in writing and must include all of the following terms and conditions:

1. A description of the terms and conditions of all proposed agreements.

2. A description of the assets and liabilities, if any, that will be transferred to the local governing authority upon

conversion of the public health care system.

3. The estimated total value of the assets and liabilities, if any, that will be transferred to the local governing authority upon conversion of the public health care system.

4. A description of the assets and liabilities, if any, that will be transferred to the succeeding nonprofit entity upon conversion of the public health care system.

5. The estimated total value of the assets and liabilities, if any, that will be transferred to the succeeding nonprofit entity upon conversion of the public health care system.

6. A provision that the remaining assets and liabilities, if any, of the public health care system which are not transferred to the local governing authority or the succeeding nonprofit entity will be resolved upon conversion of the public health care system.

7. An enforceable commitment that programs and services provided by the public health care system will continue to be provided to the affected community in perpetuity so long as the nonprofit entity is in operation or, if otherwise agreed to by the public health care system and the local governing authority, until the nonprofit entity has otherwise met all obligations set forth in the agreement.

8. A provision that transfers the rights and obligations agreed to by the public health care system and the local governing authority to the successor nonprofit entity upon conversion of the public health care system.

9. A provision that prohibits a board member of the local governing authority from serving on the board of the successor nonprofit entity; however, the agreement may allow for members

of the governing body of the public health care system to serve on the board of the successor nonprofit entity.

10. Any other terms or conditions mutually agreed upon by the public health care system and the local governing authority.

(4) Upon completing the negotiation of the agreement as provided in subsection (3), the governing body of the public health care system and the local governing authority may elect, by a majority vote plus one of each of the governing bodies, to approve the conversion of the public health care system to a nonprofit entity pursuant to the terms and conditions of the agreement and subject to all of the following:

(a) The evaluations, agreements, disclosures, and all other documents supporting the conversion must be published on the websites of the public health care system and the local governing authority and made publicly available for a period of at least 20 days before the governing bodies of the public health care system and the local governing authority may vote to approve the conversion of the public health care system to a nonprofit entity pursuant to the terms and conditions of the agreement.

(b) The governing bodies of the public health care system and the local governing authority may not vote to approve the conversion of the public health care system unless the valuation required in subparagraph (2)(b)2. was completed within the preceding 18 months.

(5) A member of the governing body of the public health care system must disclose whether he or she intends to serve on the board of the successor nonprofit entity.

(6) After the assets and liabilities, if any, are

transferred to the succeeding nonprofit entity and all necessary requirements to complete the conversion of the public health care system to a nonprofit entity are met, the public health care system and the local governing authority shall jointly submit a notice of the completion of the conversion to the President of the Senate and the Speaker of the House of Representatives. The public health care system is deemed dissolved as a matter of law effective on the date that such notice is submitted to the Legislature.

Section 2. This act shall take effect July 1, 2022.

The Florida Senate

Committee Agenda Request

To: Senator Manny Diaz, Jr., Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 12, 2022

I respectfully request that **Senate Bill #1260**, relating to Conversion of a Public Health Care System, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Sincerely,

Joe Gruters

Cc: Allen Brown, Staff Director
Daniel Looke, Deputy Staff Director
Tori Denson, Committee Administrative Assistant

File signed original with committee office

File Numbe	License Numbe	Classific	Hospital Name
110019	3954	ACUTE	BROWARD HEALTH CORAL SPRINGS
100200	3996	ACUTE	BROWARD HEALTH IMPERIAL POINT
100039	4128	ACUTE	BROWARD HEALTH MEDICAL CENTER
100086	4020	ACUTE	BROWARD HEALTH NORTH
100244	4366	ACUTE	CAPE CORAL HOSPITAL
100175	4218	RURAL	DESOTO MEMORIAL HOSPITAL
100078	4495	RURAL	DOCTORS MEMORIAL HOSPITAL
100220	4301	ACUTE	GULF COAST MEDICAL CENTER LEE MEMORIAL HEALTH SYSTEM
110009	4334	ACUTE	H LEE MOFFITT CANCER CENTER & RESEARCH INSTITUTE HOSPITAL
100017	4181	ACUTE	HALIFAX HEALTH MEDICAL CENTER
23960051	4181	ACUTE	HALIFAX HEALTH MEDICAL CENTER- PORT ORANGE
23960152	4530	ACUTE	HALIFAX HEALTH UF HEALTH MEDICAL CENTER OF DELTONA
110016	4181	PSYCH	HALIFAX PSYCHIATRIC CENTER-NORTH
120005	4186	ACUTE	HEALTHPARK MEDICAL CENTER
100098	3995	RURAL	HENDRY REGIONAL MEDICAL CENTER
100142	3999	RURAL	JACKSON HOSPITAL
100022	3998	ACUTE	JACKSON MEMORIAL HOSPITAL
100114	3998	ACUTE	JACKSON NORTH MEDICAL CENTER
100208	3998	ACUTE	JACKSON SOUTH MEDICAL CENTER
23960144	3998	ACUTE	JACKSON WEST MEDICAL CENTER
100130	3992	RURAL	LAKESIDE MEDICAL CENTER
100012	4186	ACUTE	LEE MEMORIAL HOSPITAL
100004	4346	RURAL	MADISON COUNTY MEMORIAL HOSPITAL
23960050	4480	ACUTE	MEMORIAL HOSPITAL MIRAMAR
100230	4121	ACUTE	MEMORIAL HOSPITAL PEMBROKE
111527	4316	ACUTE	MEMORIAL HOSPITAL WEST
100038	4411	ACUTE	MEMORIAL REGIONAL HOSPITAL
100225	4411	ACUTE	MEMORIAL REGIONAL HOSPITAL SOUTH
100028	4467	ACUTE	PARRISH MEDICAL CENTER
100087	4191	ACUTE	SARASOTA MEMORIAL HOSPITAL
23960161	4536	ACUTE	Sarasota Memorial Hospital - Venice

File Numbe	License Numbe	Classific	Hospital Name
100001	4063	ACUTE	UF HEALTH JACKSONVILLE
100084	4000	ACUTE	UF HEALTH LEESBURG HOSPITAL
23960123	4063	ACUTE	UF HEALTH NORTH
120011	4286	PSYCH	UF HEALTH PSYCHIATRIC HOSPITAL
100113	4286	ACUTE	UF HEALTH SHANDS HOSPITAL
23960032	4464	ACUTE	UF HEALTH THE VILLAGES HOSPITAL

File Numbe	License Numbe	Classific	Hospital Name
104000	3990	PSYCH	FLORIDA STATE HOSPITAL
104007	4004	PSYCH	NORTHEAST FLORIDA STATE HOSPITAL
110183	4006	ACUTE	RECEPTION AND MEDICAL CENTER HOSPITAL

120014	4496	PSYCH	SOUTH FLORIDA EVALUATION AND TREATMENT CENTER
104001	4013	PSYCH	SOUTH FLORIDA STATE HOSPITAL

Street Address	City	Bed Capaci
3000 CORAL HILLS DR	CORAL SPRINGS	250
6401 N FEDERAL HWY	FORT LAUDERDALE	204
1600 S ANDREWS AVE	FORT LAUDERDALE	723
201 E SAMPLE RD	POMPANO BEACH	409
636 DEL PRADO BLVD	CAPE CORAL	291
900 N ROBERT AVE	ARCADIA	49
2600 Hospital Drive	BONIFAY	20
13681 DOCTORS WAY	FORT MYERS	699
12902 MAGNOLIA DR	TAMPA	218
303 N CLYDE MORRIS BLVD	DAYTONA BEACH	563
1041 DUNLAWTON AVE	PORT ORANGE	80
3300 HALIFAX CROSSINGS BLVD	DELTONA	43
841 JIMMY ANN DR	DAYTONA BEACH	30
9981 HEALTHPARK CIR	FORT MYERS	461
524 W SAGAMORE AVE	CLEWISTON	25
4250 HOSPITAL DR	MARIANNA	100
1611 NW 12TH AVE	MIAMI	1547
160 NW 170TH ST	NORTH MIAMI BEACH	382
9333 SW 152ND ST	MIAMI	262
2801 NW 79 Ave	DORAL	98
39200 HOOKER HWY	BELLE GLADE	70
2776 CLEVELAND AVE	FORT MYERS	414
224 NW CRANE AVE	MADISON	25
1901 SW 172ND AVE	MIRAMAR	178
7800 SHERIDAN ST	PEMBROKE PINES	301
703 N FLAMINGO RD	PEMBROKE PINES	486
3501 JOHNSON ST	HOLLYWOOD	797
3600 WASHINGTON ST	HOLLYWOOD	216
951 N WASHINGTON AVE	TITUSVILLE	210
1700 S TAMIAMI TRL	SARASOTA	895
2600 Laurel Rd E	NORTH VENICE	110

Street Address	City	Bed Capaci
655 W 8TH ST	JACKSONVILLE	603
600 E DIXIE AVE	LEESBURG	330
15255 MAX LEGGETT PARKWAY	JACKSONVILLE	92
4101 NW 89TH BLVD	GAINESVILLE	81
1600 SW ARCHER RD	GAINESVILLE	1030
1451 EL CAMINO REAL	THE VILLAGES	307

Street Address	City	Bed Capaci
100 N MAIN ST	CHATTAHOOCHEE	949
7487 S STATE RD 121	MACCLENNY	1138
7765 S COUNTY RD 231	LAKE BUTLER	120

18680 SW 376TH ST	FLORIDA CITY	249
800 E CYPRESS DR	PEMBROKE PINES	350

Owner Name	Ownership Type
NORTH BROWARD HOSPITAL DISTRICT	Hospital District
NORTH BROWARD HOSPITAL DISTRICT	Hospital District
NORTH BROWARD HOSPITAL DISTRICT	Hospital District
NORTH BROWARD HOSPITAL DISTRICT	Hospital District
CAPE MEMORIAL HOSPITAL INC	Hospital District
DESOTO COUNTY HOSPITAL DISTRICT	Hospital District
HOLMES COUNTY HOSPITAL CORPORATION	Hospital District
LEE MEMORIAL HEALTH SYSTEM	Hospital District
H LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE HOSPITAL INC	Corporation
HALIFAX HOSPITAL MEDICAL CENTER	Hospital District
HALIFAX HOSPITAL MEDICAL CENTER	Hospital District
MEDICAL CENTER OF DELTONA INC	Corporation
HALIFAX HOSPITAL MEDICAL CENTER	Hospital District
LEE MEMORIAL HEALTH SYSTEM	Hospital District
HENDRY COUNTY HOSPITAL AUTHORITY	Hospital District
JACKSON COUNTY HOSPITAL DISTRICT	Hospital District
PUBLIC HEALTH TRUST OF MIAMI-DADE COUNTY	City/County
PUBLIC HEALTH TRUST OF MIAMI-DADE COUNTY	City/County
PUBLIC HEALTH TRUST OF MIAMI-DADE COUNTY	City/County
PUBLIC HEALTH TRUST OF MIAMI-DADE COUNTY	City/County
DISTRICT HOSPITAL HOLDINGS INC	Hospital District
LEE MEMORIAL HEALTH SYSTEM	Hospital District
MADISON COUNTY HOSPITAL HEALTH SYSTEMS INC	Hospital District
SOUTH BROWARD HOSPITAL DISTRICT	Hospital District
SOUTH BROWARD HOSPITAL DISTRICT	Hospital District
SOUTH BROWARD HOSPITAL DISTRICT	Hospital District
SOUTH BROWARD HOSPITAL DISTRICT	Hospital District
SOUTH BROWARD HOSPITAL DISTRICT	Hospital District
NORTH BREVARD COUNTY HOSPITAL DISTRICT	Hospital District
SARASOTA COUNTY PUBLIC HOSPITAL DISTRICT	Hospital District
SARASOTA COUNTY PUBLIC HOSPITAL DISTRICT	Hospital District

Owner Name	Ownership Type
SHANDS JACKSONVILLE MEDICAL CENTER INC	Corporation
LEESBURG REGIONAL MEDICAL CENTER INC	Corporation
SHANDS JACKSONVILLE MEDICAL CENTER INC	Corporation
SHANDS TEACHING HOSPITAL AND CLINICS, INC.	Corporation
SHANDS TEACHING HOSPITAL AND CLINICS, INC.	Corporation
THE VILLAGES TRI-COUNTY MEDICAL CENTER INC	Corporation

Owner Name	Ownership Type
STATE OF FLORIDA DEPARTMENT OF CHILDREN AND FAMILIES	State
STATE OF FLORIDA DEPARTMENT OF CHILDREN AND FAMILIES	State
STATE OF FLORIDA DEPARTMENT OF CORRECTIONS	State

STATE OF FLORIDA DEPARTMENT OF CHILDREN AND FAMILIES	State
STATE OF FLORIDA DEPARTMENT OF CHILDREN AND FAMILIES	State

Corporate Affiliation, if any
NORTH BROWARD HOSPITAL DISTRICT
NORTH BROWARD HOSPITAL DISTRICT
NORTH BROWARD HOSPITAL DISTRICT
NORTH BROWARD HOSPITAL DISTRICT
LEE MEMORIAL HEALTH SYSTEM
NA
NA
LEE MEMORIAL HEALTH SYSTEM
NA
HALIFAX HEALTH
HALIFAX HEALTH
HALIFAX HEALTH
HALIFAX HEALTH
LEE MEMORIAL HEALTH SYSTEM
NA
NA
PUBLIC HEALTH TRUST OF MIAMI-DADE COUNTY
PUBLIC HEALTH TRUST OF MIAMI-DADE COUNTY
PUBLIC HEALTH TRUST OF MIAMI-DADE COUNTY
PUBLIC HEALTH TRUST OF MIAMI-DADE COUNTY
NA
LEE MEMORIAL HEALTH SYSTEM
NA
SOUTH BROWARD HOSPITAL DISTRICT
SOUTH BROWARD HOSPITAL DISTRICT
SOUTH BROWARD HOSPITAL DISTRICT
SOUTH BROWARD HOSPITAL DISTRICT
SOUTH BROWARD HOSPITAL DISTRICT
NA
SARASOTA COUNTY PUBLIC HOSPITAL DISTRICT
SARASOTA COUNTY PUBLIC HOSPITAL DISTRICT

Corporate Affiliation, if any	Sovereign Immunity Authority
SHANDS TEACHING HOSPITAL AND CLINICS, INC.	s. 1004.41
SHANDS TEACHING HOSPITAL AND CLINICS, INC.	s. 1004.42
SHANDS TEACHING HOSPITAL AND CLINICS, INC.	s. 1004.43
SHANDS TEACHING HOSPITAL AND CLINICS, INC.	s. 1004.44
SHANDS TEACHING HOSPITAL AND CLINICS, INC.	s. 1004.45
SHANDS TEACHING HOSPITAL AND CLINICS, INC.	s. 1004.46

Corporate Affiliation, if any
STATE OF FLORIDA
STATE OF FLORIDA
STATE OF FLORIDA

STATE OF FLORIDA
STATE OF FLORIDA

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

1/26/22
Meeting Date

Health Policy
Committee

SB 1260
Bill Number or Topic

Amendment Barcode (if applicable)

Name Michael Nachef

Phone 239-343-6509

Address 9800 S. HealthPark Dr Suite 465
Street

Email Michael.Nachef@leehealth.org

Fort Myers FL 33908
City State Zip

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

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☒ I am a registered lobbyist, representing:
Lee Health

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

CourtSmart Tag Report

Room: KB 412 **Case No.:** - **Type:**
Caption: Senate Health Policy Committee **Judge:**

Started: 1/26/2022 10:04:03 AM
Ends: 1/26/2022 11:59:38 AM Length: 01:55:36

10:04:03 AM Chair Diaz brings meeting to order
10:04:23 AM Roll call quorum present
10:05:07 AM Chair opening remarks
10:05:17 AM Dr. Lapado please step forward
10:06:11 AM Please raise your right hand
10:06:17 AM Dr. Lapado opening comments
10:07:10 AM Thanks Governor DeSantis for his nomination
10:07:52 AM He received his PHD from Harvard
10:08:52 AM Received awards from John Hopkins
10:09:27 AM My vision is to improve the health in the State of Florida
10:10:13 AM Chair asks Members speak to Dr. Lapado
10:10:49 AM Senator Bean recognized for a question
10:10:57 AM Asks what is salary of the Surgeon General
10:11:19 AM Says his salary is public records
10:12:04 AM Says that's not what motivates him
10:12:23 AM Senator Bean asks again exactly what his salary is
10:12:41 AM UF pays him $430,000-440, 000
10:13:31 AM Senator Bean says if you worked private you could make twice that amount
10:14:01 AM Senator Cruz is recognized for a series of question
10:14:25 AM Senator Cruz asks about his training in public health administration
10:14:51 AM Lapado speaks on all his experience
10:15:20 AM Senator Cruz asks him to explain his previous employment
10:15:51 AM He's worked at UCLA and Public Health Programs
10:16:40 AM He's also work at NYU
10:17:27 AM Cruz asks if you have a strategy for assisting low income
10:18:10 AM Cruz asks about essential works mental health
10:21:22 AM Lapado speaks on HIV and prevention
10:22:49 AM Lapado speaks on a program about county health department liaisons
10:23:48 AM Senator Jones for a series of question
10:24:30 AM Jones asks about Lapado's training in health policy
10:25:27 AM Jones follow up on epidemiology
10:26:28 AM Jones ask about Orange County Manager being suspended
10:27:08 AM Jones asks about Dr. Peno be investigated
10:27:51 AM Lapado clarifies question on the suspension
10:28:12 AM Jones says Lapado says the Government hasn't done enough for Florida
10:28:47 AM Lapado speaks on riding the state of the pandemic
10:29:13 AM Lapado speaks on the holistic approach
10:29:38 AM Jones asks what him and the Governor have done to get control of the epidemic
10:30:35 AM Lapado says vaccinations and early detection
10:31:57 AM Jones speaks on the certain vaccinations not working on all variants
10:34:39 AM Senator Book asks a series of question
10:35:38 AM Book asks about the date on vaccinations

10:36:04 AM Book do vaccines work against COVID
10:36:23 AM Book asks again "yes or No" do the vaccines work
10:37:03 AM Book ask again about vaccines working "yes or no"
10:37:53 AM Lapado says scientific data reports that vaccines are effective
10:38:19 AM Book ask does masking prevent the spread of COVID
10:38:42 AM Lapado said scientific data says masking does help
10:39:20 AM Lapado says some trials have shown no effects of masking for COVID
10:40:25 AM Books asks about vaccines and masks assisting in the spread of COVID
10:42:15 AM Book asks if he regrets the way he treated Senator Polsky
10:43:15 AM Lapado says he has sympathy for someone suffering with other issues
10:43:54 AM Lapado says people should respect peoples personal preference
10:44:14 AM Book follow up do you regret the way you treated Senator Polsky
10:45:13 AM Book says she just wants a yes or no answer
10:45:32 AM Book asks Dr. does he regret the way he spoke to Senator Polsky
10:47:05 AM Senator Powell for a series of questions
10:48:04 AM Powell ask Lapado do you feel it's a sign of weakness for admit you are wrong
10:48:59 AM Lapado says it's a personal value question
10:49:30 AM Powell asks about his extensive training in practice of theory
10:50:29 AM Powell follow up
10:51:42 AM Powell for a clarification
10:52:43 AM Is Dr. Lapado under oath
10:52:53 AM what is the status of the control of COVID
10:54:09 AM Powell speaks on access to testing and vaccine
10:55:09 AM Powell asks about your pay being public record
10:55:51 AM did you take a pay cut to come to the State of Florida
10:56:13 AM Lapado says his pay has been increased
10:56:45 AM Senator Cruz for a series of questions
10:56:59 AM Cruz reminds him that he is under oath
10:57:12 AM Cruz says she hears arrogance and disrespect
10:57:33 AM Cruz asks about the status of Hep A
10:58:38 AM Cruz asks what are you going to do to stop this outbreak of Hep A
11:00:27 AM Lapado his office is working on the spread but the doesn't have the numbers
11:01:27 AM Chair Diaz asks Dr. to be more precious with his answers
11:02:38 AM Lapado wants to be clear and concise on the spread and vaccines
11:03:37 AM Cruz asks to believe Hep A is under control in Florida
11:05:19 AM Cruz do you believe we are under reporting COVID cases
11:06:20 AM Ladapo says he doesn't believe we are
11:06:33 AM Cruz asks Dr. about his back ground growing up
11:07:05 AM Lapado says he was born in Nigeria
11:07:23 AM His dad got a PHD
11:07:54 AM Senator Jones told Tucker Carlson about the Government not working with state department
11:08:54 AM Jones asks him about his criticizing the Federal Government
11:10:07 AM Lapado says Florida is leading their own way in recovery efforts
11:11:06 AM Jones asks why are we not reporting COVID cases on the dashboard
11:11:42 AM Leader Book has a statement to make
11:12:31 AM Books speaks on her lack of receiving answers
11:12:50 AM Senator Democrats walk out
11:13:04 AM Senator Bean makes motion to move confirmation
11:13:20 AM Senator Baxley seconds the motion
11:13:28 AM Roll Call Dr. Lapado confirmation approved
11:14:00 AM SB 1770 by Senator Book

11:14:42 AM Questions?
11:15:06 AM appearance cards
11:15:30 AM Books to close
11:15:36 AM Roll Call on SB 1770 Favorable
11:16:00 AM SB 836 by Senator Brodeur
11:16:25 AM Take up strike all 709032
11:16:38 AM Brodeur waives close
11:17:01 AM amendment adopted
11:17:07 AM appearance cards
11:17:14 AM Roll call on SB 836 Fav/CD
11:17:39 AM SB 1258 by Senator Jones
11:17:50 AM appearance cards
11:18:40 AM roll call on SB 1258
11:19:04 AM SB 1258 favorably
11:19:26 AM SB 842 by Brodeur
11:19:38 AM Amendment 720062 Adopted
11:20:17 AM Senator Cruz question on the amendment
11:20:26 AM Senator Cruz follow up
11:21:42 AM Senator Cruz asks about buy outs
11:22:41 AM Do hospitals define buy outs
11:22:56 AM debate on amendment
11:23:41 AM show amendment adopted
11:23:50 AM questions on bill as amended
11:24:03 AM Senator Jones ask about reasonability of buy outs
11:24:22 AM Senator Bean in debate
11:24:32 AM roll call on SB 842
11:25:05 AM Sb 842 favorably as a CS
11:25:19 AM Senator Bean for a recognition
11:25:31 AM Dr. J. Epstein doctor of the day
11:25:45 AM SB 768 by Senator Rodriquez
11:26:05 AM SB 768 by Senator Rodriquez
11:26:05 AM 709032 PCS by Department of Health
11:26:23 AM PCS is adopted
11:26:46 AM Melissa Viller Normal Tallahassee
11:28:44 AM Roll call on SB 768 Favorably as a CS
11:29:44 AM Senator Bradley 718
11:29:57 AM Bradley explains amendment
11:30:30 AM 430772 amendment adopted
11:30:48 AM back on bill as amended
11:31:09 AM Greg Dewitt, SWF Firefighter
11:31:41 AM Senator Bradley close
11:32:33 AM Roll call for SB 718 Fav/CS
11:33:01 AM Senator Brodeur SB 1950
11:33:35 AM Amendment adopted
11:34:47 AM Roll call on SB 1950 fav/CS
11:35:47 AM SB 1184 by Senator Broxson
11:36:07 AM 646394 Strike all adopted
11:37:07 AM Senator Jones asks question
11:37:22 AM Senator Broxson responds
11:37:54 AM Senator Jones follow up
11:38:03 AM Ellen McKnight, MD
11:40:38 AM Senator Jones clarifies

11:41:37 AM Senator Jones asks question to Dr. McKnight
11:42:05 AM Senator Book asks questions regarding free speech to doctors
11:42:56 AM amendment strike all adopted
11:43:12 AM Senator Jones asks question
11:43:34 AM Senator Powell asks about code of ethics that doctors must follow
11:45:48 AM Dr. John Ward speaks
11:47:18 AM Florida Family Policy Council
11:48:17 AM Dr. John Little MD
11:50:41 AM Bridgett Smith, Citizen
11:51:45 AM Robert Schmidt speaks for bill
11:52:45 AM PG Schafter, Citizen
11:53:18 AM Senator Jones in debate
11:54:50 AM Senator Jones says he believes in free speech but he cannot support this bill
11:55:50 AM Senator Powell speaks that he too cannot support this bill
11:57:14 AM Roll call on SB 1184 Favorably
11:58:14 AM Senator Grueters explains bill
11:58:40 AM Roll call on SB 1260 favorable
11:58:58 AM Senator Powell Tab 7 yes to no
11:59:23 AM Senator Jones moves we rise
11:59:24 AM We are adjourned