Healthcare Regulation Subcommittee

Wednesday, January 24, 2024
8:00 AM
Reed Hall (102 HOB)

Meeting Packet

Paul Renner
Speaker

Michelle Salzman
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Healthcare Regulation Subcommittee

Start Date and Time: Wednesday, January 24, 2024 08:00 am

End Date and Time: Wednesday, January 24, 2024 10:30 am

Location: Reed Hall (102 HOB)

Duration: 2.50 hrs

Consideration of the following bill(s):

HB 493 Pharmacy by Roach
HB 581 Swimming Lesson Voucher Program by Busatta Cabrera
HB 843 Naturopathic Medicine by Smith
HB 845 Fees/Naturopathic Medicine by Smith
HB 1063 Practice of Chiropractic Medicine by Hunschofsky
HB 1173 Dental Therapy by Chaney
HB 1441 Department of Health by Anderson
HB 1561 Office Surgeries by Busatta Cabrera
HB 1609 Pregnancy Support Services by Stevenson

Consideration of the following proposed committee substitute(s):

PCS for HB 865 -- Youth Athletic Activities

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m. Tuesday, January 23, 2024.

By request of the Chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Tuesday, January 23, 2024.

To submit an electronic appearance form, and for information about attending or testifying at a committee meeting, please see the “Visiting the House” tab at www.myfloridahouse.gov.

NOTICE FINALIZED on 01/22/2024 3:03PM by Arnold.Sabrina

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 493 Pharmacy
SPONSOR(S): Roach
TIED BILLS: **IDEN./SIM. BILLS:** SB 444

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		DesRochers	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The Florida Pharmacy Act (Act) regulates the practice of pharmacy in Florida. The Board of Pharmacy (Board) adopts rules to implement the provisions of the Act and sets standards of practice within the state. Any person who operates a pharmacy in Florida must have a permit in one of the seven categories: community pharmacy, institutional pharmacy, nuclear pharmacy, special pharmacy, internet pharmacy, nonresident sterile compounding pharmacy, or special sterile compounding pharmacy. A pharmacist must be present and on duty for the prescription department of a pharmacy to be considered open; however the prescription department is not considered closed if the pharmacist briefly leaves to tend to personal needs or counsel patients.

HB 493 creates a new pharmacy permit category for the operation of a remote site pharmacy. A remote site pharmacy is a location where medicinal drugs are dispensed by a registered pharmacy technician who is remotely supervised by an off-site prescription department manager. In addition to meeting all the requirements in rule and statute for permitting pharmacies, a remote pharmacy must be jointly owned by a supervising pharmacy or operated under contract with a supervising pharmacy; maintain a video surveillance system that records continuously 24 hours per day and retain video surveillance recordings for at least 30 days; display a sign, visible by the public, which indicates that the facility is a remote site pharmacy and that it is under 24-hour video surveillance; maintain a policies and procedures manual which must be made available to the Board of Pharmacy or its agent upon request; and designate a licensed pharmacist or consultant pharmacist as the prescription department manager responsible for oversight of the facility.

The bill authorizes a remote-site pharmacy to store, hold, and dispense all medicinal drugs, including proprietary drugs and controlled substances. However, a remote-site pharmacy may not dispense Schedule II controlled substances listed in s. 893.03 unless a pharmacist is present at the remote-site pharmacy.

The prescription department manager must visit the remote-site pharmacy as often as the Board's schedule states. During remote site pharmacy visits, the prescription department manager must inspect the pharmacy, address personnel matters, and provide clinical services for patients.

The bill authorizes a pharmacist to serve as the prescription department manager for up to three remote site pharmacies that are under common control of the same supervising pharmacy. The maximum allowable pharmacist-pharmacy technician ratio is 1:6.

The bill authorizes a registered pharmacy technician working in a remote site pharmacy under the remote supervision of a pharmacist to fill, compound, and dispense medicinal drugs.

The bill has a significant, negative fiscal impact on DOH and no impact on local governments. See Fiscal Analysis.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Pharmacy Regulation

The Florida Pharmacy Act (act) regulates the practice of pharmacy in Florida and contains the minimum requirements for safe practice.[1] The Board of Pharmacy (Board) is tasked with adopting rules to implement the provisions of the act and setting standards of practice within the state.[2] Any person who operates a pharmacy in Florida must have a permit, and as of June 30, 2023, there were 10,901 permitted pharmacies in the state.[3] The following permits are issued by the Department of Health (DOH):

- Community pharmacy – A permit is required for each location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.[4]
- Institutional pharmacy – A permit is required for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.[5]
- Nuclear pharmacy – A permit is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under ch. 395, F.S., or the nuclear medicine facilities of such hospitals.[6]
- Special pharmacy – A permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold if the location does not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.[7]
- Internet pharmacy – A permit is required for a location not otherwise licensed or issued a permit under this chapter, within or outside this state, which uses the Internet to communicate with or obtain information from consumers in this state to fill or refill prescriptions or to dispense, distribute, or otherwise practice pharmacy in this state.[8]
- Nonresident sterile compounding pharmacy – A permit is required for a registered nonresident pharmacy or an outsourcing facility to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state.[9]
- Special sterile compounding – A separate permit is required for a pharmacy holding an active pharmacy permit that engages in sterile compounding.[10]

A pharmacy must pass an on-site inspection for a permit to be issued,[11] and the permit is valid only for the name and address to which it is issued.[12]

[1] Chapter 465, F.S.
[2] Sections 465.005, 465.0155, and 465.022, F.S.
[3] Department of Health, *2024 Agency Legislative Bill Analysis for House Bill 493*, (Nov. 20, 2023), on file with the Healthcare Regulation Subcommittee.
[4] Sections 465.003(20)(a)1. and 465.018, F.S.
[5] Sections 465.003(20)(a)2. and 465.019, F.S.
[6] Sections 465.003(20)(a)3. and 465.0193, F.S.
[7] Sections 465.003(20)(a)4. and 465.0196, F.S.
[8] Sections 465.003(20)(a)5. and 465.0197, F.S.
[9] Section 465.0158, F.S.
[10] Rules 64B16-28.100 and 64B16-28.802, F.A.C. An outsourcing facility is considered a pharmacy and need to hold a special sterile compounding permit if it engages in sterile compounding.
[11] *Id*.
[12] Rule 64B16-28.100, F.A.C.

Regulation of Pharmacists and Pharmacy Technicians

Pharmacists

Licensure Requirements

A pharmacist is a person who is licensed under the act to practice the profession of pharmacy.[13] To be licensed as a pharmacist in Florida, a person must:[14]

- Be at least 18 years of age;
- Complete an application and remit an examination fee;
- Hold a degree from an accredited and approved school or college of pharmacy;[15]
- Have completed a Board-approved internship; and
- Successfully complete the Board-approved examination.

During each biennial licensure renewal cycle, a pharmacist must complete at least 30 hours of Board-approved continuing education.[16] If a pharmacist is certified to administer vaccines or epinephrine, the pharmacist must complete a 3-hour continuing education course on the safe and effective administration of vaccines and epinephrine autoinjections as a part of the biennial licensure renewal.[17]

Scope of Practice

The practice of the profession of pharmacy includes:[18]

- Compounding,[19] dispensing, and consulting concerning contents, therapeutic values, and uses of a medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the patient's prescribing health care provider or other persons specifically authorized by the patient, regarding the drug therapy;
- Transmitting information from prescribers to their patients;
- Administering vaccines to adults;[20]
- Administering epinephrine injections;[21] and
- Administering antipsychotic medications by injection.[22]

Pharmacists are specifically prohibited from altering a prescriber's directions, diagnosing or treating any disease, initiating any drug therapy, and practicing medicine or osteopathic medicine, unless permitted by law.[23]

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[13] Section 465.003(19), F.S.
[14] Section 465.007, F.S. DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. *See* s. 465.0075, F.S.
[15] If the applicant has graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, the applicant must demonstrate proficiency in English, pass the Board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH-licensed pharmacist.
[16] Section 465.009, F.S.
[17] Section 465.009(6), F.S.
[18] Section 465.003(22), F.S.
[19] Rule 64B16-27.700, F.A.C., defines compounding a professional act by a pharmacist incorporating ingredients to create a finished product for dispensing to a patient or to a practitioner for administration to a patient. The American Pharmacists Association, citing the U.S. Pharmacopeia Convention (USP) defines compounding as "the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner/patient/ pharmacist/compounder relationship in the course of professional practice." *See* https://www.pharmacist.com/Practice/Patient-Care-Services/Compounding/Compounding-FAQs (last visited Jan. 21, 2024).
[20] *See* s. 465.189, F.S.
[21] *Id*.
[22] Section 465.1893, F.S.
[23] *Supra* note 18.

Only a pharmacist or registered intern may:[24]

- Supervise or be responsible for the controlled substance inventory;
- Receive verbal prescriptions from a prescriber;
- Interpret and identify prescription contents;
- Engage in consultation with a health care practitioner regarding the interpretation of a prescription and date in a patient's profile record;
- Engage in professional communication with health care practitioners;
- Advise or consult with a patient, both as to the prescription and the patient profile record; and
- Perform certain duties related to the preparation of parenteral and bulk solutions.

Pharmacists must perform the final check of a completed prescription, thereby assuming complete responsibility for its preparation and accuracy.[25] A pharmacist must be personally available at the time of dispensing.[26] A prescription department is considered closed if a Florida-licensed pharmacist is not present and on duty unless the pharmacist leaves the prescription department to:[27]

- Consult, respond to inquiries, or provide assistance to customers or patients;
- Attend to personal hygiene needs; or
- Perform functions for which the pharmacist is responsible provided that such activities are performed in a manner that is consistent with the pharmacist's responsibility to provide pharmacy services.

Prescription Department Managers

Each community pharmacy must have designate a licensed pharmacist as a prescription department manager.[28] The prescription drug manager is responsible for maintaining all drug records, providing for the security of the prescription department, and ensuring that the all regulations of the practice of the profession of pharmacy are followed.[29] A pharmacist may only serve as the prescription department manager of one pharmacy.[30] However, the Board may grant an exception based on circumstances, such as the proximity of the pharmacies and the workload of the pharmacist.

Pharmacy Technicians

Registration Requirements

Pharmacy technicians assist pharmacists in dispensing medications and are accountable to a supervising pharmacist who is legally responsible for the care and safety of the patients served.[31] A person must register with DOH to practice as a pharmacy technician. To register, an individual must:[32]

- Be at least 17 years of age;
- Submit an application and remit an application fee; and
- Complete a Board-approved pharmacy technician training program.[33]

[24] Rule 64B16-27.1001(1)-(2), F.A.C. Section 465.003(12), F.S., defines a pharmacy intern as a person who is currently registered in, and attending, or is a graduate of a duly accredited college or school of pharmacy and is properly registered with DOH. The American Pharmacist Association, citing the U.S.
[25] Rule 64B16-27.1001(3), F.A.C.
[26] Rule 64B16-27.1001(4), F.A.C.
[27] Section 465.003(20)(b), F.S.
[28] Rules 64B16-27.104 and 64B16-27.450, F.A.C.
[29] *Id*.
[30] *Id*.
[31] Pharmacy Technician Certification Board, *Pharmacy Technicians*, available at https://www.ptcb.org/who-we-serve/pharmacy-technicians#.Wj1PsGyouUk (last visited on Jan. 21, 2024).
[32] Section 465.014(2), F.S.
[33] An individual is exempt from the training program if he or she was registered as a pharmacy technician before January 1, 2011, and either worked as a pharmacy technician at least 1,500 hours under a licensed pharmacists or received certification from an accredited pharmacy technician program.

The pharmacy technician must renew the registration biennially. For each renewal cycle, a pharmacy technician must complete 20 continuing education hours, 4 of which must be live.[34]

Pharmacy Technician Training Programs

A pharmacy technician may only be registered with DOH if he or she completes a Board-approved training program. These include pre-approved training programs that were accredited on or before December 1, 2018, by certain accreditation entities, such as the Accreditation Council on Pharmacy Education, as well as pharmacy technician training programs provided by a branch of the United States Armed Forces whose curriculum was developed on or before June 1, 2018.[35]

The Board may review and approve other training programs that do not meet the criteria for pre-approval. Such programs must be licensed by the Commission for Independent Education or equivalent licensing authority or be within the public school system of this state, and offer a course of study that includes:[36]

- Introduction to pharmacy and health care systems;
- Confidentiality;
- Patient rights and the Health Insurance Portability and Accountability Act (HIPAA);
- Relevant federal and state law;
- Pharmaceutical topics, including medical terminology, abbreviations, and symbols; medication safety and error prevention; and prescriptions and medication orders;
- Records management and inventory control, including pharmaceutical supplies, medication labeling, medication packaging and storage, controlled substances, and adjudication and billing;
- Interpersonal relations and ethics, including diversity of communications, empathetic communications, ethics governing pharmacy practice, patient and caregiver communications; and
- Pharmaceutical calculations.

The training program must provide the Board with educational and professional background of its faculty.[37] A licensed pharmacist or registered pharmacy technician with appropriate expertise must be involved with planning and instruction and must supervise learning experiences.[38]

The Board may also review and approve employer-based pharmacy technician training programs. An employer-based program must be offered by a Florida-permitted pharmacy, or affiliated group of pharmacies under common ownership.[39] The program must consist of 160 hours of training over a period of no more than 6 months and may only be provided to the employees of that pharmacy.[40] The employer-based training program must:[41]

- Meet the same qualifications as required for non-employment based pharmacy technician training programs as indicated above;
- Provide an opportunity for students to evaluate learning experiences, instructional methods, facilitates, and resources;
- Ensure that self-directed learning experience, such as home study or web-based courses, evaluate the participant's knowledge at the completion of the learning experience; and
- Designate a person to assume responsibility for the registered pharmacy technician training program.

Scope of Practice

[34] Section 465.014(6), F.S.
[35] Rule 64B16-26.351(1)-(2), F.A.C.
[36] Rule 64B16-26.351(3)(b), F.A.C.
[37] Rule 64B16-26.351(3)(e), F.A.C.
[38] *Id*.
[39] Rule 64B16-26.351(4), F.A.C.
[40] *Id*.
[41] *Id*.

A registered pharmacy technician may not engage in the practice of the profession of pharmacy; however, a licensed pharmacist may delegate those duties, tasks, and functions that do not fall within the definition of the practice of professional pharmacy.[42] Registered pharmacy technicians' responsibilities include: [43]

- Retrieval of prescription files;
- Data entry;
- Label preparation;
- Counting, weighing, measuring, and pouring of prescription medication;
- Initiation of communication with a prescribing practitioner regarding requests for prescription refill authorization, obtaining clarification on missing or illegible information on prescriptions, and confirmation of information such as names, medication, strength, directions, and refills;
- Acceptance of authorization for prescription renewals; and
- Any other mechanical, technical, or administrative tasks which do not themselves constitute the practice of the profession of pharmacy.

A licensed pharmacist must directly supervise the performance of a registered pharmacy technician,[44] and is responsible for acts performed by persons under his or her supervision.[45] A pharmacist may use technological means to communicate with or observe a registered pharmacy technician who is performing delegated tasks.[46] If technological means are used by a pharmacist to supervise the pharmacy technician(s), the technological means must be sufficient for the pharmacist to provide the personal assistance, direction, and approval required to meet the standard of practice for the delegated tasks.[47]

The Board specifies, by rule, certain acts that registered pharmacy technicians are prohibited from:[48]

- Receiving new verbal prescriptions or any change in the medication, strength, or directions of an existing prescription;
- Interpreting a prescription or medication order for therapeutic acceptability and appropriateness;
- Conducting a final verification of dosage and directions;
- Engaging in prospective drug review;
- Monitoring prescription drug usage;
- Transferring a prescription;
- Overriding clinical alerts without first notifying the pharmacist;
- Preparing a copy of a prescription or reading a prescription to any person for the purpose of providing reference concerning treatment of the patient for whom the prescription was written;
- Engaging in patient counseling; or
- Engaging in any other act that requires the exercise of a pharmacist's professional judgment.

A registered pharmacy technician must wear an identification badge with a designation as a "registered pharmacy technician" and identify herself or himself as a registered pharmacy technician in telephone or other forms of communication.[49]

Pharmacist-to-Technician Ratios

[42] Section 465.014(1), F.S.
[43] Rule 64B16-27.420(1), F.A.C.
[44] Direct supervision means supervision by a pharmacist who is on the premises at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who is readily available to provide personal assistance, direction, and approval throughout the time the delegated tasks are being performed (r. 64B16-27.4001(2)(a), F.A.C.)
[45] Rule 64B16-27.1001(7), F.A.C.
[46] Rule 64B16-27.4001(2)(b), F.A.C.
[47] *Id.*
[48] Rule 64B16-27.420(2), F.A.C.
[49] Rule 64B16-27.100(2), F.A.C.

When the pharmacist delegates tasks to a registered pharmacy technician, such delegation must enhance the ability of the pharmacist to practice pharmacy to serve the patient populations.[50]

Current law prohibits a pharmacist from supervising more than one registered pharmacy technician, unless otherwise permitted by Board rules.[51] The guidelines include the following restrictions:[52]

- A pharmacist engaging in sterile compounding may supervise up to 3 registered pharmacy technicians.
- A pharmacist who is not engaged in sterile compounding may supervise up to 4 registered pharmacy technicians.
- In a pharmacy that does not dispense medicinal drugs, a pharmacist may supervise up to 6 registered pharmacy technicians, as long as the pharmacist or pharmacy is not involved in sterile compounding.
- In a pharmacy that dispenses medicinal drugs in a physically separate area[53] of the pharmacy from which medicinal drugs are not dispensed, a pharmacist may supervise up to 6 registered pharmacy technicians.

In all other situations, the Board rules provide the prescription department manager or the consultant pharmacist of record with the discretion to use their independent professional judgment to determine and set the appropriate pharmacist-technician supervision ratios.[54]

Telehealth

Telehealth means the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide the following, nonexhaustive types of health care services:[55]

- assessment, diagnosis, consultation, treatment, and monitoring of a patient;
- transfer of medical data;
- patient and professional health-related education;
- public health services; and
- health administration.

Telehealth providers mean any Florida-licensed or Florida-certified individual who provides health care and related services using telehealth, including pharmacists. Current law also recognizes telehealth providers who are licensed under a multistate health care licensure compact of which Florida is a member state. Current law lets health care professionals not licensed in Florida to use telehealth as long as they register with the applicable Board (e.g., The Board of Pharmacy) and provides health care services within the applicable scope of practice (e.g., the practice of pharmacy) established by Florida law or rule (e.g., the Florida Pharmacy Act).[56]

Current law specifies that the delivery of health care services occurs at the place of the patient's location (or the patient's county of residence).[57] A telehealth provider must document the health care services provided to a patient via telehealth in the patient's medical record.[58]

Current law holds telehealth providers to the duty to practice in a manner consistent with their scope of practice and the prevailing professional standard of practice for a health care professional who provides in-person health care services to patients in this state. A nonphysician telehealth provider (e.g., a

[50] Rule 64B16-27.410(1), F.A.C.
[51] Section 465.014(1), F.S.
[52] Rule 64B16-27.410, F.A.C.
[53] A "physically separate area" is a part of the pharmacy which is separated by a permanent wall or other barrier which restricts access between the two areas.
[54] Rule 64B16-27.410(7), F.A.C.
[55] s. 456.47(1)(a), F.S.
[56] *Id*., ss. 456.47(4), (6), F.S. Registration is not required in the event an out-of-state licensed health care professional provides telehealth services in response to an emergency medical condition or in consultation with a Florida-licensed health care professional who has ultimate authority over the diagnosis and care of the patient.
[57] s. 456.47(5), F.S.
[58] s. 456.47(3), F.S.

pharmacist) using telehealth and acting within his or her relevant scope of practice is not in violation of the practice of medicine or an attempt to practice medicine without a license to practice in Florida.[59]

Telepharmacy

Telepharmacy is the provision of pharmaceutical care by pharmacies and pharmacists through the use of telepharmacy technologies to patients or their agents at a distance.[60] Telepharmacy operations include, but are not limited to, drug review and monitoring, dispensing of medications, medication therapy management, clinical consultation, and patient counseling.[61]

Effect of Proposed Changes

HB 493 creates a remote-site pharmacy permit. A remote-site pharmacy includes every location where medicinal drugs are dispensed by a registered pharmacy technician who is remotely supervised by an off-site pharmacist acting in the capacity of prescription department manager.

Remote Site Pharmacy

The bill requires a DOH-issued permit to operate a remote-site pharmacy. A remote-site pharmacy must:

- Be jointly owned by a supervising pharmacy or operated under contract with a supervising pharmacy;[62]
- Maintain a video surveillance system that records continuously 24 hours per day and retain video surveillance recordings for at least 30 days;
- Display a sign, visible by the public, which indicates that the facility is a remote site pharmacy and that it is under 24-hour video surveillance;
- Maintain a policies and procedures manual which must be made available to the Board of Pharmacy or its agent upon request. The policies and procedures manual must include at the very least all of the following:
    - A description of how the pharmacy will comply with federal and state laws and rules.
    - The procedures for supervising the remote site pharmacy and counseling its patients.
    - The procedures for reviewing the prescription drug inventory and drug records maintained by the remote site pharmacy.
    - The policies and procedures for providing security adequate to protect the confidentiality and integrity of patient information.
    - The written plan for recovery from an event that interrupts or prevents the prescription department manager from supervising the remote-site pharmacy's operation.
    - The procedures for use of the state prescription drug monitoring program by the prescription department manager before they may authorize the dispensing of any controlled substance.
    - The procedures for maintaining a perpetual inventory of the controlled substances listed in Schedule II of s. 893.03, F.S.
    - The specific duties, tasks, and functions that registered pharmacy technicians are authorized to perform at the remote site pharmacy.
- Designate a licensed pharmacist or consultant pharmacist as the prescription department manager responsible for oversight of the facility.

[59] s. 456.47(2), F.S.
[60] National Association of Boards of Pharmacy, "Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy," https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/ (last visited Jan. 21, 2024). Telepharmacy technologies means secure electronic communications, information exchange, or other methods that meet state and federal requirements.
[61] E. Alexander et al, *ASHP Statement on Telepharmacy*, 74 AM J HEALTH-SYSTEM PHARM., e236 (May 2017), available at https://academic.oup.com/ajhp/article-abstract/74/9/e236/5102780?redirectedFrom=fulltext (last visited Jan. 21, 2024).
[62] The bill defines a supervising pharmacy as a Florida-licensed pharmacy that employs or contracts with a Florida-licensed pharmacist who remotely supervises a registered pharmacy technician at a remote site pharmacy at a ratio of one pharmacist to up to six registered pharmacy technicians.

DOH must issue a permit if the Board certifies that an application for a permit complies with the laws and rules governing pharmacies.

Operation of a Remote Site Pharmacy

The bill authorizes a remote-site pharmacy to store, hold, and dispense all medicinal drugs, including proprietary drugs and controlled substances. However, a remote site pharmacy may not dispense Schedule II controlled substances[63] listed in s. 893.03 unless a pharmacist is present at the remote-site pharmacy.

The prescription department manager must visit the remote site pharmacy as often as the Board schedule states. During remote-site pharmacy visits, the prescription department manager must inspect the pharmacy, address personnel matters, and provide clinical services for patients.

Generally, a remote-site pharmacy may not be open when the supervising pharmacy is closed. However, the bill creates two exceptions. First, when a pharmacist employed by or under contract with a supervising pharmacy is present at the remote-site pharmacy or is providing remote supervision as required under the bill, the remote site pharmacy may be open. Second, when a pharmacy under contract with the supervising pharmacy is present at the remote-site pharmacy or is providing remote supervision as required under the bill, the remote-site pharmacy may be open.

Generally, a registered pharmacist cannot serve as the prescription department manager in more than one location. However, the bill authorizes a pharmacist to serve as the prescription department manager for up to three remote-site pharmacies that are under common control of the same supervising pharmacy. The maximum allowable pharmacist-pharmacy technician ratio is 1:6.

Pharmacy Technicians

The bill authorizes a registered pharmacy technician working in a remote-site pharmacy under the remote supervision of a pharmacist to fill, compound, and dispense medicinal drugs.

[63] Section 893.03(2), F.S., defines a Schedule II drug as a substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment, and the abuse of the substance may lead to severe psychological or physical dependence.

Board of Pharmacy

The bill grants the Board of Pharmacy rulemaking authority to adopt rules as necessary to specify additional criteria for a remote-site pharmacy. Any additional criteria adopted by the board must be limited to rules concerning one or more of the following:

- Application requirements.
- Structural and equipment requirements.
- Training requirements.
- Inventory recordkeeping and storage requirements.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Amends s. 465.003, F.S., relating to definitions.
Section 2: Amends s. 465.014, F.S., relating to pharmacy technician.
Section 3: Amends s. 465.015, F.S., relating to violations and penalties.
Section 4: Creates s. 465.0198, F.S., relating to remote-site pharmacy permits.
Section 5: Amends s. 465.022, F.S., relating to pharmacies; general requirements; fees.
Section 6: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   According to DOH, the Department will require 7 FTEs to implement the provisions of this bill.[64]

   - 2 FTEs (Government Analyst II) to process new permit applications.
   - 4 FTEs (1 Senior Attorney, 2 Government Analyst II, and 2 Investigation Specialist II) to handle complaints, investigations, and prosecution cases.
   - 1 FTE (System Project Consultant) to establish and maintain additional transactions in the Enforcement Information Database System (LEIDS), the Online Service Portal (Versa Online) the License Verification Search Site, and the Board of Pharmacy website.

   According to DOH, the total estimated annual cost is $982,229 in the following categories:[65]

   Annual Estimated Cost
   - Salary: $759,732/Recurring
   - Salary Rate: 533,325 units of rate
   - Expense: $62,125/Recurring + $46,613/Non-recurring
   - Human Resources: $2,519
   - Contracted Services: $111,240/Non-recurring

   Because the bill does not authorize a fee for this new permit type, it is unclear how DOH will cover the costs of implementing its provisions.

[64] *Supra*, FN 3 at p. 6-7.
[65] *Id*. at 7-8.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:
   None.

2. Expenditures:
   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:
None.

D. FISCAL COMMENTS:
None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:
   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:
   None.

B. RULE-MAKING AUTHORITY:
The Board has sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to pharmacy; amending s. 465.003, F.S.; revising the definition of the term "dispense"; revising the definition of the term "pharmacy" to include remote-site pharmacies; revising construction of the term "not present and on duty"; amending s. 465.014, F.S.; authorizing registered pharmacy technicians to dispense medicinal drugs under certain circumstances; providing an exception to certain supervision limitations; amending s. 465.015, F.S.; providing applicability; exempting certain registered pharmacy technicians from specified prohibitions; creating s. 465.0198, F.S.; defining the terms "supervising pharmacy" and "telepharmacy"; providing for the permitting of remote-site pharmacies; requiring a licensed or consultant pharmacist to serve as the prescription department manager of a remote-site pharmacy; requiring remote-site pharmacies to notify the Department of Health of a change in the pharmacy's prescription department manager within a specified timeframe; providing requirements for remote-site pharmacies; authorizing remote-site pharmacies to store, hold, and dispense medicinal drugs; prohibiting the dispensing of Schedule II medications at remote-site pharmacies unless a

pharmacist is present; requiring prescription department managers to visit remote-site pharmacies, based on a certain schedule, to perform specified tasks; prohibiting remote-site pharmacies from being open when the supervising pharmacy is closed unless a certain pharmacist is present or providing remote supervision at the remote-site pharmacy; prohibiting registered pharmacists from serving as prescription department managers for more than three remote-site pharmacies under certain circumstances; authorizing the Board of Pharmacy to adopt specified rules; amending s. 465.022, F.S.; exempting registered pharmacists serving as prescription department managers for remote-site pharmacies from certain practice limitations; providing an effective date.

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

Section 1. Subsections (13) and (20) of section 465.003, Florida Statutes, are amended to read:

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

(13) "Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist, or by a registered pharmacy technician who is remotely supervised by an offsite pharmacist, to the ultimate consumer or her or his

agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. The actual sales transaction and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.

(20)(a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, ~~and~~ an Internet pharmacy, and a remote-site pharmacy.

1. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

2. The term "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.

3. The term "nuclear pharmacy" includes every location

where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.

5. The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of the profession of pharmacy.

6. The term "remote-site pharmacy" includes every location where medicinal drugs are dispensed by a registered pharmacy technician who is remotely supervised by an offsite pharmacist acting in the capacity of a prescription department manager.

(b) The pharmacy department of any permittee is ~~shall be~~ considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" may ~~shall~~ not be construed to prevent any of the following:

1. A pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers.

2. A pharmacist from~~,~~ attending to personal hygiene needs.

3. A pharmacist from~~, or~~ performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

4. An offsite pharmacist, acting in the capacity of a prescription department manager, from remotely supervising a registered pharmacy technician at a remote-site pharmacy.

Section 2. Subsection (1) of section 465.014, Florida Statutes, is amended to read:

465.014 Pharmacy technician.—

(1) A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. 465.003, and a registered pharmacy technician operating under remote supervision of an offsite pharmacist under s. 465.0198 may dispense medicinal drugs under such supervision. All such delegated acts must be performed under the direct supervision of a licensed pharmacist who is responsible for all such acts performed by persons under his or her

supervision. A registered pharmacy technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician, except as provided in s. 465.0198 or unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one pharmacy technician.

Section 3. Paragraph (b) of subsection (1) and paragraph (b) of subsection (2) of section 465.015, Florida Statutes, are amended to read:

465.015 Violations and penalties.—

(1) It is unlawful for any person to own, operate, maintain, open, establish, conduct, or have charge of, either alone or with another person or persons, a pharmacy:

(b) In which a person not licensed as a pharmacist in this state or not registered as an intern in this state or in which an intern who is not acting under the direct and immediate personal supervision of a licensed pharmacist fills, compounds, or dispenses any prescription or dispenses medicinal drugs. This paragraph does not apply to any person who owns, operates, maintains, opens, establishes, conducts, or has charge of a

remote-site pharmacy under s. 465.0198.

(2) It is unlawful for any person:

(b) To fill, compound, or dispense prescriptions or to dispense medicinal drugs if such person does not hold an active license as a pharmacist in this state, is not registered as an intern in this state, ~~or~~ is an intern not acting under the direct and immediate personal supervision of a licensed pharmacist, or is not a registered pharmacy technician at a remote-site pharmacy who is acting under remote supervision of a licensed pharmacist pursuant to s. 465.0198.

Section 4. Section 465.0198, Florida Statutes, is created to read:

465.0198 Remote-site pharmacy permits.—

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

(a) "Supervising pharmacy" means a pharmacy licensed in this state which employs or contracts with a pharmacist licensed in this state who remotely supervises a registered pharmacy technician at a remote-site pharmacy at a ratio of one pharmacist to up to six registered pharmacy technicians.

(b) "Telepharmacy" means the practice of pharmacy by a pharmacist located in this state using telecommunications or other automations and technologies to provide or supervise the provision of pharmacy services to patients and their agents who are located at sites other than where the pharmacist is located, including dispensing of prescriptions to and counseling of

patients.

(2) Any person desiring a permit to operate a remote-site pharmacy must apply to the department. If the board certifies that the application complies with the laws and rules of the board, the department must issue the permit. A permit may not be issued unless a licensed pharmacist or consultant pharmacist is designated as the prescription department manager responsible for the oversight of the remote-site pharmacy. The permittee must notify the department within 10 days after any change of the prescription department manager.

(3) A remote-site pharmacy must comply with all of the following:

(a) Be jointly owned by or operated under a contract with a supervising pharmacy.

(b) Maintain a video surveillance system that records continuously 24 hours per day and retain video surveillance recordings for at least 30 days.

(c) Display a sign visible to the public indicating that the location is a remote-site pharmacy and that the facility is under 24-hour video surveillance.

(d) Maintain a policies and procedures manual, which must be made available to the board or its agent upon request and must include, but need not be limited to, all of the following:

1. A description of how the pharmacy will comply with federal and state laws and rules.

2. The procedures for supervising the remote-site pharmacy and counseling its patients.

3. The procedures for reviewing the prescription drug inventory and drug records maintained by the remote-site pharmacy.

4. The policies and procedures for providing security adequate to protect the confidentiality and integrity of patient information.

5. The written plan for recovery from an event that interrupts or prevents the prescription department manager from supervising the remote-site pharmacy's operation.

6. The procedures for use of the state prescription drug monitoring program by the prescription department manager before he or she may authorize the dispensing of any controlled substance.

7. The procedures for maintaining a perpetual inventory of the controlled substances listed in Schedule II of s. 893.03.

8. The specific duties, tasks, and functions that registered pharmacy technicians are authorized to perform at the remote-site pharmacy.

(4) A remote-site pharmacy may store, hold, or dispense any medicinal drug, including proprietary drugs and controlled substances. However, a remote-site pharmacy may not dispense Schedule II controlled substances listed in s. 893.03 unless a pharmacist is present at the remote-site pharmacy.

(5) The prescription department manager must visit the remote-site pharmacy, based on a schedule determined by the board, to inspect the pharmacy, address personnel matters, and provide clinical services for patients.

(6) A remote-site pharmacy may not be open when the supervising pharmacy is closed, unless a pharmacist employed by or under contract with the supervising pharmacy, or a pharmacy under contract with the supervising pharmacy, is present at the remote-site pharmacy or is providing remote supervision as required under this section.

(7) A registered pharmacist may not serve as the prescription department manager for more than three remote-site pharmacies that are under common control of the same supervising pharmacy, at a ratio of one pharmacist to up to six registered pharmacy technicians at each remote-site pharmacy.

(8) The board may adopt rules as necessary to specify additional criteria for a remote-site pharmacy. Any additional criteria adopted by the board must be limited to rules concerning one or more of the following:

(a) Application requirements.

(b) Structural and equipment requirements.

(c) Training requirements.

(d) Inventory recordkeeping and storage requirements.

Section 5. Paragraph (c) of subsection (11) of section 465.022, Florida Statutes, is amended to read:

465.022 Pharmacies; general requirements; fees.—

(11) A permittee must notify the department of the identity of the prescription department manager within 10 days after employment. The prescription department manager must comply with the following requirements:

(c) A registered pharmacist may not serve as the prescription department manager in more than one location, except as authorized under s. 465.0198, unless approved by the board.

Section 6. This act shall take effect July 1, 2024.

HB 581

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 581 Swimming Lesson Voucher Program
SPONSOR(S): Busatta Cabrera
TIED BILLS: **IDEN./SIM. BILLS:** SB 544

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Curry	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

In Florida, drowning is the leading cause of accidental death for children under age five. In 2023, 94 children died in Florida from accidental drowning. Florida ranked highest in the country for unintentional drowning death rates for children ages zero to nine and third for children ages zero to 17 years of age. Studies show that swimming lessons can reduce the likelihood of child drownings.

HB 581 creates the Swimming Lesson Voucher Program within the Department of Health (DOH) to increase water safety in Florida and to offer vouchers for swimming lessons, at no cost, to low income families with children ages four and under. The bill requires DOH to implement the voucher program and contract with swimming lesson vendors to establish a network of providers to participate in the voucher program.

The bill requires DOH to establish a method for the public to apply for vouchers and for determining applicant eligibility criteria. The bill requires vendors offering swimming lessons at a public pool that is owned or maintained by a county or municipality to participate in the program, if requested by DOH.

The bill requires DOH to issue vouchers for the program to eligible applicants, subject to specific appropriation, and authorizes DOH to seek grants or other public or private funding for the program. The bill requires DOH to adopt rules to implement the swimming lesson voucher program.

HB 581 has a significant negative fiscal impact on DOH and no fiscal impact on local government.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Accidental Drownings

On average 3,500 to 4,000 people lose their lives to drowning each year in the United States (U.S.). That is an average of 10 fatal drownings per day.[1] For every fatal drowning, an estimated 5 to 10 individuals receive hospital related care for non-fatal drowning injuries. For children ages one to four, drowning is the leading cause of unintentional injury related death in the U.S.[2]

Drowning is also the leading cause of accidental death in Florida for children ages five and under.[3] In 2023, 94 children died in Florida from accidental drowning.[4] According to the Centers for Disease Control's national injury data, from 2018 to 2020 combined, Florida ranked highest in the country for unintentional drowning death rates for children ages zero to nine and third for children ages zero to 17.[5] According to the Department of Children and Families (DCF), teaching children water safety skills is important in reducing the number child drownings.[6]

Water Safety and Drowning Prevention

Water safety refers to the procedures, precautions, and policies associated with safety in, on and around bodies of water, where there is a risk of injury or drowning.[7] Components of water safety include supervision, creating barriers of protection to prevent access to water, swimming lessons, water safety training to improve water competency, and teaching emergency preparedness, such as training in cardiopulmonary resuscitation (CPR).[8] Water competency is the ability to anticipate, avoid, and survive common drowning situations.[9]

Swimming Lessons

Learning to swim is major component of water safety. It is also a key strategy for reducing accidental drowning deaths. The American Academy of Pediatrics recommends that children ages four and older learn to swim, including through swim lessons that provide instruction on swimming techniques and water survival skills taught by instructors certified through a nationally recognized curriculum.[10] Studies

[1] National Drowning Prevention Alliance (NDPA), *Drowning Quick Facts*, available at https://ndpa.org/drowning-quick-facts/, (last visited January 18, 2024).
[2] *Id*.
[3] Florida Department of Health, Seminole County, *Guide to Drowning Prevention*, available at https://seminole.floridahealth.gov/programs-and-services/environmental-health/drowning-prevention.html, (last visited January 18, 2024).
[4] Florida Department of Children and Families (DCF), *Child Fatality Prevention; Statewide Data*, available at https://www2.myflfamilies.com/childfatality/stateresults.shtml?minage=0&maxage=18&year=2023&cause=Drowning&prior12=&verified=, (last visited January 18, 2024).
[5] Florida Department of Health (DOH), *Drowning Prevention*, available at https://www.floridahealth.gov/programs-and-services/prevention/drowning-prevention/index.html#:~:text=Florida%20had%20the%20highest%20unintentional,(CDC%20national%20injury%20data)., (last visited January 18, 2024).
[6] DCF, *Water Safety for Kids*, available at https://www.myflfamilies.com/services/ child-family/child-and-family-well-being/summer-safety-tips/water-safety/water-safety-kids, (last visited January 18, 2024).
[7] NDPA, *5 Water Safety Facts*, available at https://ndpa.org/5-water-safety-facts/#:~:text=Water%20Safety%20is%20defined%20as,home%20and%20in%20real%20life., (last visited January 18, 2024).
[8] DOH, *Guide to Drowning Prevention*, available at https://seminole.floridahealth.gov/programs-and-services/environmental-health/drowning-prevention.html, and Steve Wallen Swim School, *The Importance of Water Safety and Learning to Swim*, available at https://wallenswim.com/the-importance-of-water-safety-and-learning-to-swim/, (last visited January 18, 2024).
[9] The components of water competency include water-safety awareness, basic swim skills, and the ability to recognize and respond to a swimmer in trouble. See American Academy of Pediatrics, *Prevention of Drowning*, available at https://publications.aap.org/pediatrics/article/143/5/e20190850/37134/Prevention-of-Drowning?autologincheck=redirected, (last visited January 18, 2024).
[10] American Academy of Pediatrics, Swim Lessons: When to Start & What Parents Should Know, https://www.healthychildren.org/English/safety-prevention/at-play/Pages/swim-lessons.aspx, (last visited January 18, 2024).

show that participation in formal swimming lessons reduces the risk of drowning by 88 percent for children ages one to four.[11] Participation in swimming lessons has also been shown to reduce drowning risks among children ages 1 to 19. Evidence suggest that teaching children water competency skills causes no increased risk, particularly if combined with other components of water safety and drowning prevention strategies.[12]

Water Safety Initiatives in Florida

In Florida, public schools are required to provide parents initially enrolling their child in school with information on the important role water safety education courses and swimming lessons play in saving lives by helping to prevent drownings.[13] The information provided must include local options for age-appropriate water safety courses and swimming lessons that result in a certificate indicating successful completion. Information on courses and lessons offered for free or at a reduced price must also be included.[14]

The DCF along with several state and local partners, launched the Eyes on the Kids and Water Safety for Kids initiatives to help reduce child drowning fatalities in Florida.[15] The Eyes on the Kids initiative encourages parents to practice the four water safety rules: supervision, barriers, swimming lessons and emergency preparedness. The Water Safety for Kids initiative provides short water safety presentations to elementary schools, book store story times, child care centers, libraries, summer camps, etc. The presentations can include reading water safety books, puppet shows, coloring sheets, costumed characters, and giveaways of small water safety items such as beach balls, stickers, and book marks.[16]

Effect of Bill

HB 581 creates the Swimming Lesson Voucher Program within the Department of Health (DOH) for the purpose of increasing water safety in Florida. The program offers vouchers for swimming lessons, at no cost, to families with an income of no more than 200 percent of the federal poverty level who have children age four or younger. The bill requires DOH to implement the program; in doing so, DOH must contract with swimming lesson vendors to establish a network of vendors who will accept the vouchers offered by the program in exchange for providing swimming lessons. The bill requires DOH to attempt to secure a least one vendor in each county to ensure availability of swimming lessons throughout the state. Any swimming lesson vendor who offers swimming lessons at a public pool that is owned or maintained by a county or municipality must participate in the program, if requested by DOH.

The bill requires DOH to establish a method for members of the public to apply for swimming lesson vouchers and for determining applicant eligibility. The eligibility requirements must include criteria necessary for a family to receive one or more vouchers from the program, including, but not limited to the following:

- The age of each child for whom a voucher is being sought, who may be no more than 4 years of age;
- The family income level, which may be up to 200 percent of the federal poverty level; and
- The family's address of residency in the state.

[11] National Institute of Health, *Association Between Swimming Lessons and Drowning in Childhood,* Archives Pediatric Medicine, Vol 163 No 3, March 2009, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4151293/pdf/_nihms617357.pdf, (last visited January 19, 2024).
[12] National Library of Medicine, *Learning to Swim: An Exploration of Negative Prior Aquatic Experiences Among Children*, Int J Environ Res Public Health. 2020 May; 17(10): 3557., available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7277817/#:~:text=Participation%20in%20formal%20swimming%20lessons,the%20additional%20drowning%20prevention%20strategies, (last visited January 19, 2024).
[13] S. 1003.225, F.S.
[14] *Id.*
[15] DCF, *Water Safety*¸ available at https://www.myflfamilies.com/services/child-family/child-and-family-well-being/summer-safety-tips/water-safety, (last visited January 18, 2024).
[16] *Id.*

The bill requires vouchers for the program to be issued to eligible applicants, subject to specific appropriation, and authorizes DOH to seek grants or other public or private funding for the program. The bill requires DOH to adopt rules to implement the swimming lesson voucher program.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Creates s. 514.073, F.S., relating to the swimming lesson voucher program.
Section 2: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill will have a significant negative impact on DOH to establish the swimming lesson voucher program and issue vouchers to eligible families. According to DOH, the department will need additional staff consisting of two full-time-equivalent (FTE) contract managers at $190,000, and $300,000 for contracted services, for a total fiscal impact of $500,000, recurring.[17]

This total only includes the administrative cost to establish the program, and does not include issuance of the vouchers to eligible families. Voucher funding is dependent on the desired number of eligible children served by the program and the method in which vouchers are distributed. This number is unknown and the bill does not specify a proposed scale or provide appropriation.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may have a positive fiscal impact on eligible families seeking swimming lesson vouchers for children through the program.

D. FISCAL COMMENTS:

HB 581 authorizes vouchers for the swimming lesson voucher program be issued subject to specific appropriation. However, the bill does not appropriate funding to DOH for the program.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

[17] Information was provided via telephone conversation with DOH staff Daniel Leyte-Vidal, on January 22, 2024.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill authorizes DOH to adopt rules to implement the swimming lesson voucher program.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the Swimming Lesson Voucher Program; creating s. 514.073, F.S.; creating the program within the Department of Health for a specified purpose; requiring the department to contract with and establish a network of swimming lesson vendors to participate in the program; requiring the department to attempt to secure a vendor in each county; requiring certain vendors to participate in the program if requested by the department; requiring the department to establish an application process; specifying eligibility criteria for the program; providing that the program is subject to specific appropriation; authorizing the department to seek grants or other public and private funding for the program; requiring the department to adopt rules; providing an effective date.

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

Section 1. Section 514.073, Florida Statutes, is created to read:

514.073 Swimming Lesson Voucher Program.—

(1) There is created within the department the Swimming Lesson Voucher Program. The purpose of the program is to

increase water safety in this state by offering vouchers for swimming lessons at no cost to families with an income of no more than 200 percent of the federal poverty level who have one or more children 4 years of age or younger.

(2) The department shall do all of the following to implement the program:

(a) Contract with and establish a network of swimming lesson vendors that will accept the vouchers offered by the program in exchange for providing swimming lessons. To ensure that the swimming lessons are available throughout this state, the department must attempt to secure at least one such vendor in each county. Any swimming lesson vendor that offers swimming lessons at a public pool that is owned or maintained by a county or municipality must, if requested by the department, participate in the program.

(b) Establish a method for members of the public to apply for swimming lesson vouchers and for determining an applicant's eligibility. The department shall establish eligibility criteria necessary for a family to receive one or more vouchers from the program, including, but not limited to, the following:

1. The age of each child for whom a voucher is being sought, who may be no more than 4 years of age.

2. The family income level, which may be up to 200 percent of the federal poverty level.

3. The family's address of residency in this state.

(c) Subject to specific appropriation, issue vouchers to eligible applicants.

(3) The department may seek grants or other public or private funding for the program.

(4) The department shall adopt rules to implement the program.

Section 2. This act shall take effect July 1, 2024.

COMMITTEE/SUBCOMMITTEE ACTION

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

Committee/Subcommittee hearing bill: Healthcare Regulation Subcommittee
Representative Busatta Cabrera offered the following:

Amendment

Remove lines 27-50 and insert:

swimming lessons at no cost to families who have one or more children 4 years of age or younger.

(2) The department shall do all of the following to implement the program:

(a) Contract with and establish a network of swimming lesson vendors that will accept the vouchers offered by the program in exchange for providing swimming lessons. To ensure that the swimming lessons are available throughout this state, the department must attempt to secure at least one such vendor in each county. Any swimming lesson vendor that offers swimming

lessons at a public pool that is owned or maintained by a county or municipality must, if requested by the department, participate in the program.

(b) Establish a method for members of the public to apply for swimming lesson vouchers and for determining an applicant's eligibility. The department shall establish eligibility criteria necessary for a family to receive one or more vouchers from the program, including, but not limited to, the following:

1. The age of each child for whom a voucher is being sought, who may be no more than 4 years of age.

2. The family's address of residency in this state.

HB 843

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 843 Naturopathic Medicine
SPONSOR(S): Smith
TIED BILLS: HB 845 **IDEN./SIM. BILLS:** SB 898

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Guzzo	McElroy
2) Appropriations Committee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Naturopathic physicians diagnose, treat, and care for patients using a system of practice that bases treatment on natural laws governing the human body. These practitioners may provide treatment to patients using psychological, mechanical, and other means to purify, cleanse, and normalize human tissues for the preservation and restoration of health. This may include the use of air, water, light, heat, earth, food and herb therapy, psychotherapy, electrotherapy, physiotherapy, minor surgery, and naturopathic manipulation. Naturopathic physicians are trained in standard medical sciences and in the use and interpretation of standard diagnostic instruments. Naturopathic medicine stresses a holistic approach to health care, which involves studying, and working with the patient mentally and spiritually, as well as physically, and developing an understanding of the patient in the patient's chosen environment.

Naturopathic practitioners were licensed in Florida from 1927 to 1959 when the Legislature abolished the licensing authority for naturopathy. Only those naturopathic practitioners licensed at that time who had been residents of Florida for two years were authorized to renew their licenses.

HB 843 reestablishes licensure and regulation of naturopathic physicians, and establishes new standards for the practice. The bill provides licensure authority over naturopathic physicians to the Department of Health (DOH). The bill creates the Board of Naturopathic Medicine to assist DOH in the regulation of naturopathic physicians.

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

The bill provides an effective date of December 31, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Naturopathy

The term "naturopathy" was used in the late nineteenth century to refer to an emerging system of natural therapies and philosophy to treat disease. Naturopathic physicians diagnose, treat, and care for patients using a system of practice that bases treatment on natural laws governing the human body. These practitioners may provide treatment to patients using psychological, mechanical, and other means to purify, cleanse, and normalize human tissues for the preservation and restoration of health. This may include the use of air, water, light, heat, earth, food and herb therapy, psychotherapy, electrotherapy, physiotherapy, minor surgery, and naturopathic manipulation. Naturopathic physicians are trained in standard medical sciences and in the use and interpretation of standard diagnostic instruments. Naturopathic medicine stresses a holistic approach to health care, which involves studying, and working with the patient mentally and spiritually, as well as physically, and developing an understanding of the patient in the patient's chosen environment.

Florida Licensure and Regulation of Naturopathy

Naturopathy was initially recognized by the Legislature in the Medical Act of 1921[1], which defined the practice of medicine and exempted naturopaths from the medical practice act. Naturopathic practitioners were first licensed in Florida in 1927.[2] Doctors of Naturopathy were required to observe state, county, and municipal regulations regarding the control of communicable diseases, the reporting of births and deaths, and all matters relating to the public health as was required of other "practitioners of the healing arts." Between 1947 and 1954, legal cases were decided regarding the rights of naturopaths to prescribe narcotic drugs. The Circuit Court in Pinellas County held that practitioners of naturopathy had the right to prescribe narcotic drugs.[3] On appeal, the Florida Supreme Court affirmed the lower court's decision.[4]

In 1957, the Legislature abolished the Board of Naturopathic Examiners, significantly revised the regulation of naturopathy, and placed the regulation under the Florida State Board of Health.[5] Naturopaths were classified into three groups based on the length of time that the practitioner was licensed in the state. Under that law, those licensed less than two years could not renew their licenses; those licensed more than two years but less than 15 years could not prescribe medicine in any form; and those licensed more than 15 years could not prescribe narcotic drugs. The Florida Supreme Court held that the naturopathic laws, as amended by ch. 57-129, L.O.F., were unconstitutional and void.[6]

In 1959, the Legislature abolished the licensing authority for naturopathy.[7] Only those naturopathic practitioners licensed at that time who had been residents of Florida for two years prior to enactment of ch. 59-164, L.O.F., were authorized to renew their licenses.

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[1] See chapter 8415, Laws of Florida.
[2] See chapter 12286, Laws of Florida.
[3] *In re: Complaint of Melser*, 32 So.2d 742 (Fla.1947). See also *State Department of Public Works v. Melser*, 69 So.2d 347 at 353 (Fla. 1954).
[4] *Supra.* See also Attorney General Opinion 54-96 and s. 893.02(19), F.S., relating to controlled substances, which defines "practitioner" to include "… a naturopath licensed pursuant to chapter 462, F.S." In 1939, the 5th Circuit Fed. Ct. (which includes Louisiana, Mississippi, and Texas) interpreted the Federal Narcotic Drug Act which determined that a "naturopath" was not a "physician;" therefore, they were prohibited from prescribing narcotic drugs. The court determined that even under phytotherapy, they could not prescribe drugs. Perry v. Larson, 104 F.2d 728 (1939).
[5] Ch. 57-129, Laws of Fla.
[6] *See Eslin v. Collins*, 108 So.2d 889 (Fla. 1959).
[7] *See* ch. 59-164, Laws of Fla.

Currently, chapter 462, F.S., governs the practice of naturopathy within the Department of Health (DOH). The current practice act includes a wide variety of healing techniques but prohibits surgery, chiropractic medicine, and the practice of "materia medica", a term that includes the prescription of drugs.[8]

Chapter 462, F.S., prohibits the issuance of a license to any person who was not practicing naturopathy in Florida as of July 1, 1959.[9] The chapter also authorizes DOH to adopt rules to implement the regulation of naturopathic medicine including the establishment of fees.[10] Additionally, it provides procedures for naturopathic physicians licensed prior to 1959 to renew their license.

Draft legislation proposed by the Florida Naturopathic Physician Association was introduced in 2004 and 2006 to reestablish regulation of naturopathic medicine through licensure. A 2004 Sunrise Report on Proposed Licensure of Naturopathic Physicians, by the Florida House of Representatives, Committee on Health Care, concluded that "while there is evidence for support of licensure based on the existence of accredited training programs and licensure examinations, there is no documented evidence of substantial risk from not licensing naturopathic physicians. Moreover, there is potential risk from licensing naturopathic physicians and allowing them to provide a broad range of primary care services."[11]

National Accreditation

The Council on Naturopathic Medical Education (CNME) accredits four-year, campus-based doctoral programs in naturopathic medicine (ND programs) that qualify graduates for licensure in the U.S. and Canada. CNME-accredited ND programs may also incorporate online/distance education coursework, as well as hybrid courses that combine online and in-person components. The CNME does not accredit ND programs that are taught entirely or primarily using online/distance instruction, and these types of programs do not qualify individuals for licensure. CNME's accreditation standards cover areas such as ND program length and content, clinical training requirements, faculty qualifications, student services, student and program assessment, facilities, and library resources.[12]

There are five accredited colleges of naturopathic medicine in the United States: Bastyr University, San Diego, California; Bastyr University, Kenmore, Washington; National University of Health Sciences, Chicago, Illinois; National University of Natural Medicine, Portland, Oregon; and Sonoran University of Health Sciences, Tempe, Arizona.[13] The graduates of these programs receive a Doctor of Naturopathic Medicine degree after four years of professional study. Admission requirements include completion of a bachelor's degree before matriculation into the naturopathic medicine program with specified exceptions, including the following courses: inorganic chemistry with lab, organic chemistry with lab, biology with lab, physics, and psychology.

[8] S. 462.01(1), F.S., "Natureopathy" and "naturopathy" are defined as synonymous terms and mean the use and practice of psychological, mechanical, and material health sciences to aid in purifying, cleansing, and normalizing human tissues for the preservation or restoration of health, according to the fundamental principles of anatomy, physiology, and applied psychology, as may be required. Naturopathic practice employs, among other agencies, phytotherapy (botanical \herbal medicine), dietetics, psychotherapy, suggestotherapy (process of influencing attitudes and behaviors by suggestions), hydrotherapy (scientific use of water in the treatment of diseases), zone therapy (a process of using various points on the human body causing a reflex action in another part of the body to treat disease and relieve pain), biochemistry, external applications, electrotherapy (generation of heat in the body by use of electrical current), mechanotherapy (manipulation of the body tissues and joints), mechanical and electrical appliances, hygiene, first aid, sanitation, and heliotherapy (the use of sun rays in the treatment).
[9] S. 462.023, F.S.
[10] *Id.*
[11] Florida House of Representatives, Committee on Health Care, *Sunrise Report on Proposed Licensure of Naturopathic Physicians* (Jan. 2004), available at https://centerforinquiry.org/wp-content/uploads/sites/33/quackwatch/fl_sunrise_2004.pdf (last visited January 21, 2024).
[12] Council on Naturopathic Medical Education, Naturopathic Program Accreditation, available at https://cnme.org/naturopathic-accreditation/#overview (last visited January 21, 2024).
[13] Council on Naturopathic Medical Education, Accredited Naturopathic Schools, available at https://cnme.org/accredited-programs/#schools (last visited January 21, 2024).

Other State Licensure of Naturopathy

Currently, 24 states regulate naturopathic doctors.[14]

According to the Association of Accredited Naturopathic Medical Colleges, to be licensed as a primary care naturopathic physician by a state which requires licensing, one must:[15]

- Graduate from a four-year, professional-level program at an accredited naturopathic medical school that is recognized by the United States Department of Education;
- Pass the two-part Naturopathic Physicians Licensing Exam, which covers basic sciences, diagnostic and therapeutic subjects, and clinical sciences; and
- Pass jurisprudence examinations and meet other state requirements for regulated professions including background checks and continuing education.

Effect of the Bill

The bill creates standards for the licensure and regulation of naturopathic physicians.

Board of Naturopathic Medicine

The bill creates the Board of Naturopathic Medicine within DOH. The bill provides for the composition of the seven-member board, appointed by the Governor and confirmed by the Senate, to include the following:

- Five licensed naturopathic physicians who are Florida residents.
- Two who are not health care practitioners and who are Florida residents.
- At least one who is 55 years of age or older.

The bill provides for staggered terms by requiring three members to be initially appointed for four-year terms, two members for three-year terms, and two members for two-year terms. As the terms expire, the Governor must appoint successors for terms of 4 years.

The bill requires the board, in conjunction with DOH, to establish a disciplinary training program for board members. The disciplinary training program must provide initial and periodic training on the grounds for disciplinary action, the actions that may be taken by the board and DOH, changes in relevant statutes and rules, and any relevant judicial and administrative decisions. A member of the board may not participate on a probable cause panel or in a disciplinary decision of the board unless they have completed the disciplinary training program.

Board members must attempt to complete their work on a probable cause panel during their terms of service. However, if consideration of a case has begun but it is not completed during a board members term of service, the board may reconvene as a probable cause panel to complete their deliberations on the case.

Scope of Practice

The bill establishes the scope of practice for naturopathic physicians to include the diagnosis, prevention, and treatment of any human disease, pain, injury, deformity, or other physical or mental condition for therapeutic or preventative purposes. Treatment by a naturopathic physician may include the prescription of lifestyle changes, natural medicines, vitamins, minerals, dietary supplements, botanical medicines, medicinal fungi, and homeopathic medicines. Naturopathic physicians may prescribe legend drugs as specified by the Naturopathic Medical Formulary established under s.

[14] Association of Accredited Naturopathic Medical Colleges, Naturopathic Doctor Licensure, available at https://aanmc.org/licensure/ (last visited January 21, 2024). The states include Alaska, Arizona, California, Colorado, Connecticut, Hawaii, Idaho, Kansas, Maine, Maryland, Massachusetts, Minnesota, Montana, New Hampshire, New Mexico, North Dakota, Oregon, Pennsylvania, Rhode Island, Utah, Vermont, Washington, and Wisconsin (plus the District of Columbia and Puerto Rico).
[15] *Id.*

462.025, F.S., in accordance with the educational standards and requirements set by the Council on Naturopathic Medical Education, or an equivalent body.

The bill authorizes the board to establish by rule standards of practice and standards of care for particular practice areas, including, but not limited to, education and training, equipment and supplies, medications as specified by the Naturopathic Medical Formulary under s. 462.025, assistance from and delegation to other personnel, transfer agreements, sterilization, records, performance of complex or multiple procedures, informed consent, and policy and procedure manuals.

The bill prohibits a naturopathic physician from performing any of the following duties:

- Prescribing, dispensing, or administering and legend drug other than those authorized under the Naturopathic Medical Formulary established under s. 462.025, F.S.
- Performing any surgical procedures.
- Practicing or claiming to practice as a medical doctor or physician, osteopathic physician, dentist, podiatric physician, optometrist, psychologist, nurse practitioner, physician assistant, chiropractic physician, physical therapist, acupuncturist, midwife, or any other health care practitioner as defined in s. 456.001, F.S.
- Using general or spinal anesthetics.
- Administering ionizing radioactive substances.
- Performing chiropractic or osteopathic adjustments or manipulations that include high-velocity thrusts at or beyond the end range of normal joint motion, unless the naturopathic physician is also licensed as a chiropractic physician or an osteopathic physician.
- Performing acupuncture, unless also licensed as an acupuncturist.
- Prescribing, dispensing, or administering for cosmetic purposes any nonprescription drug or legend drug listed in the Naturopathic Medical Formulary.

Licensure

Initial Licensure

The bill requires an applicant for licensure as a naturopathic physician to meet the following requirements, which must be certified by the board:

- Be at least 21 years of age.
- Have a bachelor's degree from one of the following:
    - A college or university accredited by an accrediting agency recognized by the United States Department of Education or the Council for Higher Education Accreditation or its successor entity;
    - A college or university in Canada which is a member of Universities Canada; or
    - A college or university in a foreign country and has provided evidence that her or his educational credentials are deemed equivalent to those provided in this country. To have educational credentials deemed equivalent, the applicant must provide her or his foreign educational credentials, including transcripts, course descriptions or syllabi, and diplomas, to a nationally recognized educational credential evaluating agency approved by the board for the evaluation and determination of equivalency of the foreign educational credentials.
- Have a naturopathic doctoral degree from a college or program accredited by the Council on Naturopathic Medical Education or another accrediting agency recognized by the U.S. Department of Education.
- Be physically and mentally fit to practice as a naturopathic physician.
- Be of good moral character.
- Not have committed any act or offense in this or any other jurisdiction which would constitute the basis for disciplining a naturopathic physician pursuant to s. 462.017.
- Not have had an application for licensure in any profession denied or had her or his license to practice any profession revoked or suspended by any other state, district, or territory of the

United States or another country for reasons that relate to her or his ability to practice skillfully and safely as a naturopathic physician.
- Not have been found guilty of a felony.
- Submit fingerprints to DOH for a criminal background check.
- Demonstrate compliance with the financial responsibility requirements of s. 462.015, F.S.
- Obtain a passing score, as determined by the board, on Part I – Biomedical Science Examination, Part II – Core Clinical Science Examination, and Part II – Clinical Elective Pharmacology Examination of the competency-based national Naturopathic Physician Licensing Examination administered by the North American Board of Naturopathic Examiners, or an equivalent exam offered by an equivalent or successor entity, as approved by the board.

The bill also authorizes DOH to issue a license by endorsement to any person who:

- Has been licensed to practice naturopathic medicine for at least five years in another state or territory of the United States or Canada, if the applicant meets all the above licensure requirements.
- Has held an active license to practice naturopathic medicine in another state or territory of the United States or Canada for less than five years immediately preceding the filing of their application, if they have obtained a passing score on the national licensing exam.

If the board determines that an applicant for licensure, including licensure by endorsement, has failed to meet any of the above requirements, it may enter an order imposing one ore more of the following:

- Refusal to certify an application for licensure to DOH;
- Certification to DOH of an application for licensure with restrictions on the scope of practice of the naturopathic physician; or
- Certification to DOH of an application for licensure with a probationary period for the applicant, subject to such conditions as the board specifies, including, requiring the naturopathic physician to submit to treatment, attend continuing education courses, submit to reexamination, or work under the supervision of another naturopathic physician.

The bill prohibits DOH from issuing a license, including a license by endorsement, to any individual who:

- Is under investigation in another jurisdiction for an offense that would constitute a violation of ch. 462, F.S., or ch. 456, F.S., until the investigation has been completed;
- Has committed an act or offense in any jurisdiction which would constitute the basis for disciplining a naturopathic physician under s. 462.017, F.S., until the investigation has been completed;

If the board finds that an applicant for licensure, including licensure by endorsement, has committed an act or offense in any jurisdiction which would constitute the basis for disciplining a naturopathic physician under s. 462.017, F.S., the board may enter an order imposing one or more of the sanctions set forth in that section and s. 456.072(2), F.S., as applicable, including refusing to certify an application for licensure or certifying an application for licensure with conditions.

Licensure Renewal

The bill requires licensed naturopathic physicians to renew their licenses biennially in order to continue practicing naturopathic medicine. The amount of the biennial renewal fee, which may not be more than $1,000, must be determined by DOH. Upon licensure renewal, an applicant must also provide proof of compliance with continuing education requirements and financial responsibility requirements. The bill requires DOH to adopt rules to establish standards for biennial licensure renewal.

An applicant for licensure renewal must complete 60 hours of continuing education during each biennial renewal period, which must include at least 10 hours in pharmacology, addressing the use of legend drugs that are consistent with the education and training of naturopathic physicians. The board must

approve organizations that accredit naturopathic continuing education providers, including, but not limited to, the American Association of Naturopathic Physicians, the North American Naturopathic Continuing Education Accreditation Council, and the Oregon Association of Naturopathic Physicians.

Reactivating an Inactive License

The bill authorizes a licensee to reactivate an inactive license by paying any applicable fees, and submitting proof of compliance with the financial responsibility requirements of s. 462.015, F.S.

The bill requires the board to adopt rules relating to reactivation of inactive licenses, which must address requirements for continuing education and may not require less than 20 classroom hours for each year the license was inactive. The board may also adopt rules to determine fees, including a fee for placing a license in inactive status, a biennial renewal fee for licenses in inactive status, a delinquency fee, and a fee for the reactivation of a license. None of these fees may exceed the biennial renewal fee established by the board (which may not be more than $1,000).

Patient Records

The bill requires the board to adopt rules for the handling of medical records by licensed naturopathic physicians, including when a naturopathic physician sells or otherwise terminates their practice. The rules must provide for notification of the naturopathic physician's patients and for an opportunity for the patients to request the transfer of their medical records to another physician or health care practitioner upon payment of actual costs for such transfer.

Disciplinary Action

The bill authorizes the board to take disciplinary action[16] against a naturopathic physician who commits any of the following acts:

- Giving false testimony in the course of any legal or administrative proceedings related to the practice of naturopathic medicine or the delivery of health care services.
- Refusing to provide health care based on a patient's participation in pending or past litigation or participation in any disciplinary action conducted pursuant to this chapter, unless such litigation or disciplinary action directly involves the naturopathic physician requested to provide services.
- Fraudulently altering or destroying records relating to patient care or treatment, including, but not limited to, patient histories, examination results, test results, X rays, records of medicine prescribed, dispensed, or administered, and reports of consultations and hospitalizations.
- Committing medical malpractice or gross medical malpractice.
- Failing to adequately supervise the activities of any persons acting under the supervision of the naturopathic physician.
- Misrepresenting or concealing a material fact at any time during any phase of a licensing or disciplinary process or procedure.
- Interfering with an investigation or with any disciplinary proceeding.
- Failing to report to DOH any person licensed under chapter 458, chapter 459, whom the naturopathic physician knows has violated the grounds for disciplinary action set out in the law under which that person is licensed and who provides health care services in a facility licensed under chapter 395, or a health maintenance organization certificated under part I of chapter 641, in which the naturopathic physician also provides services.
- Being found by any court in this state to have provided, without reasonable investigation, corroborating written medical expert opinion attached to any statutorily required notice of claim or intent, or to any statutorily required response rejecting a claim.

[16] S. 456.072(2), F.S. Action taken by the board may include: refusal to certify, or to certify with restrictions, an application for a license; suspension or permanent revocation of a license; restriction of practice or license; imposition of an administrative fine not to exceed $10,000 for each count or separate offense; issuance of a reprimand or letter of concern; licensure probation; corrective action; imposition of an administrative fine of up to $100 for non-willful violations and up to $500 for willful violations; refund of fees billed and collected from the patient; or remedial education.

- Failing to provide patients with information about their patient rights and how to file a patient complaint.
- Providing deceptive or fraudulent expert witness testimony related to the practice of naturopathic medicine.
- Promoting or advertising through any communication medium the use, sale, or dispensing of any controlled substance appearing on any schedule in chapter 893 which is not within the scope of the Naturopathic Medical Formulary established under s. 462.025.

If DOH receives information that a naturopathic physician has had three or more claims filed against them, each with indemnities exceeding $50,000, within the previous 5-year period, DOH must investigate the occurrences upon which the claims were based and determine if action against the naturopathic physician is warranted.

If any naturopathic physician commits unprofessional conduct or negligence or demonstrates mental or physical incapacity or impairment such that DOH determines that she or he is unable to practice with reasonable skill and safety and presents a danger to patients, DOH may bring an action in circuit court enjoining such naturopathic physician from providing medical services to the public until the naturopathic physician demonstrates the ability to practice with reasonable skill and safety and without danger to patients.

If an investigation of a naturopathic physician is undertaken, DOH must promptly furnish to the naturopathic physician or her or his attorney a copy of the complaint or document that prompted initiation of the investigation. A naturopathic physician may submit to DOH a written response to the information contained in the complaint or document that prompted the initiation of the investigation within 45 days after she or he receives service of such complaint or document. The naturopathic physician's written response must be considered by the probable cause panel, if held on the matter.

The bill provides that certain acts committed by a naturopathic physician constitute a third-degree felony, including:

- Practicing, or attempting to practice, naturopathic medicine without an active license.
- Practicing beyond the scope of practice for a naturopathic physician.
- Obtaining, or attempting to obtain, a license to practice naturopathic medicine by a knowing misrepresentation.
- Obtaining, or attempting to obtain, a position as a naturopathic physician or naturopathic medical resident in a clinic or hospital by knowingly misrepresenting education, training, or experience.
- Dispensing a controlled substance listed in Schedule II or Schedule III of s. 893.03 in violation of s. 465.0276.

The bill provides that certain acts committed by a naturopathic physician constitute a first-degree misdemeanor, including:

- Knowingly concealing information relating to a committed violation.
- Making a false oath or affirmation when an oath or affirmation is required.

The bill provides that certain acts committed by a naturopathic physician constitute a second-degree misdemeanor, including:

- Fraudulently altering, defacing, or falsifying any records relating to patient care or treatment, including, but not limited to, patient histories, examination results, and test results.
- Referring any patient for health care goods or services to any partnership, firm, corporation, or other business entity in which the naturopathic physician or the naturopathic physician's employer has an equity interest of 10 percent or more, unless, before such referral, the naturopathic physician notifies the patient of her or his financial interest and of the patient's right to obtain such goods or services at the location of the patient's choice.

- Paying or receiving any commission, bonus, kickback, or rebate or engaging in any split-fee arrangement in any form with a physician, an organization, an agency, a person, a partnership, a firm, a corporation, or other business entity for patients referred to providers of health care goods and services, including, but not limited to, hospitals, nursing homes, clinical laboratories, ambulatory surgical centers, or pharmacies.

Naturopathic Medical Formulary Council

The bill creates the Naturopathic Medical Formulary Council within DOH. The bill requires the council to establish the Naturopathic Medical Formulary of legend drugs that a licensed naturopathic physician may prescribe in the practice of naturopathic medicine. The bill prohibits the formulary from including the following drugs:

- Drugs that are inconsistent with the education and training provided by approved colleges and programs of naturopathic medicine or board-approved continuing education courses for naturopathic physicians; or
- Drugs the prescription of which requires education and training beyond that of a naturopathic physician.

The bill provides an effective date of December 31, 2024.

B. SECTION DIRECTORY:

Section 1: Redesignates chapter 462, Florida Statutes, entitled "Naturopathy," as "Naturopathic Medicine.
Section 2: Creates s. 462.001, F.S., relating to legislative findings; purpose.
Section 3: Creates s. 462.002, F.S., relating to exceptions.
Section 4: Renumbers s. 462.01, F.S., as s. 462.003, F.S., and amends s. 462.003, relating to definitions.
Section 5: Creates s. 462.004, F.S., relating to board of naturopathic medicine.
Section 6: Renumbers s. 462.023, F.S., as s. 462.005, F.S., and amends s. 462.005, F.S., relating to rulemaking authority; powers and duties of the board.
Section 7: Creates s. 462.006, F.S., relating to licensure required.
Section 8: Creates s. 462.007, F.S., relating to licensure by examination.
Section 9: Creates s. 462.008, F.S., relating to licensure by endorsement.
Section 10: Renumbers s. 462.08, F.S., as s. 462.009, F.S., and amends s. 462.009, F.S., relating to renewal of license to practice naturopathic medicine.
Section 11: Renumbers s. 462.18, F.S., as s. 462.011, F.S., and amends s. 462.011, F.S., relating to continuing education.
Section 12: Renumbers s. 462.19, F.S., as s. 462.012, F.S., and amends s. 462.012, F.S., relating to inactive status; reactivation of license.
Section 13: Renumbers s. 462.11, F.S., as s. 462.013, F.S., and amends s. 462.013, F.S., relating to obligations of naturopathic physicians.
Section 14: Creates s. 462.014, F.S., relating to patient records; termination of practice.
Section 15: Creates s. 462.015, F.S., relating to financial responsibility.
Section 16: Renumbers s. 462.13, F.S., as s. 462.016, F.S., and amends s. 462.016, F.S., relating to additional powers and duties of the board and the department.
Section 17: Renumbers s. 462.14, F.S., as s. 462.017, F.S., and amends s. 462.017, F.S., relating to grounds for disciplinary action; action by the board and department.
Section 18: Creates s. 462.018, F.S., relating to specialties.
Section 19: Renumbers s. 462.17, F.S., as s. 462.019, F.S., and amends s. 462.019, F.S., relating to penalty for offenses.
Section 20: Creates s. 462.024, F.S., relating to disclosure of medications by patients.
Section 21: Creates s. 462.025, F.S., relating to naturopathic medical formulary council; establishment of formulary.
Section 22: Creates s. 462.026, F.S., relating to severability.
Section 23: Renumber s. 462.09, F.S., as s. 462.027, F.S.
Section 24: Repeals s. 462.16, F.S., relating to reissue of license.

Section 25: Repeals s. 462.2001, F.S., relating to saving clause.
Section 26: Amends s. 921.0022, F.S., relating to criminal punishment code; offense severity ranking chart.
Section 27: Provides an effective date of December 31, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

HB 845, which is linked to HB 843, authorizes DOH to collect the following licensure fees:

- Initial licensure fee not to exceed $2,000;
- Initial licensure by endorsement fee not to exceed $2,000;
- Biennial licensure renewal fee not to exceed $1,000;
- Inactive status licensure fee not to exceed $1,000;
- Biennial renewal fee for inactive status not to exceed $1,000;
- Delinquency fee not to exceed $1,000; and a
- Reactivation fee not to exceed $1,000.

The total revenue DOH will receive from such fees is indeterminate because the number of individuals who will choose to become licensed as a naturopathic physician is unknown.

2. Expenditures:

DOH will incur costs to implement the bill's provisions. Current resources and new revenue from licensure fees are adequate to absorb these costs.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rule-making authority to DOH to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to naturopathic medicine; redesignating the title of ch. 462, F.S., from "Naturopathy" to "Naturopathic Medicine"; creating s. 462.001, F.S.; providing legislative findings and purpose; creating s. 462.002, F.S.; providing applicability and construction; renumbering and amending s. 462.01, F.S.; revising and defining terms; creating s. 462.004, F.S.; creating the Board of Naturopathic Medicine within the Department of Health; providing for membership of the board; requiring the board, in conjunction with the department, to establish a disciplinary training program for board members; providing requirements for the program; providing that board members may not participate in probable cause panels or disciplinary decisions unless they have completed the training program; requiring board members appointed to probable cause panels to attempt to complete their work on every case presented to them; authorizing board members to reconvene a probable cause panel under certain circumstances; providing applicability; renumbering and amending s. 462.023, F.S.; authorizing the board to adopt rules; deleting obsolete language; creating s. 462.006, F.S.; prohibiting certain unlicensed persons from practicing

naturopathic medicine or promoting, identifying, or describing themselves using specified titles or abbreviations; providing construction; creating ss. 462.007 and 462.008, F.S.; providing for licensure by examination and by endorsement, respectively, of naturopathic physicians; requiring the department and the board to use an investigative process to ensure that applicants meet the applicable criteria; authorizing the State Surgeon General or her or his designee to issue a 90-day licensure delay under certain circumstances; providing construction; prohibiting the board from certifying for licensure certain applicants until a certain investigation is completed; providing applicability; prohibiting the department from issuing a license to certain applicants until the board has reviewed the application and certified the applicant for licensure; authorizing the board to enter an order imposing certain sanctions against or conditions on an applicant for licensure under certain circumstances; renumbering and amending s. 462.08, F.S.; revising requirements for licensure renewal for naturopathic physicians; requiring the department to adopt rules; renumbering and amending s. 462.18, F.S.; revising continuing education requirements for naturopathic

physicians; requiring naturopathic physicians to use the department's electronic continuing education tracking system to demonstrate compliance with continuing education requirements; renumbering and amending s. 462.19, F.S.; revising provisions related to reactivation of inactive naturopathic physician licenses; requiring the board to adopt rules relating to the reactivation of inactive licenses; providing requirements for the rules; authorizing the board to adopt rules to determine certain fees; prohibiting the department from reactivating a license until certain conditions have been met; renumbering and amending s. 462.11, F.S.; conforming a provision to changes made by the act; creating s. 462.014, F.S.; requiring the board to adopt rules providing for the handling of medical records by licensed naturopathic physicians; providing requirements for such rules; creating s. 462.015, F.S.; providing financial responsibility requirements as a condition of licensure for naturopathic physicians; providing exemptions from such requirements; requiring certain insuring entities to promptly notify the department of a naturopathic physician's cancellation or nonrenewal of insurance; requiring the department to suspend the license of a naturopathic physician under certain circumstances

until the licensee demonstrates compliance with specified requirements; providing applicability; requiring certain naturopathic physicians to provide a specified notice to their patients; providing requirements for the notice; providing for permanent disqualification from any exemption from the financial responsibility requirements, and for disciplinary action, for specified conduct; requiring certain naturopathic physicians to notify the department in writing of any change in circumstance and demonstrate compliance with certain requirements; requiring the department to suspend the license of a naturopathic physician under certain circumstances until certain requirements are met; providing applicability; requiring the board to adopt rules; renumbering and amending s. 462.13, F.S.; conforming a provision to changes made by the act; renumbering and amending s. 462.14, F.S.; revising grounds for disciplinary action; providing construction; providing for disciplinary actions by the board and department; providing for the standard of proof in certain administrative actions; providing requirements for the reinstatement of a license for certain persons; providing requirements for disciplinary guidelines adopted by the board; providing requirements and

procedures for the department's receipt of certain closed claims and reports involving a licensed naturopathic physician; authorizing the department to bring an action to enjoin a naturopathic physician from providing medical services under certain circumstances; requiring the department to promptly furnish certain documents to a naturopathic physician or her or his attorney upon undertaking an investigation of the naturopathic physician; authorizing a naturopathic physician who is the subject of such investigation to submit a written response within a specified timeframe; requiring the response to be considered by the probable cause panel, if held on the matter; creating s. 462.018, F.S.; prohibiting licensed naturopathic physicians from holding themselves out as board-certified specialists unless certified by the board regulating such specialty; authorizing licensed naturopathic physicians to accurately indicate or state which services or types of services they provide within the scope of practice of naturopathic medicine; renumbering and amending s. 462.17, F.S.; providing criminal penalties for specified violations relating to the practice of naturopathic medicine; creating s. 462.024, F.S.; providing that patients are responsible

for advising treating health care practitioners about any legend drugs, nutrients, or natural medicinal substances that a naturopathic physician has prescribed or recommended to the patient; requiring naturopathic physicians to advise their patients of such responsibility; creating a rebuttable presumption that certain injuries sustained by a patient are caused by her or his failure to disclose such information as required; providing for the rebuttal of such presumption under certain circumstances; providing construction; providing that a naturopathic physician is not required to confirm whether a patient has disclosed this information to another treating health care practitioner; creating s. 462.025, F.S.; establishing the Naturopathic Medical Formulary Council, separate and distinct from the board; providing for membership of the council; requiring the council to establish the Naturopathic Medical Formulary; providing requirements for the formulary; requiring the council to review the formulary annually and at any time upon board request; providing that naturopathic physicians may prescribe, administer, and dispense only those drugs included in the formulary; providing construction; creating s. 462.026, F.S.; providing severability; renumbering s. 462.09, F.S.,

relating to disposition of fees; repealing s. 462.16, F.S., relating to reissue of license; repealing s. 462.2001, F.S., relating to saving clause; amending s. 921.0022, F.S.; conforming a cross-reference; providing an effective date.

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

Section 1. Chapter 462, Florida Statutes, entitled "Naturopathy," is redesignated as "Naturopathic Medicine."

Section 2. Section 462.001, Florida Statutes, is created to read:

462.001 Legislative findings; purpose.—

(1) The Legislature finds that a significant number of this state's residents choose naturopathic medicine for their health care needs, and the Legislature acknowledges that naturopathic medicine is a distinct health care profession that affects the public health, safety, and welfare and contributes to freedom of choice in health care.

(2) The purpose of this chapter is to provide standards for the licensing and regulation of naturopathic physicians in order to protect the public health, safety, and welfare; to ensure that naturopathic health care provided by qualified naturopathic physicians is available to residents of this state; and to provide a means of identifying qualified naturopathic

physicians.

Section 3. Section 462.002, Florida Statutes, is created to read:

462.002 Exceptions.—

(1) This chapter does not apply to:

(a) Other duly licensed health care practitioners acting within their scopes of practice, as authorized by statute.

(b) Students practicing under the direct supervision of a licensed naturopathic physician as part of a preceptorship program while enrolled in a college or university program that is accredited by, or has candidacy status with, the Council on Naturopathic Medical Education or an equivalent accrediting body for the naturopathic medical profession which is recognized by the United States Department of Education and the board.

(c) Naturopathic residents practicing under the direct supervision of a licensed naturopathic physician at a residency site recognized by the Council on Naturopathic Medical Education or by an equivalent accrediting body for the naturopathic medical profession which is recognized by the United States Department of Education and the board.

(d) The practice of the religious tenets of any church in this state.

(e) The domestic administration of recognized family remedies.

(2) This chapter may not be construed to prohibit any

service rendered by a person if such service is rendered under the direct supervision and control of a licensed naturopathic physician who is available if needed, provides specific direction for any service to be performed, and gives final approval for all services performed.

Section 4. Section 462.01, Florida Statutes, is renumbered as section 462.003, Florida Statutes, and amended to read:

462.003 ~~462.01~~ Definitions.—As used in this chapter, the term:

(1) "Board" means the Board of Naturopathic Medicine ~~"Natureopathy" and "Naturopathy" shall be construed as synonymous terms and mean the use and practice of psychological, mechanical, and material health sciences to aid in purifying, cleansing, and normalizing human tissues for the preservation or restoration of health, according to the fundamental principles of anatomy, physiology, and applied psychology, as may be required. Naturopathic practice employs, among other agencies, phytotherapy, dietetics, psychotherapy, suggestotherapy, hydrotherapy, zone therapy, biochemistry, external applications, electrotherapy, mechanotherapy, mechanical and electrical appliances, hygiene, first aid, sanitation, and heliotherapy; provided, however, that nothing in this chapter shall be held or construed to authorize any naturopathic physician licensed hereunder to practice materia medica or surgery or chiropractic medicine, nor shall the provisions of this law in any manner~~

~~apply to or affect the practice of osteopathic medicine, chiropractic medicine, Christian Science, or any other treatment authorized and provided for by law for the cure or prevention of disease and ailments~~.

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

(3) "Division" means the Division of Medical Quality Assurance of the department.

(4) "Legend drug" has the same meaning as "prescription drug" as defined in s. 499.003.

(5) "Naturopathic doctoral degree" means the "Doctor of Naturopathic Medicine," "Doctor of Naturopathy," or "Diploma of Naturopathic Medicine" degree, designated as "N.D." or "N.M.D.," from a college or university that is accredited by, or has candidacy with, the Council on Naturopathic Medical Education or an equivalent accrediting body for the naturopathic medical profession which is recognized by the United States Department of Education and the board. When referring to a naturopathic school of medicine degree, each of these degrees must be construed as equivalent to each other.

(6) "Naturopathic Medical Formulary" or "formulary" means the Naturopathic Medical Formulary established under s. 462.025, which authorizes licensed naturopathic physicians to prescribe, dispense, and administer specific legend drugs that are consistent with the practice of naturopathic medicine.

(7) "Naturopathic physician" means a person licensed to

practice naturopathic medicine under this chapter.

(8) "Naturopathic therapeutic order" means a set of guidelines to help naturopathic physicians completely resolve a patient's symptoms and address the underlying cause while using the least force necessary.

(9)(a) "Practice of naturopathic medicine" means the diagnosis, prevention, treatment, and prescription of lifestyle change, natural medicines, including vitamins, minerals, dietary supplements, botanical medicines, medicinal fungi, and homeopathic medicines, and legend drugs as specified by the Naturopathic Medical Formulary established under s. 462.025 which are provided and administered, through the appropriate route of administration, by a naturopathic physician for preventative and therapeutic purposes for any human disease, pain, injury, deformity, or other physical or mental condition; which is based on and consistent with the naturopathic educational standards and requirements of the Council on Naturopathic Medical Education or an equivalent accrediting body for the naturopathic medical profession which is recognized by the United States Department of Education and the board; and which emphasizes the importance of the principles of naturopathic medicine and the naturopathic therapeutic order in the maintenance and restoration of health.

(b) The term does not include any of the following:

1. Prescribing, dispensing, or administering any legend

drug other than those authorized under the Naturopathic Medical Formulary established under s. 462.025.

2. Performing any surgical procedure.

3. Practicing or claiming to practice as a medical doctor or physician, an osteopathic physician, a dentist, a podiatric physician, an optometrist, a psychologist, a nurse practitioner, a physician assistant, a chiropractic physician, a physical therapist, an acupuncturist, a midwife, or any other health care practitioner as defined in s. 456.001.

4. Using general or spinal anesthetics.

5. Administering ionizing radioactive substances.

6. Performing chiropractic or osteopathic adjustments or manipulations that include high-velocity thrusts at or beyond the end range of normal joint motion, unless the naturopathic physician is also licensed as a chiropractic physician or an osteopathic physician.

7. Performing acupuncture, unless the naturopathic physician is also licensed as an acupuncturist.

8. Prescribing, dispensing, or administering for cosmetic purposes any nonprescription drug or legend drug listed in the Naturopathic Medical Formulary.

(10) "Preceptorship program" means a component of a naturopathic doctoral degree program which allows naturopathic medical students to observe health care practitioners while attending patients, giving naturopathic medical students a wide

variety of experiences in different health care settings in order to develop clinical knowledge, attitudes, and skills relevant to the role of a naturopathic physician.

(11) "Principles of naturopathic medicine" means the foundations of naturopathic medical education and practice as set forth by the American Association of Naturopathic Physicians, including all of the following principles:

(a) The healing power of nature.

(b) Identify and treat the causes.

(c) First do no harm.

(d) Doctor as teacher.

(e) Treat the whole person.

(f) Prevention.

Section 5. Section 462.004, Florida Statutes, is created to read:

462.004 Board of Naturopathic Medicine.—

(1) There is created within the department the Board of Naturopathic Medicine, composed of seven members appointed by the Governor and confirmed by the Senate.

(2)(a) Five members of the board must be licensed naturopathic physicians in good standing in this state who are residents of this state.

(b) Two members must be residents of this state who are not, and have never been, licensed health care practitioners.

(c) At least one member must be 55 years of age or older.

(3) For the purpose of staggering terms, the Governor shall initially appoint to the board three members for terms of 4 years each, two members for terms of 3 years each, and two members for terms of 2 years each. As the terms of board members expire, the Governor shall appoint successors for terms of 4 years, and such members shall serve until their successors are appointed.

(4) The board, in conjunction with the department, shall establish a disciplinary training program for members of the board. The program must provide for initial and, thereafter, periodic training on the grounds for disciplinary action, the actions that may be taken by the board and the department, changes in relevant statutes and rules, and any relevant judicial and administrative decisions. A member of the board may not participate on a probable cause panel or in a disciplinary decision of the board unless she or he has completed the disciplinary training program.

(5) During the terms of service of members of the board on a probable cause panel, such members shall attempt to complete their work on every case presented to them. If consideration of a case has begun but is not completed during the terms of service of the board members on the panel, the board members may reconvene as a probable cause panel for the purpose of completing their deliberations on that case.

(6) All provisions of chapter 456 relating to activities

of boards apply to the board.

Section 6. Section 462.023, Florida Statutes, is renumbered as section 462.005, Florida Statutes, and amended to read:

462.005 ~~462.023~~ Rulemaking authority; powers and duties of the board ~~department~~.—The board ~~department~~ may adopt ~~such~~ rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it and ~~as are necessary~~ to carry out the purposes of this chapter, may initiate disciplinary action as provided by this chapter, and shall establish fees based on its estimates of the revenue required to administer this chapter but shall not exceed the fee amounts provided in this chapter. ~~The department shall not adopt any rules which would cause any person who was not licensed in accordance with this chapter on July 1, 1959, and had not been a resident of the state for 2 years prior to such date, to become licensed.~~

Section 7. Section 462.006, Florida Statutes, is created to read:

462.006 License required.—Unless licensed under this chapter, a person may not practice naturopathic medicine in this state and may not promote, identify, or describe himself or herself as a "doctor of naturopathic medicine," a "naturopathic doctor," a "doctor of naturopathy," or a "naturopathic physician" or use the abbreviations "N.D." or "N.M.D." However,

this section may not be construed to prohibit any person licensed in this state under any other law from engaging in the practice for which she or he is licensed.

Section 8. Section 462.007, Florida Statutes, is created to read:

462.007 Licensure by examination.—

(1) Any person desiring to be licensed as a naturopathic physician must apply to the department on forms furnished by the department. The department shall license each applicant who completes the application form and who the board certifies has met all of the following criteria:

(a) Is at least 21 years of age.

(b) Has received a bachelor's degree from one of the following:

1. A college or university accredited by an accrediting agency recognized by the United States Department of Education or the Council for Higher Education Accreditation or its successor entity.

2. A college or university in Canada which is a member of Universities Canada.

3. A college or university in a foreign country and has provided evidence that her or his educational credentials are deemed equivalent to those provided in this country. To have educational credentials deemed equivalent, the applicant must provide her or his foreign educational credentials, including

transcripts, course descriptions or syllabi, and diplomas, to a nationally recognized educational credential evaluating agency approved by the board for the evaluation and determination of equivalency of the foreign educational credentials.

(c) Has received a naturopathic doctoral degree from a college or program accredited by the Council on Naturopathic Medical Education or another accrediting agency recognized by the United States Department of Education.

(d) Is physically and mentally fit to practice as a naturopathic physician.

(e) Is of good moral character and has not:

1. Committed any act or offense in this or any other jurisdiction which would constitute the basis for disciplining a naturopathic physician pursuant to s. 462.017.

2. Had an application for licensure in any profession denied or had her or his license to practice any profession revoked or suspended by any other state, district, or territory of the United States or another country for reasons that relate to her or his ability to practice skillfully and safely as a naturopathic physician.

3. Been found guilty of a felony.

The board and the department shall ensure that applicants for licensure meet the criteria of this paragraph by independently verifying the provided information through the department's

investigative process.

(f) Has submitted to the department a set of fingerprints on a form and in accordance with procedures specified by the department under s. 456.039(4), along with payment in an amount equal to the costs incurred by the department for the criminal background check of the applicant.

(g) Has demonstrated compliance with the financial responsibility requirements imposed under s. 462.015.

(h) Has obtained a passing score, as determined by board rule, on Part I - Biomedical Science Examination, Part II - Core Clinical Science Examination, and Part II - Clinical Elective Pharmacology Examination of the competency-based national Naturopathic Physician Licensing Examination administered by the North American Board of Naturopathic Examiners, or an equivalent examination offered by an equivalent or successor entity, as approved by the board.

(2) The department and the board shall ensure that applicants for licensure satisfy applicable criteria in this section through an investigative process. If the investigative process is not completed within the timeframe established in s. 120.60(1) and the department or board has reason to believe that the applicant does not meet such criteria, the State Surgeon General or her or his designee may issue a 90-day licensure delay, which must be in writing and sufficient to notify the applicant of the reason for the delay. This subsection prevails

over any conflicting provisions of s. 120.60(1).

(3) The board may not certify to the department for licensure any applicant who is under investigation in another jurisdiction for an offense that would constitute a violation of this chapter or chapter 456 until the investigation has been completed. Upon completion of the investigation, s. 462.017 applies.

(4)(a) The department may not issue a license to any individual who has committed an act or offense in any jurisdiction which would constitute the basis for disciplining a naturopathic physician under s. 462.017 until the board has reviewed the application and certified the applicant for licensure.

(b) If the board finds that an applicant for licensure has committed an act or offense in any jurisdiction which would constitute the basis for disciplining a naturopathic physician under s. 462.017, the board may enter an order imposing one or more of the sanctions set forth in that section and s. 456.072(2) as applicable to applicants for licensure, including refusing to certify an application for licensure or certifying an application for licensure with conditions.

(5) If the board determines that an applicant for licensure has failed to meet, to the board's satisfaction, any of the requirements of this section, it may enter an order imposing one or more of the following:

(a) Refusal to certify to the department an application for licensure.

(b) Certification to the department of an application for licensure with restrictions on the scope of practice of the naturopathic physician.

(c) Certification to the department of an application for licensure with a probationary period for the applicant, subject to such conditions as the board specifies, including, but not limited to, requiring the naturopathic physician to submit to treatment, attend continuing education courses, submit to reexamination, or work under the supervision of another naturopathic physician.

Section 9. Section 462.008, Florida Statutes, is created to read:

462.008 Licensure by endorsement.—

(1) Any person licensed to practice naturopathic medicine in another state or territory of the United States or in Canada who desires to be licensed as a naturopathic physician in this state must apply to the department on forms furnished by the department. The department shall issue a license by endorsement to any applicant who completes the application form and who the board certifies has met all of the following criteria:

(a) Has met the qualifications for licensure established in s. 462.007(1)(a)-(g).

(b)1. Has submitted evidence of holding an active license

to practice naturopathic medicine in another state or territory of the United States or in Canada for at least the 5 years immediately preceding the filing of her or his application; or

2. If an applicant has held an active license to practice naturopathic medicine in another state or territory of the United States or in Canada for less than the 5 years immediately preceding the filing of her or his application, has obtained a passing score on the national licensing examination, as specified in s. 462.007(1)(h), within the year immediately preceding the filing of the application.

(2) The department and the board shall ensure that applicants for licensure by endorsement meet applicable criteria in this section through an investigative process. When the investigative process is not completed within the timeframe established in s. 120.60(1) and the department or board has reason to believe that the applicant does not meet the criteria, the State Surgeon General or her or his designee may issue a 90-day licensure delay, which must be in writing and sufficient to notify the applicant of the reason for the delay. This subsection controls over any conflicting provisions of s. 120.60(1).

(3) The board may not certify to the department for licensure by endorsement any applicant who is under investigation in another jurisdiction for an offense that would constitute a violation of this chapter or chapter 456 until the

investigation has been completed. Upon completion of the investigation, s. 462.017 applies.

(4)(a) The department may not issue a license by endorsement to any individual who has committed an act or offense in any jurisdiction which would constitute the basis for disciplining a naturopathic physician under s. 462.017 until the board has reviewed the application and certified the applicant for licensure.

(b) If the board finds that an applicant for licensure by endorsement has committed an act or offense in any jurisdiction which would constitute the basis for disciplining a naturopathic physician under s. 462.017, the board may enter an order imposing one or more of the sanctions set forth in that section and s. 456.072(2) as applicable to applicants for licensure, including refusing to certify an application for licensure or certifying an application for licensure with conditions.

(5) If the board determines that an applicant for licensure has failed to meet, to the board's satisfaction, any of the requirements of this section, it may enter an order imposing one or more of the following:

(a) Refusal to certify to the department an application for licensure.

(b) Certification to the department of an application for licensure with restrictions on the scope of practice of the naturopathic physician.

(c) Certification to the department of an application for licensure with a probationary period for the applicant, subject to such conditions as the board specifies, including, but not limited to, requiring the naturopathic physician to submit to treatment, attend continuing education courses, submit to reexamination, or work under the supervision of another naturopathic physician.

Section 10. Section 462.08, Florida Statutes, is renumbered as section 462.009, Florida Statutes, and amended to read:

462.009 ~~462.08~~ Renewal of license to practice naturopathic medicine ~~naturopathy~~.—

(1) In order to continue practicing naturopathic medicine in this state, each licensed naturopathic physician must ~~licenseholder shall~~ biennially renew her or his license to practice naturopathic medicine ~~naturopathy~~. The applicant for license renewal must furnish to the board ~~department~~ such evidence as it requires of the applicant's compliance with s. 462.011 ~~s. 462.18~~, relating to continuing education ~~educational~~ requirements, and s. 462.015, relating to financial responsibility requirements. The biennial renewal fee, the amount of which shall be determined by the department but which may not exceed $1,000, must be paid at the time the application for renewal of the license is filed.

(2) The department shall adopt rules establishing

procedures for the biennial renewal of licenses under this chapter.

Section 11. Section 462.18, Florida Statutes, is renumbered as section 462.011, Florida Statutes, and amended to read:

462.011 ~~462.18~~ Continuing education ~~Educational~~ requirements.—

(1) At the time each licensee renews ~~shall renew~~ her or his license as ~~otherwise~~ provided in s. 462.009 ~~this chapter~~, each licensee must, in addition to the payment of the regular renewal fee, ~~shall~~ furnish to the board ~~department~~ satisfactory evidence that, in the preceding biennial period, the licensee has completed the continuing education requirements of this section.

(2) The board shall require each naturopathic physician to receive at least 60 hours of continuing education during each biennial renewal period.

(a) At least 10 hours of the 60 hours of continuing education must be in pharmacology, addressing the use of legend drugs that are consistent with the education and training of naturopathic physicians.

(b) The board shall approve organizations that accredit naturopathic continuing education providers, including, but not limited to, the American Association of Naturopathic Physicians, the North American Naturopathic Continuing Education

Accreditation Council, and the Oregon Association of Naturopathic Physicians.

(c) The determination of whether substitute continuing education programs are permissible is solely within the discretion of the board.

(3) The naturopathic physician must use the electronic continuing education tracking system developed by the department under s. 456.0361 to demonstrate compliance with the continuing education requirements of this section ~~year preceding each such application for renewal, the licensee has attended the 2-day educational program as promulgated and conducted by the Florida Naturopathic Physicians Association, Inc., or, as a substitute therefor, the equivalent of that program as approved by the department. The department shall send a written notice to this effect to every person holding a valid license to practice naturopathy within this state at least 30 days prior to May 1 in each even-numbered year, directed to the last known address of such licensee, and shall enclose with the notice proper blank forms for application for annual license renewal. All of the details and requirements of the aforesaid educational program shall be adopted and prescribed by the department. In the event of national emergencies, or for sufficient reason, the department shall have the power to excuse the naturopathic physicians as a group or as individuals from taking this postgraduate course.~~

~~(2) The determination of whether a substitute annual educational program is necessary shall be solely within the discretion of the department~~.

Section 12. Section 462.19, Florida Statutes, is renumbered as section 462.012, Florida Statutes, and amended to read:

462.012 ~~462.19~~ ~~Renewal of license;~~ Inactive status; reactivation of license.—

(1) A licensee may reactivate an inactive license by applying to the department, paying any applicable fees, and submitting proof of compliance with the financial responsibility requirements of s. 462.015.

(2) The board shall adopt rules relating to reactivation of licenses that have become inactive and for the renewal of inactive licenses. The rules must include continuing education requirements as a condition of reactivating a license. The continuing education requirements for reactivating a license may not be fewer than 20 classroom hours for each year the license was inactive. The board may also adopt rules to determine fees, including a fee for placing a license into inactive status, a biennial renewal fee for licenses in inactive status, a delinquency fee, and a fee for the reactivation of a license. None of these fees may exceed the biennial renewal fee determined by the board in s. 462.009.

(3) The department may not reactivate a license unless the

applicable fees have been paid and the financial responsibility requirements of s. 462.015 have been satisfied ~~The department shall renew a license upon receipt of the renewal application and fee.~~

~~(2) A licensee may request that her or his license be placed in an inactive status by making application to the department and paying a fee in an amount set by the department not to exceed $50~~.

Section 13. Section 462.11, Florida Statutes, is renumbered as section 462.013, Florida Statutes, and amended to read:

462.013 ~~462.11~~ Obligations of naturopathic physicians ~~Naturopaths to observe regulations~~.—Naturopathic physicians ~~Doctors of naturopathy~~ shall comply with ~~observe~~ and are ~~be~~ subject to all state, county, and municipal regulations relating ~~in regard~~ to the control of contagious and infectious diseases, the reporting of births and deaths, and ~~to~~ any ~~and all~~ other matters pertaining to the public health in the same manner as is required of other health care practitioners ~~of the healing art~~.

Section 14. Section 462.014, Florida Statutes, is created to read:

462.014 Patient records; termination of practice.—The board shall adopt rules providing for the handling of medical records by licensed naturopathic physicians, including when a naturopathic physician sells or otherwise terminates a practice.

The rules must provide for notification of the naturopathic physician's patients and for an opportunity for the patients to request the transfer of their medical records to another physician or health care practitioner upon payment of actual costs for such transfer.

Section 15. Section 462.015, Florida Statutes, is created to read:

462.015 Financial responsibility.—

(1) As a condition of licensure, a naturopathic physician must, by one of the following methods, demonstrate to the satisfaction of the board and the department that she or he has the ability to pay claims and ancillary costs arising from the rendering of, or the failure to render, medical care or services:

(a) Establishing and maintaining an escrow account consisting of cash or assets eligible for deposit in accordance with s. 625.52 in the per-claim amounts specified in paragraph (b). Expenditures may not be made from the escrow amount for litigation costs or attorney fees for the defense of any medical malpractice claim.

(b) Obtaining and maintaining professional liability coverage in an amount not less than $100,000 per claim, with a minimum annual aggregate of not less than $300,000, from an authorized insurer as defined under s. 624.09, from an eligible surplus lines insurer as defined under s. 626.914(2), from a

risk retention group as defined under s. 627.942, from the Joint Underwriting Association operated under s. 627.351(4), or through self-insurance as provided in s. 627.357. Expenditures may not be made from the required coverage amount for litigation costs or attorney fees for the defense of any medical malpractice claim.

(c) Obtaining and maintaining an unexpired, irrevocable letter of credit, issued pursuant to chapter 675, in an amount not less than $100,000 per claim, with a minimum aggregate availability of credit of not less than $300,000. The letter of credit must be payable to the naturopathic physician as beneficiary upon presentment of a final judgment indicating liability and awarding damages to be paid by the naturopathic physician or upon presentment of a settlement agreement signed by all parties to such agreement when such final judgment or settlement is a result of a claim arising out of the rendering of, or the failure to render, medical care or services. The letter of credit may not be used for litigation costs or attorney fees for the defense of any medical malpractice claim. The letter of credit must be nonassignable and nontransferable and be issued by a bank or savings association organized and existing under the laws of this state or a bank or savings association organized under the laws of the United States which has its principal place of business in this state or has a branch office that is authorized under the laws of this state or

of the United States to receive deposits in this state.

(2)(a) Meeting the financial responsibility requirements of this section or the criteria for any exemption from such requirements must be demonstrated at the time of issuance, renewal, or reactivation of a naturopathic physician license.

(b) Any person may, at any time, submit to the department a request for an advisory opinion regarding such person's qualifications for exemption.

(3)(a) Each insurer, self-insurer, or risk retention group or the Joint Underwriting Association must promptly notify the department of a cancellation or nonrenewal of insurance required by this section. Unless the naturopathic physician demonstrates that she or he is otherwise in compliance with the requirements of this section, the department shall suspend the license of the naturopathic physician pursuant to ss. 120.569 and 120.57 and notify all health care facilities licensed under part IV of chapter 394 or chapter 395 or a health maintenance organization certified under part I of chapter 641 of such action. Any suspension imposed under this subsection remains in effect until the naturopathic physician demonstrates compliance with the requirements of this section. If any judgments or settlements are pending at the time of suspension, those judgments or settlements must be paid in accordance with this section unless otherwise mutually agreed to in writing by the parties. This paragraph does not abrogate a judgment debtor's obligation to

satisfy the entire amount of any judgment.

(b) If the financial responsibility requirements are met by maintaining an escrow account or letter of credit as provided in this section, upon the entry of an adverse final judgment arising from a medical malpractice arbitration award, from a claim in contract or tort of medical malpractice, or from noncompliance with the terms of a settlement agreement arising from a claim in contract or tort of medical malpractice, the naturopathic physician must pay the entire amount of the judgment together with all accrued interest or the amount maintained in the escrow account or provided in the letter of credit as required by this section, whichever is less, within 60 days after the date such judgment becomes final and subject to execution, unless otherwise mutually agreed to in writing by the parties. If timely payment is not made by the naturopathic physician, the department must suspend the license of the naturopathic physician pursuant to procedures set forth in subparagraphs (4)(f)3., 4., and 5. This paragraph does not abrogate a judgment debtor's obligation to satisfy the entire amount of any judgment.

(4) The requirements imposed in subsection (1) do not apply to:

(a) Any person licensed under this chapter who practices naturopathic medicine exclusively as an officer, employee, or agent of the Federal Government or of the state or its agencies

or subdivisions. For purposes of this subsection, an agent of the state, its agencies, or its subdivisions is a person who is eligible for coverage under any self-insurance or insurance program as provided in s. 768.28(16).

(b) Any person whose license has become inactive under this chapter and who is not practicing naturopathic medicine in this state. Any person applying for reactivation of a naturopathic physician license must either:

1. Demonstrate that she or he maintained tail insurance coverage that provided liability coverage for incidents that occurred on or after the initial date of licensure in this state and for incidents that occurred before the date on which the license became inactive; or

2. Submit an affidavit stating that she or he has no unsatisfied medical malpractice judgments or settlements at the time of application for reactivation of the license.

(c) Any person licensed under this chapter who practices only in conjunction with her or his teaching duties at a college of naturopathic medicine. Such person may engage in the practice of naturopathic medicine to the extent that such practice is incidental to and a necessary part of duties in connection with the teaching position in the college of naturopathic medicine.

(d) Any person holding an active naturopathic physician license under this chapter who is not practicing naturopathic medicine in this state. If such person initiates or resumes any

practice of naturopathic medicine in this state, she or he must notify the department of such activity and fulfill the financial responsibility requirements of this section before resuming the practice of naturopathic medicine in this state.

(e) Any person holding an active naturopathic physician license under this chapter who meets all of the following criteria:

1. Has held an active license to practice naturopathic medicine in this state or another state or some combination thereof for more than 15 years.

2. Has either retired from the practice of naturopathic medicine or maintains a part-time practice of naturopathic medicine of no more than 1,000 patient contact hours per year.

3. Has had no more than two claims for medical malpractice resulting in an indemnity exceeding $25,000 within the previous 5-year period.

4. Has not been convicted of, or pled guilty or nolo contendere to, any criminal violation specified in this chapter or the practice act of any other state.

5. Has not been subject, within the last 10 years of practice, to license revocation or suspension for any period of time, probation for a period of 3 years or longer, or a fine of $500 or more for a violation of this chapter or the naturopathic medical practice act of another jurisdiction. A regulatory agency's acceptance of a naturopathic physician's relinquishment

of her or his license or of a stipulation, consent order, or other settlement, offered in response to or in anticipation of the filing of administrative charges against her or his license, constitutes action against the naturopathic physician's license for the purposes of this paragraph.

6. Has submitted a form supplying necessary information as required by the department and an affidavit affirming compliance with this paragraph.

7. Biennially submits to the department a certification stating compliance with this paragraph. The naturopathic physician must also demonstrate compliance with this paragraph at any time upon department request.

A naturopathic physician who meets the requirements of this paragraph must provide notice to patients, either by prominently displaying a sign in the reception area of her or his practice in a manner clearly visible to patients or by providing a written statement to each patient to whom she or he provides naturopathic medical services. The sign or statement must read as follows: "Under Florida law, naturopathic physicians are generally required to carry medical malpractice insurance or otherwise demonstrate financial responsibility to cover potential claims for medical malpractice. However, certain part-time naturopathic physicians who meet certain criteria are exempt from the financial responsibility requirements. YOUR

NATUROPATHIC PHYSICIAN MEETS THE EXEMPTION CRITERIA AND HAS DECIDED NOT TO CARRY MEDICAL MALPRACTICE INSURANCE. This notice is provided pursuant to Florida law."

(f) Any person holding an active naturopathic physician license under this chapter who agrees to all of the following conditions:

1. Upon the entry of an adverse final judgment arising from a medical malpractice arbitration award, from a claim of medical malpractice either in contract or tort, or from noncompliance with the terms of a settlement agreement arising from a claim of medical malpractice either in contract or tort, the naturopathic physician agrees to pay the judgment creditor the lesser of the entire amount of the judgment with all accrued interest or either $100,000, if the naturopathic physician is licensed pursuant to this chapter but does not maintain hospital staff privileges, or $250,000, if the naturopathic physician is licensed pursuant to this chapter and maintains hospital staff privileges, within 60 days after the date such judgment becomes final and subject to execution, unless otherwise mutually agreed to in writing by the parties. Such adverse final judgment must include any cross-claim, counterclaim, or claim for indemnity or contribution arising from the claim of medical malpractice. Upon notification of the existence of an unsatisfied judgment or payment pursuant to this subparagraph, the department shall notify the naturopathic physician by certified mail that she or

he is subject to disciplinary action unless, within 30 days after the date of mailing, the naturopathic physician either:

a. Shows proof that the unsatisfied judgment has been paid in the amount specified in this subparagraph; or

b. Furnishes the department with a copy of a timely filed notice of appeal and either:

(I) A copy of a supersedeas bond properly posted in the amount required by law; or

(II) An order from a court of competent jurisdiction staying execution on the final judgment, pending disposition of the appeal.

2. The department shall issue an emergency order suspending the license of any naturopathic physician who, 31 days or more after receipt of a notice from the department, has failed to satisfy a medical malpractice claim against him or her; furnish the department a copy of a timely filed notice of appeal; furnish the department a copy of a supersedeas bond properly posted in the amount required by law; or furnish the department an order from a court of competent jurisdiction staying execution on the final judgment pending disposition of the appeal.

3. Upon the next meeting of the probable cause panel of the board 31 days or more after the date of mailing the notice of disciplinary action to the naturopathic physician, the panel shall make a determination as to whether probable cause exists

to take disciplinary action against the naturopathic physician for a violation of subparagraph 1.

4. If the board determines that the factual requirements of subparagraph 1. are met, it must take disciplinary action as it deems appropriate against the naturopathic physician. Such disciplinary action must include, at a minimum, probation of the license with the restriction that the naturopathic physician must make payments to the judgment creditor on a schedule determined by the board to be reasonable and within the financial capability of the naturopathic physician. Notwithstanding any other disciplinary penalty imposed, the disciplinary penalty may include suspension of the license for a period not to exceed 5 years. In the event that an agreement to satisfy a judgment has been met, the board must remove any restriction on the license.

5. The naturopathic physician must complete a form supplying necessary information as required by department rule.

A naturopathic physician who agrees to the conditions of this paragraph must provide notice to patients, either by prominently displaying a sign in the reception area of her or his practice in a manner clearly visible to patients or by providing a written statement to each patient to whom she or he provides naturopathic medical services. The sign or statement must read as follows: "Under Florida law, naturopathic physicians are

generally required to carry medical malpractice insurance or otherwise demonstrate financial responsibility to cover potential claims for medical malpractice. However, certain part-time naturopathic physicians who meet certain criteria are exempt from the financial responsibility requirements. YOUR NATUROPATHIC PHYSICIAN MEETS THE EXEMPTION CRITERIA AND HAS DECIDED NOT TO CARRY MEDICAL MALPRACTICE INSURANCE. This notice is provided pursuant to Florida law."

(5) A naturopathic physician who makes any deceptive, untrue, or fraudulent representation with respect to any provision of this section is permanently disqualified from any exemption from financial responsibility requirements under this section and is subject to disciplinary action under s. 462.017 for such conduct.

(6) Any naturopathic physician who relies on an exemption from the financial responsibility requirements must notify the department in writing of any change of circumstance regarding her or his qualifications for such exemption and must demonstrate that she or he is in compliance with the requirements of this section.

(7) Notwithstanding any other provision of this section, the department shall suspend the license of any naturopathic physician against whom a final judgment, arbitration award, or other order has been entered or who has entered into a settlement agreement to pay damages arising out of a claim for

medical malpractice if all appellate remedies have been exhausted and payment up to the amounts required by this section has not been made within 30 days after the entering of such judgment, award, or order or agreement. A suspension under this subsection remains in effect until proof of payment is received by the department or a payment schedule has been agreed upon by the naturopathic physician and the claimant and presented to the department. This subsection does not apply to a naturopathic physician who has met the financial responsibility requirements under paragraph (1)(b).

(8) The board shall adopt rules to implement this section.

Section 16. Section 462.13, Florida Statutes, is renumbered as section 462.016, Florida Statutes, and amended to read:

462.016 ~~462.13~~ Additional powers and duties of the board and the department.—The board and the department may administer oaths, summon witnesses, and take testimony in all matters relating to their respective ~~its~~ duties under ~~pursuant to~~ this chapter. Evidence of an active, ~~Every~~ unrevoked license must ~~shall~~ be presumed by ~~presumptive evidence in~~ all courts and places to be evidence that the person therein named is legally licensed to practice naturopathic medicine in this state ~~naturopathy~~. The board and the department shall aid the prosecuting attorneys of the state in the enforcement of this chapter.

Section 17. Section 462.14, Florida Statutes, is renumbered as section 462.017, Florida Statutes, and amended to read:

462.017 ~~462.14~~ Grounds for disciplinary action; action by the board and department.—

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

(a) Attempting to obtain, obtaining, or renewing a license to practice naturopathic medicine by bribery, by fraudulent misrepresentation, or through an error of the board or the department.

(b) Having a license to practice naturopathic medicine revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of another state, territory, or country. The licensing authority's acceptance of a naturopathic physician's relinquishment of her or his license or of a stipulation, a consent order, or other settlement offered in response to or in anticipation of the filing of administrative charges against her or his license shall be construed as action against the naturopathic physician's license.

(c) Being convicted or found guilty, regardless of adjudication, of a crime in any jurisdiction which directly relates to the practice of naturopathic medicine or to the ability to practice naturopathic medicine. Any plea of nolo

contendere creates a rebuttable presumption of guilt to the underlying criminal charges ~~shall be considered a conviction for purposes of this chapter~~.

(d) False, deceptive, or misleading advertising.

(e) ~~Advertising, practicing, or attempting to practice under a name other than one's own.~~

~~(f)~~ Failing to report to the department or the department's impaired practitioner program consultant, as applicable, any person whom ~~who~~ the licensee knows is in violation of this chapter or of the rules of the board or department. However, a person whom ~~who~~ the licensee knows is unable to practice naturopathic medicine with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material, or as a result of a mental or physical condition, may be reported to a consultant operating an impaired practitioner program as described in s. 456.076 rather than to the department.

(f) ~~(g)~~ Aiding, assisting, procuring, or advising any unlicensed person to practice naturopathic medicine contrary to this chapter or to a rule of the board or department.

(g) ~~(h)~~ Failing to perform any statutory or legal obligation placed upon a licensed naturopathic physician.

(h) Giving false testimony in the course of any legal or administrative proceedings relating to the practice of naturopathic medicine or the delivery of health care services.

(i) Making or filing a report which the licensee knows to be false, intentionally or negligently failing to file a report or record required by state or federal law, willfully impeding or obstructing such filing or inducing another person to do so. Such reports or records must ~~shall~~ include only those which are signed in the capacity as a licensed naturopathic physician.

(j) Paying or receiving any commission, bonus, kickback, or rebate, or engaging in any split-fee arrangement in any form whatsoever with a physician, an organization, an agency, a ~~or~~ person, a partnership, a firm, a corporation, or other business entity, either directly or indirectly, for patients referred to providers of health care goods and services, including, but not limited to, hospitals, nursing homes, clinical laboratories, ambulatory surgical centers, or pharmacies. ~~The provisions of~~ This paragraph may ~~shall~~ not be construed to prevent a naturopathic physician from receiving a fee for professional consultation services.

(k) Refusing to provide health care based on a patient's participation in pending or past litigation or participation in any disciplinary action conducted pursuant to this chapter, unless such litigation or disciplinary action directly involves the naturopathic physician requested to provide services.

(l) Exercising influence within a patient-physician relationship for purposes of engaging a patient in sexual activity. A patient is ~~shall be~~ presumed to be incapable of

giving free, full, and informed consent to sexual activity with her or his naturopathic physician.

(m) ~~(l)~~ Making deceptive, untrue, or fraudulent representations in or related to the practice of naturopathic medicine or employing a trick or scheme in the practice of naturopathic medicine ~~when such scheme or trick fails to conform to the generally prevailing standards of treatment in the medical community~~.

(n) ~~(m)~~ Soliciting patients, either personally or through an agent, through the use of fraud, intimidation, undue influence, or a form of overreaching or vexatious conduct. A ~~"~~solicitation~~"~~ is any communication which directly or implicitly requests an immediate oral response from the recipient.

(o) ~~(n)~~ Failing to keep legible, written medical records, as defined by department rule in consultation with the board, which identify by name and professional title the licensed naturopathic physician or the supervising naturopathic physician who is responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and which justify ~~justifying~~ the course of treatment of the patient, including, but not limited to, patient histories, examination results, test results, X rays, ~~and~~ records of medicine prescribed, dispensed, or administered, and reports of consultations and hospitalizations ~~the prescribing, dispensing and administering of drugs~~.

(p) Fraudulently altering or destroying records relating to patient care or treatment, including, but not limited to, patient histories, examination results, test results, X rays, records of medicine prescribed, dispensed, or administered, and reports of consultations and hospitalizations.

(q) ~~(o)~~ Exercising influence on the patient ~~or client~~ in such a manner as to exploit the patient ~~or client~~ for the financial gain of the licensee or of a third party, which includes ~~shall include~~, but is not ~~be~~ limited to, the promoting or selling of services, goods, appliances, or medicines. ~~drugs and the~~

(r) Promoting or advertising on any prescription form of a community pharmacy unless the form also states "This prescription may be filled at any pharmacy of your choice."

(s) ~~(p)~~ Performing professional services that ~~which~~ have not been duly authorized by the patient ~~or client,~~ or her or his legal representative, except as provided in s. 743.064, s. 766.103, or s. 768.13.

(t) ~~(q)~~ Except as authorized by the Naturopathic Medical Formulary established under s. 462.025, prescribing, dispensing, administering, supplying, selling, giving, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the naturopathic physician's professional practice. For the purposes of this paragraph, it is ~~shall be~~ legally presumed that prescribing, dispensing,

administering, supplying, selling, giving, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the scope ~~course~~ of the naturopathic physician's professional practice, regardless of ~~without regard to~~ her or his intent.

(u) ~~(r)~~ Prescribing or~~,~~ dispensing~~, or administering~~ any legend ~~medicinal~~ drug appearing on any schedule set forth in chapter 893 ~~by the naturopathic physician~~ to herself or himself or administering any such drug to herself or himself unless such drug is~~, except one~~ prescribed for~~, dispensed, or administered to~~ the naturopathic physician by another practitioner authorized to prescribe legend~~, dispense, or administer medicinal~~ drugs.

(v) ~~(s)~~ Being unable to practice naturopathic medicine with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition. In enforcing this paragraph, the department ~~shall have~~, upon a showing of probable cause, has the authority to issue an order to compel a naturopathic physician to submit to a mental or physical examination by naturopathic physicians designated by the department. If the ~~failure of a~~ naturopathic physician refuses to comply with such order, the department's order directing ~~submit to~~ such ~~an~~ examination may be enforced by filing a petition for enforcement in the circuit court where the

naturopathic physician resides or does business. The naturopathic physician against whom the petition is filed may not be named or identified by initials in any public court records or documents, and the proceedings must be closed to the public. The department is entitled to the summary procedure provided in s. 51.011 ~~when so directed shall constitute an admission of the allegations against her or him upon which a default and final order may be entered without the taking of testimony or presentation of evidence, unless the failure was due to circumstances beyond the naturopathic physician's control~~. A naturopathic physician subject to an order issued ~~affected~~ under this paragraph must, ~~shall~~ at reasonable intervals, be afforded an opportunity to demonstrate that she or he can resume the competent practice of naturopathic medicine with reasonable skill and safety to patients. In any proceeding under this paragraph, neither the record of proceedings nor the orders entered by the department may be used against a naturopathic physician in any other proceeding.

(w) Notwithstanding s. 456.072(2) but as specified in s. 456.50(2):

1. Committing medical malpractice as defined in s. 456.50. The board shall give great weight to s. 766.102 when enforcing this paragraph. Medical malpractice may not be construed to require more than one instance, event, or act.

2. Committing gross medical malpractice.

3. Committing repeated medical malpractice as defined in s. 456.50. A person found by the board to have committed such repeated malpractice may not be licensed or continue to be licensed to provide health care services as a naturopathic physician in this state.

This paragraph may not be construed to require that a naturopathic physician be deemed incompetent to practice naturopathic medicine in order to be disciplined pursuant to this paragraph. A recommended order by an administrative law judge or a final order of the board finding a violation under this paragraph must specify whether the naturopathic physician was found to have committed gross medical malpractice, repeated medical malpractice, or medical malpractice, or any combination thereof, and any publication by the board must include the specified finding.

~~(t) Gross or repeated malpractice or the failure to practice naturopathic medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances. The department shall give great weight to the provisions of s. 766.102 when enforcing this paragraph.~~

(x) ~~(u)~~ Performing any procedure or prescribing any therapy that ~~which~~, by the prevailing standards of medical practice in the naturopathic medical community, constitutes experimentation

on a human subject, without first obtaining full, informed, and written consent.

(y) ~~(v)~~ Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities that ~~which~~ the licensee knows or has reason to know ~~that~~ she or he is not competent to perform. The board may establish by rule standards of practice and standards of care for particular practice areas, including, but not limited to, education and training, equipment and supplies, medications as specified by the Naturopathic Medical Formulary under s. 462.025, assistance from and delegation to other personnel, transfer agreements, sterilization, records, performance of complex or multiple procedures, informed consent, and policy and procedure manuals.

(z) ~~(w)~~ Delegating professional responsibilities to a person when the licensee delegating such responsibilities knows or has reason to know that such person is not qualified by training, experience, or licensure to perform them.

(aa) ~~(x)~~ Violating a lawful order of the board or the department previously entered in a disciplinary hearing or failing to comply with a lawfully issued subpoena of the board or department.

(bb) ~~(y)~~ Conspiring with another licensee or with any other person to commit an act, or committing an act, which would tend to coerce, intimidate, or preclude another licensee from

lawfully advertising her or his services.

(cc) ~~(z)~~ Procuring, or aiding or abetting in the procuring of, an unlawful termination of pregnancy.

(dd) ~~(aa)~~ Presigning blank prescription forms.

(ee) Failing to adequately supervise the activities of any persons acting under the supervision of the naturopathic physician.

~~(bb) Prescribing by the naturopathic physician for office use any medicinal drug appearing on Schedule II in chapter 893.~~

~~(cc) Prescribing, ordering, dispensing, administering, supplying, selling, or giving any drug which is an amphetamine or sympathomimetic amine drug, or a compound designated pursuant to chapter 893 as a Schedule II controlled substance to or for any person except for:~~

~~1. The treatment of narcolepsy; hyperkinesis; behavioral syndrome in children characterized by the developmentally inappropriate symptoms of moderate to severe distractability, short attention span, hyperactivity, emotional lability, and impulsivity; or drug-induced brain dysfunction.~~

~~2. The differential diagnostic psychiatric evaluation of depression or the treatment of depression shown to be refractory to other therapeutic modalities.~~

~~3. The clinical investigation of the effects of such drugs or compounds when an investigative protocol therefor is submitted to, reviewed, and approved by the department before~~

~~such investigation is begun.~~

(ff) ~~(dd)~~ Prescribing, ordering, dispensing, administering, supplying, selling, or giving growth hormones, testosterone or its analogs, human chorionic gonadotropin (HCG), or other hormones for the purpose of muscle building or to enhance athletic performance. For the purposes of this subsection, the term "muscle building" does not include the treatment of injured muscle. A prescription written for the drug products identified in this paragraph ~~listed above~~ may be dispensed by the pharmacist with the presumption that the prescription is for legitimate medical use.

(gg) Misrepresenting or concealing a material fact at any time during any phase of a licensing or disciplinary process or procedure.

(hh) Interfering with an investigation or with any disciplinary proceeding.

(ii) Failing to report to the department any person licensed under chapter 458, chapter 459, or this chapter whom the naturopathic physician knows has violated the grounds for disciplinary action set out in the law under which that person is licensed and who provides health care services in a facility licensed under chapter 395, or a health maintenance organization certificated under part I of chapter 641, in which the naturopathic physician also provides services.

(jj) Being found by any court in this state to have

provided, without reasonable investigation, corroborating written medical expert opinion attached to any statutorily required notice of claim or intent or to any statutorily required response rejecting a claim.

(kk) Except as provided in s. 462.018, advertising or holding oneself out as a board-certified specialist in violation of this chapter.

(ll) Failing to comply with the requirements of ss. 381.026 and 381.0261 to provide patients with information about their patient rights and how to file a patient complaint.

(mm) ~~(ee)~~ Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto.

(nn) Providing deceptive or fraudulent expert witness testimony related to the practice of naturopathic medicine.

(oo) Promoting or advertising through any communication medium the use, sale, or dispensing of any controlled substance appearing on any schedule in chapter 893 which is not within the scope of the Naturopathic Medical Formulary established under s. 462.025.

(pp) Willfully failing to comply with s. 627.64194 or s. 641.513 with such frequency as to indicate a general business practice.

(2) The board ~~department~~ may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who commits a

violation of ~~is found guilty of violating any provision of~~ subsection (1) ~~of this section~~ or ~~who is found guilty of violating any provision of~~ s. 456.072(1). In determining what action is appropriate, the board must first consider which sanctions are necessary to protect the public or to compensate the patient. Only after those sanctions have been imposed may the board consider and include in the order other requirements designed to rehabilitate the naturopathic physician. All costs associated with compliance with orders issued under this subsection are the obligation of the naturopathic physician.

(3) In any administrative action against a naturopathic physician which does not involve a revocation or suspension of license, the division has the burden, by the greater weight of the evidence, to establish the existence of grounds for disciplinary action. The division shall establish grounds for revocation or suspension of license by clear and convincing evidence.

(4) The board may ~~department shall~~ not reinstate the license of a naturopathic physician or cause a license to be issued to a person it has deemed unqualified until such time as it ~~the department~~ is satisfied that such person has complied with all the terms and conditions set forth in the final order and that such person is capable of safely engaging in the practice of naturopathic medicine. However, the board may not issue a license to, or reinstate the license of, any person

found by the board to have committed repeated medical malpractice as defined in s. 456.50, regardless of the extent to which the licensed naturopathic physician or prospective licensed naturopathic physician has complied with all terms and conditions set forth in the final order or whether she or he is capable of safely engaging in the practice of naturopathic medicine.

(5) ~~(4)~~ The board ~~department~~ shall establish by rule ~~establish~~ guidelines for the disposition of disciplinary cases involving specific types of violations. Such guidelines must establish offenses and circumstances for which revocation will be presumed to be appropriate, as well as offenses and circumstances for which suspension for particular periods of time will be presumed to be appropriate. The guidelines must also ~~may~~ include minimum and maximum fines, periods of supervision or probation, ~~or~~ conditions of probation, and conditions for ~~or~~ reissuance of a license with respect to particular circumstances and offenses. Gross medical malpractice, repeated medical malpractice, and medical malpractice, respectively, as specified in paragraph (1)(w), must each be considered a distinct violation requiring specific individual guidelines.

(6) Upon the department's receipt of a closed claim against a naturopathic physician submitted by an insurer or self-insurer pursuant to s. 627.912 or information reported to

the Office of Insurance Regulation by a health care practitioner pursuant to s. 456.049, or receipt from a claimant of presuit notice against a naturopathic physician under s. 766.106, the department shall review such information and determine whether it potentially involves conduct by a licensed naturopathic physician which is subject to disciplinary action, in which case s. 456.073 applies. However, if the department receives information that a naturopathic physician has had three or more claims filed against her or him, each with indemnities exceeding $50,000, within the previous 5-year period, the department must investigate the occurrences upon which the claims were based and determine if action by the department against the naturopathic physician is warranted.

(7) Upon the department's receipt of a report from the Agency for Health Care Administration pursuant to s. 395.0197 related to a naturopathic physician whose conduct may constitute grounds for disciplinary action, the department shall investigate the occurrences upon which the report was based and determine if action by the department against the naturopathic physician is warranted.

(8) If any naturopathic physician commits such unprofessional conduct or negligence or demonstrates mental or physical incapacity or impairment such that the department determines that she or he is unable to practice with reasonable skill and safety and presents a danger to patients, the

department may bring an action in circuit court enjoining such naturopathic physician from providing medical services to the public until the naturopathic physician demonstrates the ability to practice with reasonable skill and safety and without danger to patients.

(9)(a) If an investigation of a naturopathic physician is undertaken, the department must promptly furnish to the naturopathic physician or her or his attorney a copy of the complaint or document that prompted initiation of the investigation. For purposes of this subsection, such documents include, but are not limited to:

1. The pertinent portions of an annual report submitted by a licensed facility to the Agency for Health Care Administration pursuant to s. 395.0197(6).

2. A report of an adverse incident which is provided by a licensed facility to the department pursuant to s. 395.0197.

3. A report of peer review disciplinary action submitted to the department pursuant to s. 395.0193(4), provided that the investigations, proceedings, and records relating to such peer review disciplinary action continue to retain their privileged status even as to the naturopathic physician who is the subject of the investigation, as provided by s. 395.0193(8).

4. A closed claim report submitted pursuant to s. 627.912.

5. A presuit notice submitted pursuant to s. 766.106(2).

6. A petition brought under the Florida Birth-Related

Neurological Injury Compensation Plan pursuant to s. 766.305(2).

(b) A naturopathic physician may submit to the department a written response to the information contained in the complaint or document that prompted the initiation of the investigation within 45 days after she or he receives service of such complaint or document. The naturopathic physician's written response must be considered by the probable cause panel, if held on the matter.

Section 18. Section 462.018, Florida Statutes, is created to read:

462.018 Specialties.—A naturopathic physician licensed under this chapter may not hold himself or herself out as a board-certified specialist unless the naturopathic physician has successfully completed the requirements for certification as set forth by the board regulating such specialty. A naturopathic physician may indicate the services offered and may state that her or his practice is limited to one or more types of services if it accurately reflects the scope of practice of the naturopathic physician.

Section 19. Section 462.17, Florida Statutes, is renumbered as section 462.019, Florida Statutes, and amended to read:

462.019 ~~462.17~~ Penalty for offenses ~~relating to naturopathy~~. ~~Any person who shall:~~

(1) Each of the following acts constitutes a felony of the

third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084:

(a) Practicing, or attempting to practice, naturopathic medicine without an active license issued under this chapter.

(b) A licensed naturopathic physician practicing beyond the scope of practice authorized under this chapter.

(c) Obtaining, or attempting to obtain, a license to practice naturopathic medicine by a knowing misrepresentation.

(d) Obtaining, or attempting to obtain, a position as a naturopathic physician or naturopathic medical resident in a clinic or hospital by knowingly misrepresenting education, training, or experience.

(e) Dispensing a controlled substance listed in Schedule II or Schedule III of s. 893.03 in violation of s. 465.0276.

(2) Each of the following acts constitutes a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083:

(a) Knowingly concealing information relating to violations of this chapter.

(b) Making a false oath or affirmation when an oath or affirmation is required by this chapter.

(3) Each of the following constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083:

(a) Fraudulently altering, defacing, or falsifying any

records relating to patient care or treatment, including, but not limited to, patient histories, examination results, and test results.

(b) Referring any patient for health care goods or services to any partnership, firm, corporation, or other business entity in which the naturopathic physician or the naturopathic physician's employer has an equity interest of 10 percent or more, unless, before such referral, the naturopathic physician notifies the patient of her or his financial interest and of the patient's right to obtain such goods or services at the location of the patient's choice. This section does not apply to the following types of equity interest:

1. The ownership of registered securities issued by a publicly held corporation or the ownership of securities issued by a publicly held corporation, the shares of which are traded on a national exchange or the over-the-counter market.

2. A naturopathic physician's own practice, whether the naturopathic physician is a sole practitioner or part of a group, when the health care good or service is prescribed or provided solely for the naturopathic physician's own patients and is provided or performed by the naturopathic physician or under the naturopathic physician's supervision.

3. An interest in real property resulting in a landlord-tenant relationship between the naturopathic physician and the entity in which the equity interest is held, unless the rent is

determined, in whole or in part, by the business volume or profitability of the tenant or is otherwise unrelated to fair market value.

(c) Paying or receiving any commission, bonus, kickback, or rebate or engaging in any split-fee arrangement in any form with a physician, an organization, an agency, a person, a partnership, a firm, a corporation, or other business entity for patients referred to providers of health care goods and services, including, but not limited to, hospitals, nursing homes, clinical laboratories, ambulatory surgical centers, or pharmacies. This paragraph may not be construed to prevent a naturopathic physician from receiving a fee for professional consultation services ~~Sell, fraudulently obtain, or furnish any naturopathic diploma, license, record, or registration or aid or abet in the same;~~

~~(2) Practice naturopathy under the cover of any diploma, license, record, or registration illegally or fraudulently obtained or secured or issued unlawfully or upon fraudulent representations;~~

~~(3) Advertise to practice naturopathy under a name other than her or his own or under an assumed name;~~

~~(4) Falsely impersonate another practitioner of a like or different name;~~

~~(5) Practice or advertise to practice naturopathy or use in connection with her or his name any designation tending to~~

~~imply or to designate the person as a practitioner of naturopathy without then being lawfully licensed and authorized to practice naturopathy in this state; or~~

~~(6) Practice naturopathy during the time her or his license is suspended or revoked~~

~~shall be guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084~~.

Section 20. Section 462.024, Florida Statutes, is created to read:

462.024 Disclosure of medications by patients.—

(1) A patient who takes prescribed legend drugs consistent with the Naturopathic Medical Formulary established under s. 462.025 or nutrients or other natural medicinal substances upon the recommendation of her or his treating naturopathic physician is responsible for advising any other treating health care practitioner of her or his use of such legend drugs, nutrients, or other natural medicinal substances.

(2) Naturopathic physicians shall advise their patients of this requirement in writing, maintain a signed copy of a patient's disclosure in the patient's medical records, and provide a copy of the disclosure to their patients, upon request.

(3) A patient's failure to disclose her or his use of prescribed legend drugs or recommended nutrients or other

natural medicinal substances to any other treating health care practitioner creates a rebuttable presumption that any subsequent related injuries sustained by the patient were caused by the patient's failure to disclose such information. This presumption may be rebutted by clear and convincing evidence that the patient's injuries were caused by the negligence of the other treating health care practitioner.

(4) This section may not be construed to preclude a patient of a naturopathic physician from consulting with a medical physician, an osteopathic physician, or other health care practitioner.

(5) A naturopathic physician is not required to confirm a patient's consultation with, or disclosure to, any other health care practitioner.

Section 21. Section 462.025, Florida Statutes, is created to read:

462.025 Naturopathic Medical Formulary Council; establishment of formulary.—

(1) The Naturopathic Medical Formulary Council is established, separate and distinct from the board, to be composed of five members.

(a) Two members must be naturopathic physicians licensed under this chapter, appointed by the board.

(b) Three members must be pharmacists licensed under chapter 465, appointed by the board from a list of nominees

provided by the Board of Pharmacy.

(c) Each member shall be appointed for a 3-year term; however, for the purpose of providing staggered terms, the initial appointments to the council shall be as follows: one naturopathic physician appointed for a 1-year term, one pharmacist appointed for a 2-year term, and two pharmacists and one naturopathic physician, each appointed for a 3-year term.

(d) A quorum consists of three members and is required for any vote to be taken.

(2)(a) The council shall establish the Naturopathic Medical Formulary of legend drugs that a licensed naturopathic physician may prescribe in the practice of naturopathic medicine. The formulary may not include drugs:

1. That are inconsistent with the education and training provided by approved colleges and programs of naturopathic medicine or board-approved continuing education courses for naturopathic physicians; or

2. The prescription of which requires education and training beyond that of a naturopathic physician.

(b) The council shall submit the formulary to the board immediately upon adoption of, and any revision to, the formulary. The board shall adopt the formulary, and any revision thereto, by rule.

(c) The council shall review the formulary at least annually and at any time upon board request.

(d) A naturopathic physician may prescribe, administer, or dispense only those drugs included in the formulary adopted by the board. This section may not be construed to authorize a naturopathic physician to prescribe, administer, or dispense any controlled substance under s. 893.03 unless such substance is specifically included in the formulary.

Section 22. Section 462.026, Florida Statutes, is created to read:

462.026 Severability.—The provisions of this chapter are severable. If any provision of this chapter or its application is held invalid or unconstitutional by any court of competent jurisdiction, that invalidity or unconstitutionality does not affect other provisions or applications of this chapter which can be given effect without the invalid or unconstitutional provision or application.

Section 23. Section 462.09, Florida Statutes, is renumbered as section 462.027, Florida Statutes.

Section 24. Section 462.16, Florida Statutes, is repealed.

Section 25. Section 462.2001, Florida Statutes, is repealed.

Section 26. Paragraph (g) of subsection (3) of section 921.0022, Florida Statutes, is amended to read:

921.0022 Criminal Punishment Code; offense severity ranking chart.—

(3) OFFENSE SEVERITY RANKING CHART

(g) LEVEL 7

Florida Statute	Felony Degree	Description
316.027(2)(c)	1st	Accident involving death, failure to stop; leaving scene.
316.193(3)(c)2.	3rd	DUI resulting in serious bodily injury.
316.1935(3)(b)	1st	Causing serious bodily injury or death to another person; driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.

327.35(3)(c)2.	3rd	Vessel BUI resulting in serious bodily injury.
402.319(2)	2nd	Misrepresentation and negligence or intentional act resulting in great bodily harm, permanent disfiguration, permanent disability, or death.
409.920 (2)(b)1.a.	3rd	Medicaid provider fraud; $10,000 or less.
409.920 (2)(b)1.b.	2nd	Medicaid provider fraud; more than $10,000, but less than $50,000.
456.065(2)	3rd	Practicing a health care profession without a license.
456.065(2)	2nd	Practicing a health care profession without a license which results in

			serious bodily injury.
458.327(1)		3rd	Practicing medicine without a license.
459.013(1)		3rd	Practicing osteopathic medicine without a license.
460.411(1)		3rd	Practicing chiropractic medicine without a license.
461.012(1)		3rd	Practicing podiatric medicine without a license.
462.019 ~~462.17~~		3rd	Practicing naturopathic medicine ~~naturopathy~~ without a license.
463.015(1)		3rd	Practicing optometry without a license.
464.016(1)		3rd	Practicing nursing without a license.
465.015(2)		3rd	Practicing pharmacy

			without a license.
466.026(1)		3rd	Practicing dentistry or dental hygiene without a license.
467.201		3rd	Practicing midwifery without a license.
468.366		3rd	Delivering respiratory care services without a license.
483.828(1)		3rd	Practicing as clinical laboratory personnel without a license.
483.901(7)		3rd	Practicing medical physics without a license.
484.013(1)(c)		3rd	Preparing or dispensing optical devices without a prescription.
484.053		3rd	Dispensing hearing aids without a license.

494.0018(2)	1st	Conviction of any violation of chapter 494 in which the total money and property unlawfully obtained exceeded $50,000 and there were five or more victims.
560.123(8)(b)1.	3rd	Failure to report currency or payment instruments exceeding $300 but less than $20,000 by a money services business.
560.125(5)(a)	3rd	Money services business by unauthorized person, currency or payment instruments exceeding $300 but less than $20,000.
655.50(10)(b)1.	3rd	Failure to report financial transactions exceeding $300 but less

			than $20,000 by financial institution.
775.21(10)(a)	3rd	Sexual predator; failure to register; failure to renew driver license or identification card; other registration violations.	
775.21(10)(b)	3rd	Sexual predator working where children regularly congregate.	
775.21(10)(g)	3rd	Failure to report or providing false information about a sexual predator; harbor or conceal a sexual predator.	
782.051(3)	2nd	Attempted felony murder of a person by a person other than the perpetrator or the perpetrator of an attempted felony.	

782.07(1)	2nd	Killing of a human being by the act, procurement, or culpable negligence of another (manslaughter).
782.071	2nd	Killing of a human being or unborn child by the operation of a motor vehicle in a reckless manner (vehicular homicide).
782.072	2nd	Killing of a human being by the operation of a vessel in a reckless manner (vessel homicide).
784.045(1)(a)1.	2nd	Aggravated battery; intentionally causing great bodily harm or disfigurement.
784.045(1)(a)2.	2nd	Aggravated battery; using deadly weapon.

784.045(1)(b)	2nd	Aggravated battery; perpetrator aware victim pregnant.
784.048(4)	3rd	Aggravated stalking; violation of injunction or court order.
784.048(7)	3rd	Aggravated stalking; violation of court order.
784.07(2)(d)	1st	Aggravated battery on law enforcement officer.
784.074(1)(a)	1st	Aggravated battery on sexually violent predators facility staff.
784.08(2)(a)	1st	Aggravated battery on a person 65 years of age or older.
784.081(1)	1st	Aggravated battery on specified official or

		employee.
784.082(1)	1st	Aggravated battery by detained person on visitor or other detainee.
784.083(1)	1st	Aggravated battery on code inspector.
787.06(3)(a)2.	1st	Human trafficking using coercion for labor and services of an adult.
787.06(3)(e)2.	1st	Human trafficking using coercion for labor and services by the transfer or transport of an adult from outside Florida to within the state.
790.07(4)	1st	Specified weapons violation subsequent to previous conviction of s. 790.07(1) or (2).

790.16(1)	1st	Discharge of a machine gun under specified circumstances.
790.165(2)	2nd	Manufacture, sell, possess, or deliver hoax bomb.
790.165(3)	2nd	Possessing, displaying, or threatening to use any hoax bomb while committing or attempting to commit a felony.
790.166(3)	2nd	Possessing, selling, using, or attempting to use a hoax weapon of mass destruction.
790.166(4)	2nd	Possessing, displaying, or threatening to use a hoax weapon of mass destruction while committing or attempting to commit a felony.
790.23	1st,PBL	Possession of a firearm by a person who qualifies for the

		penalty enhancements provided for in s. 874.04.
794.08(4)	3rd	Female genital mutilation; consent by a parent, guardian, or a person in custodial authority to a victim younger than 18 years of age.
796.05(1)	1st	Live on earnings of a prostitute; 2nd offense.
796.05(1)	1st	Live on earnings of a prostitute; 3rd and subsequent offense.
800.04(5)(c)1.	2nd	Lewd or lascivious molestation; victim younger than 12 years of age; offender younger than 18 years of age.
800.04(5)(c)2.	2nd	Lewd or lascivious molestation; victim 12

			years of age or older but younger than 16 years of age; offender 18 years of age or older.
800.04(5)(e)	1st	Lewd or lascivious molestation; victim 12 years of age or older but younger than 16 years; offender 18 years or older; prior conviction for specified sex offense.	
806.01(2)	2nd	Maliciously damage structure by fire or explosive.	
810.02(3)(a)	2nd	Burglary of occupied dwelling; unarmed; no assault or battery.	
810.02(3)(b)	2nd	Burglary of unoccupied dwelling; unarmed; no assault or battery.	
810.02(3)(d)	2nd	Burglary of occupied	

			conveyance; unarmed; no assault or battery.
810.02(3)(e)		2nd	Burglary of authorized emergency vehicle.
812.014(2)(a)1.		1st	Property stolen, valued at $100,000 or more or a semitrailer deployed by a law enforcement officer; property stolen while causing other property damage; 1st degree grand theft.
812.014(2)(b)2.		2nd	Property stolen, cargo valued at less than $50,000, grand theft in 2nd degree.

812.014(2)(b)3.	2nd	Property stolen, emergency medical equipment; 2nd degree grand theft.
812.014(2)(b)4.	2nd	Property stolen, law enforcement equipment from authorized emergency vehicle.
812.014(2)(f)	2nd	Grand theft; second degree; firearm with previous conviction of s. 812.014(2)(c)5.

812.0145(2)(a)	1st	Theft from person 65 years of age or older; $50,000 or more.
812.019(2)	1st	Stolen property; initiates, organizes, plans, etc., the theft of property and traffics in stolen property.
812.131(2)(a)	2nd	Robbery by sudden snatching.

812.133(2)(b)	1st	Carjacking; no firearm, deadly weapon, or other weapon.
817.034(4)(a)1.	1st	Communications fraud, value greater than $50,000.
817.234(8)(a)	2nd	Solicitation of motor vehicle accident victims with intent to defraud.
817.234(9)	2nd	Organizing, planning, or participating in an intentional motor vehicle collision.
817.234(11)(c)	1st	Insurance fraud; property value $100,000 or more.
817.2341 (2)(b) & (3)(b)	1st	Making false entries of material fact or false statements regarding property

			values relating to the solvency of an insuring entity which are a significant cause of the insolvency of that entity.
817.418(2)(a)	3rd	Offering for sale or advertising personal protective equipment with intent to defraud.	
817.504(1)(a)	3rd	Offering or advertising a vaccine with intent to defraud.	
817.535(2)(a)	3rd	Filing false lien or other unauthorized document.	
817.611(2)(b)	2nd	Traffic in or possess 15 to 49 counterfeit credit cards or related documents.	
825.102(3)(b)	2nd	Neglecting an elderly person or disabled adult causing	

			great bodily harm, disability, or disfigurement.
825.103(3)(b)	2nd	Exploiting an elderly person or disabled adult and property is valued at $10,000 or more, but less than $50,000.	
827.03(2)(b)	2nd	Neglect of a child causing great bodily harm, disability, or disfigurement.	
827.04(3)	3rd	Impregnation of a child under 16 years of age by person 21 years of age or older.	
837.05(2)	3rd	Giving false information about alleged capital felony to a law enforcement officer.	
838.015	2nd	Bribery.	

838.016	2nd	Unlawful compensation or reward for official behavior.
838.021(3)(a)	2nd	Unlawful harm to a public servant.
838.22	2nd	Bid tampering.
843.0855(2)	3rd	Impersonation of a public officer or employee.
843.0855(3)	3rd	Unlawful simulation of legal process.
843.0855(4)	3rd	Intimidation of a public officer or employee.
847.0135(3)	3rd	Solicitation of a child, via a computer service, to commit an unlawful sex act.
847.0135(4)	2nd	Traveling to meet a minor to commit an unlawful sex act.

872.06	2nd	Abuse of a dead human body.
874.05(2)(b)	1st	Encouraging or recruiting person under 13 to join a criminal gang; second or subsequent offense.
874.10	1st,PBL	Knowingly initiates, organizes, plans, finances, directs, manages, or supervises criminal gang-related activity.
893.13(1)(c)1.	1st	Sell, manufacture, or deliver cocaine (or other drug prohibited under s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5.) within 1,000 feet of a child care facility, school, or state, county, or

			municipal park or publicly owned recreational facility or community center.
893.13(1)(e)1.		1st	Sell, manufacture, or deliver cocaine or other drug prohibited under s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5., within 1,000 feet of property used for religious services or a specified business site.
893.13(4)(a)		1st	Use or hire of minor; deliver to minor other controlled substance.
893.135(1)(a)1.		1st	Trafficking in cannabis, more than 25 lbs., less than 2,000 lbs.
893.135		1st	Trafficking in cocaine,

	(1)(b)1.a.		more than 28 grams, less than 200 grams.
1712			
	893.135 (1)(c)1.a.	1st	Trafficking in illegal drugs, more than 4 grams, less than 14 grams.
1713			
	893.135 (1)(c)2.a.	1st	Trafficking in hydrocodone, 28 grams or more, less than 50 grams.
1714			
	893.135 (1)(c)2.b.	1st	Trafficking in hydrocodone, 50 grams or more, less than 100 grams.
1715			
	893.135 (1)(c)3.a.	1st	Trafficking in oxycodone, 7 grams or more, less than 14 grams.
1716			
	893.135 (1)(c)3.b.	1st	Trafficking in oxycodone, 14 grams or more, less than 25 grams.
1717			
	893.135 (1)(c)4.b.(I)	1st	Trafficking in fentanyl, 4 grams or more, less

			than 14 grams.
893.135 (1)(d)1.a.		1st	Trafficking in phencyclidine, 28 grams or more, less than 200 grams.
893.135(1)(e)1.		1st	Trafficking in methaqualone, 200 grams or more, less than 5 kilograms.
893.135(1)(f)1.		1st	Trafficking in amphetamine, 14 grams or more, less than 28 grams.
893.135 (1)(g)1.a.		1st	Trafficking in flunitrazepam, 4 grams or more, less than 14 grams.
893.135 (1)(h)1.a.		1st	Trafficking in gamma-hydroxybutyric acid (GHB), 1 kilogram or more, less than 5 kilograms.

893.135 (1)(j)1.a.	1st	Trafficking in 1,4-Butanediol, 1 kilogram or more, less than 5 kilograms.	
893.135 (1)(k)2.a.	1st	Trafficking in Phenethylamines, 10 grams or more, less than 200 grams.	
893.135 (1)(m)2.a.	1st	Trafficking in synthetic cannabinoids, 280 grams or more, less than 500 grams.	
893.135 (1)(m)2.b.	1st	Trafficking in synthetic cannabinoids, 500 grams or more, less than 1,000 grams.	
893.135 (1)(n)2.a.	1st	Trafficking in n-benzyl phenethylamines, 14 grams or more, less than 100 grams.	
893.1351(2)	2nd	Possession of place for trafficking in or manufacturing of controlled substance.	

896.101(5)(a)	3rd	Money laundering, financial transactions exceeding $300 but less than $20,000.
896.104(4)(a)1.	3rd	Structuring transactions to evade reporting or registration requirements, financial transactions exceeding $300 but less than $20,000.
943.0435(4)(c)	2nd	Sexual offender vacating permanent residence; failure to comply with reporting requirements.
943.0435(8)	2nd	Sexual offender; remains in state after indicating intent to leave; failure to comply with reporting requirements.
943.0435(9)(a)	3rd	Sexual offender; failure

			to comply with reporting requirements.
943.0435(13)	3rd		Failure to report or providing false information about a sexual offender; harbor or conceal a sexual offender.
943.0435(14)	3rd		Sexual offender; failure to report and reregister; failure to respond to address verification; providing false registration information.
944.607(9)	3rd		Sexual offender; failure to comply with reporting requirements.
944.607(10)(a)	3rd		Sexual offender; failure to submit to the taking of a digitized photograph.

944.607(12)	3rd	Failure to report or providing false information about a sexual offender; harbor or conceal a sexual offender.
944.607(13)	3rd	Sexual offender; failure to report and reregister; failure to respond to address verification; providing false registration information.
985.4815(10)	3rd	Sexual offender; failure to submit to the taking of a digitized photograph.
985.4815(12)	3rd	Failure to report or providing false information about a sexual offender; harbor or conceal a sexual offender.

985.4815(13)	3rd	Sexual offender; failure to report and reregister; failure to respond to address verification; providing false registration information.

Section 27. This act shall take effect December 31, 2024.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 845 Fees/Naturopathic Medicine
SPONSOR(S): Smith
TIED BILLS: HB 843 **IDEN./SIM. BILLS:** SB 900

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Guzzo	McElroy
2) Appropriations Committee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

HB 843 creates new standards for the licensure and regulation of naturopathic physicians. The bill provides licensure authority over naturopathic physicians to the Department of Health (DOH).

HB 845, which is linked to HB 843, authorizes DOH to collect the following licensure fees:

- Initial licensure fee not to exceed $2,000;
- Initial licensure by endorsement fee not to exceed $2,000;
- Biennial licensure renewal fee not to exceed $1,000;
- Inactive status licensure fee not to exceed $1,000;
- Biennial renewal fee for inactive status not to exceed $1,000;
- Delinquency fee not to exceed $1,000; and a
- Reactivation fee not to exceed $1,000.

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

The bill will be effective on the same date that HB 843 or similar legislation takes effect.

This bill authorizes a new state fee, requiring a two-thirds vote of the membership of the House. See Section III.A.2. of the analysis.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Legislation Imposing or Raising State Fees or Taxes

The Florida Constitution provides that no state tax or fee may be imposed, authorized, or raised by the Legislature except through legislation approved by two-thirds of the membership of each house of the Legislature.[1] For purposes of this requirement, a "fee" is any charge or payment required by law, including any fee or charge for services and fees or costs for licenses and to "raise" a fee or tax means to:[2]

- Increase or authorize an increase in the rate of a state tax or fee imposed on a percentage or per mill basis;
- Increase or authorize an increase in the amount of a state tax or fee imposed on a flat or fixed amount basis; or
- Decrease or eliminate a state tax or fee exemption or credit.

A bill that imposes, authorizes, or raises any state fee or tax may only contain the fee or tax provision(s) and may not contain any other subject.[3]

The constitutional provision does not authorize any state tax or fee to be imposed if it is otherwise prohibited by the constitution and does not apply to any tax or fee authorized or imposed by a county, municipality, school board, or special district.[4]

Health Practitioner Licensure Fees

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners.[5] The MQA works in conjunction with 22 boards and four councils to license and regulate seven types of health care facilities and more than 40 health care professions.[6] Each profession is regulated by an individual practice act and by ch. 456, F.S., which provides general regulatory and licensure authority for the MQA.

Under current law, the costs of regulation of health care practitioners must be borne by the licensees and licensure applicants.[7] Regulatory boards, in consultation with DOH, must set renewal fees by rule that must be:[8]

- Based on revenue projections prepared using generally accepted accounting practices;
- Adequate to cover all expenses relating to that board;
- Reasonable, fair, and not serve as a barrier to licensure;
- Be based on potential earnings from working under the scope of the license;
- Similar to fees imposed on similar licensure types; and

[1] Fla. Const. art. VII, s. 19(a)-(b). The amendment appeared on the 2018 ballot as Amendment 5.
[2] Fla. Const. art. VII, s. 19(d).
[3] Fla. Const. art. VII, s. 19(e).
[4] Fla. Const. art. VII s. 19(c).
[5] Pursuant to s. 456.001(4), F.S., health care practitioners are defined to include acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists, midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, counselors, and psychotherapists, among others.
[6] Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2022-23*, available at https://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/index.html (last visited January 22, 2024).
[7] Section 456.025(1), F.S.
[8] *Id.*

- No more than 10 percent greater than the actual cost to regulate that profession for the previous biennium.

Effect of the Bill

HB 845, which is linked to HB 843, authorizes DOH to collect the following licensure fees:

- Initial licensure fee not to exceed $2,000;
- Initial licensure by endorsement fee not to exceed $2,000;
- Biennial licensure renewal fee not to exceed $1,000;
- Inactive status licensure fee not to exceed $1,000;
- Biennial renewal fee for inactive status not to exceed $1,000;
- Delinquency fee not to exceed $1,000; and a
- Reactivation fee not to exceed $1,000.

The bill become effective on the same date that HB 843 or similar legislation takes effect.

B. SECTION DIRECTORY:

Section 1: Amends s. 462.005, F.S., relating to rulemaking authority; powers and duties of the board.
Section 2: Amends s. 462.007, F.S., relating to licensure by examination.
Section 3: Amends s. 462.008, F.S., relating to licensure by endorsement.
Section 4: Amends s. 462.009, F.S., relating to renewal of license to practice naturopathic medicine.
Section 5: Amends s. 462.011, F.S., relating to continuing education requirements.
Section 6: Amends s. 462.012, F.S., relating to inactive status; reactivation of license.
Section 7: Provides an effective date of December 31, 2024, which is contingent upon the passage of HB 843 or similar legislation.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Applicants will be subject to the following licensure fees:

   - Initial licensure fee not to exceed $2,000;
   - Initial licensure by endorsement fee not to exceed $2,000;
   - Biennial licensure renewal fee not to exceed $1,000;
   - Inactive status licensure fee not to exceed $1,000;
   - Biennial renewal fee for inactive status not to exceed $1,000;
   - Delinquency fee not to exceed $1,000; and a
   - Reactivation fee not to exceed $1,000.

   The total revenue DOH will receive from such fees is indeterminate because the number of individuals who will choose to become licensed as a naturopathic physician is unknown.

2. Expenditures:

   DOH will incur costs to implement the bill's provisions. Current resources and new revenue from licensure fees are adequate to absorb these costs.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

Article VII, s. 19 of the Florida Constitution requires the imposition, authorization, or raising of a state tax or fee be contained in a separate bill that contains no other subject and be approved by two-thirds of the membership of each house of the Legislature. As such, the bill appears to implicate Art. VII, s. 19 of the Florida Constitution because the bill authorizes a state fee.

B. RULE-MAKING AUTHORITY:

The Board of Nursing has sufficient rule-making authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to fees; amending s. 462.005, F.S.; requiring the Board of Naturopathic Medicine to establish certain fees; amending ss. 462.007 and 462.008, F.S.; providing for fees for licensure by examination and licensure by endorsement, respectively, of naturopathic physicians; amending s. 462.009, F.S.; providing for licensure renewal fees; amending s. 462.011, F.S.; conforming a provisions to changes made by the act; amending s. 462.012, F.S.; authorizing the board to set by rule certain fees related to inactive licenses and reactivation of licensure; providing a contingent effective date.

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

Section 1. Section 462.023, Florida Statutes, as renumbered as section 462.005, Florida Statutes, and amended by HB 843, 2024 Regular Session, is amended to read:

462.005 Rulemaking authority; powers and duties of the board.—The board may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it and to carry out the purposes of this chapter, ~~and~~ may initiate disciplinary action as provided by this chapter, and shall establish fees based on its estimates of the

revenue required to administer this chapter, which fees may not exceed the fee amounts provided in this chapter.

Section 2. Subsection (1) of section 462.007, Florida Statutes, as created by HB 843, 2024 Regular Session, is amended to read:

462.007 Licensure by examination.—

(1) Any person desiring to be licensed as a naturopathic physician must apply to the department on forms furnished by the department. The department shall license each applicant who completes the application form and remits a nonrefundable fee not to exceed $2,000, as set by the board, and who the board certifies has met all of the following criteria:

(a) Is at least 21 years of age.

(b) Has received a bachelor's degree from one of the following:

1. A college or university accredited by an accrediting agency recognized by the United States Department of Education or the Council for Higher Education Accreditation or its successor entity.

2. A college or university in Canada which is a member of Universities Canada.

3. A college or university in a foreign country and has provided evidence that her or his educational credentials are deemed equivalent to those provided in this country. To have educational credentials deemed equivalent, the applicant must

provide her or his foreign educational credentials, including transcripts, course descriptions or syllabi, and diplomas, to a nationally recognized educational credential evaluating agency approved by the board for the evaluation and determination of equivalency of the foreign educational credentials.

(c) Has received a naturopathic doctoral degree from a college or program accredited by the Council on Naturopathic Medical Education or another accrediting agency recognized by the United States Department of Education.

(d) Is physically and mentally fit to practice as a naturopathic physician.

(e) Is of good moral character and has not:

1. Committed any act or offense in this or any other jurisdiction which would constitute the basis for disciplining a naturopathic physician pursuant to s. 462.017.

2. Had an application for licensure in any profession denied or had her or his license to practice any profession revoked or suspended by any other state, district, or territory of the United States or another country for reasons that relate to her or his ability to practice skillfully and safely as a naturopathic physician.

3. Been found guilty of a felony.

The board and the department shall ensure that applicants for licensure meet the criteria of this paragraph by independently

verifying the provided information through the department's investigative process.

(f) Has submitted to the department a set of fingerprints on a form and in accordance with procedures specified by the department under s. 456.039(4), along with payment in an amount equal to the costs incurred by the department for the criminal background check of the applicant.

(g) Has demonstrated compliance with the financial responsibility requirements imposed under s. 462.015.

(h) Has obtained a passing score, as determined by board rule, on Part I - Biomedical Science Examination, Part II - Core Clinical Science Examination, and Part II - Clinical Elective Pharmacology Examination of the competency-based national Naturopathic Physician Licensing Examination administered by the North American Board of Naturopathic Examiners, or an equivalent examination offered by an equivalent or successor entity, as approved by the board.

Section 3. Subsection (1) of section 462.008, Florida Statutes, as created by HB 843, 2024 Regular Session, is amended to read:

462.008 Licensure by endorsement.—

(1) Any person licensed to practice naturopathic medicine in another state or territory of the United States or in Canada who desires to be licensed as a naturopathic physician in this state must apply to the department on forms furnished by the

department. The department shall issue a license by endorsement to any applicant who completes the application form and remits a nonrefundable fee not to exceed $2,000, as determined by the board, and who the board certifies has met all of the following criteria:

(a) Has met the qualifications for licensure established in s. 462.007(1)(a)-(g).

(b)1. Has submitted evidence of holding an active license to practice naturopathic medicine in another state or territory of the United States or in Canada for at least the 5 years immediately preceding the filing of her or his application; or

2. If an applicant has held an active license to practice naturopathic medicine in another state or territory of the United States or in Canada for less than the 5 years immediately preceding the filing of her or his application, has obtained a passing score on the national licensing examination, as specified in s. 462.007(1)(h), within the year immediately preceding the filing of the application.

Section 4. Subsection (1) of section 462.08, Florida Statutes, as renumbered as section 462.009, Florida Statutes, and amended by HB 843, 2024 Regular Session, is amended to read:

462.009 Renewal of license to practice naturopathic medicine.—

(1) In order to continue practicing naturopathic medicine in this state, each licensed naturopathic physician must

biennially renew her or his license to practice naturopathic medicine. The applicant for license renewal must furnish to the board such evidence as it requires of the applicant's compliance with s. 462.011, relating to continuing education requirements, and s. 462.015, relating to financial responsibility requirements. The biennial renewal fee, the amount of which shall be determined by the board but may not exceed $1,000, must be paid at the time the application for license renewal is filed.

Section 5. Subsection (1) of section 462.18, Florida Statutes, as renumbered as section 462.011, Florida Statutes, and amended by HB 843, 2024 Regular Session, is amended to read:

462.011 Continuing education requirements.—

(1) At the time each licensee renews her or his license as provided in s. 462.009, each licensee must, in addition to the payment of the regular renewal fee, furnish to the board satisfactory evidence that, in the preceding biennial period, the licensee has completed the continuing education requirements of this section.

Section 6. Section 462.19, Florida Statutes, as renumbered as section 462.012, Florida Statutes, and amended by HB 843, 2024 Regular Session, is amended to read:

462.012 Inactive status; reactivation of license.—

(1) A licensee may reactivate an inactive license by applying to the department, paying any applicable fees, and

submitting proof of compliance with the financial responsibility requirements of s. 462.015.

(2) The board shall adopt rules relating to reactivation of licenses that have become inactive and for the renewal of inactive licenses. The rules must include continuing education requirements as a condition of reactivating a license. The continuing education requirements for reactivating a license may not be fewer than 20 classroom hours for each year the license was inactive. The board may also adopt rules to set fees, including a fee for placing a license into inactive status, a biennial renewal fee for licenses in inactive status, a delinquency fee, and a fee for the reactivation of a license. None of these fees may exceed the biennial renewal fee established by the board in s. 462.009.

(3) The department may not reactivate a license unless the applicable fees have been paid and the financial responsibility requirements of s. 462.015 have been satisfied.

Section 7. This act shall take effect on the same date that HB 843 or similar legislation takes effect, if such legislation is adopted in the same legislative session or an extension thereof and becomes a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1063 Practice of Chiropractic Medicine
SPONSOR(S): Hunschofsky
TIED BILLS: **IDEN./SIM. BILLS:** SB 1474

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		DesRochers	McElroy
2) Health & Human Services Committee			

SUMMARY ANALYSIS

Dry needling is a technique that acupuncturists, physical therapists, and other trained healthcare providers use to treat musculoskeletal pain and movement issues. Healthcare providers may incorporate dry needling as a part of a larger pain management point that could include exercise, stretching, massage, and other techniques. Dry needling may help relieve pain and increase range of motion. Depending on the state, dry needling may be performed by licensed physical therapists, athletic trainers, chiropractors, or medical doctors who have been trained in the procedure.

Under current law, the practice of chiropractic medicine is a noncombative principle and practice consisting of the science, philosophy, and art of the adjustment, manipulation, and treatment of the human body. Specifically, chiropractic medicine targets vertebral subluxations and other malpositioned articulations and structures that interfere with the normal generation, transmission, and expression of nerve impulse between the brain, organs, and tissue cells of the body.

The Florida Board of Chiropractic Medicine (Board) ensures that every chiropractic physician practicing in Florida meets minimum requirements for safe practice. The Board is responsible for the licensure and quality control of chiropractic professionals to assure competency and safety. Any person desiring to be licensed as a chiropractic physician must apply to DOH to take the licensure examination. The Board has not opined on whether dry needling is within the scope of practice for chiropractic physicians.

HB 1063 authorizes chiropractic physicians to adjust, manipulate, or treat the human body by the use of monofilament intramuscular stimulation, also known as dry needling, treatment for trigger points or myofascial pain.

Current law requires DOH to examine each applicant whom the Board certifies meets the necessary matriculation prerequisites. The bill gives the Board authority to recognize chiropractic physician applicants for licensure if they provide a credential evaluation report from a board-approved corporation that is equivalent to a bachelor's degree.

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

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

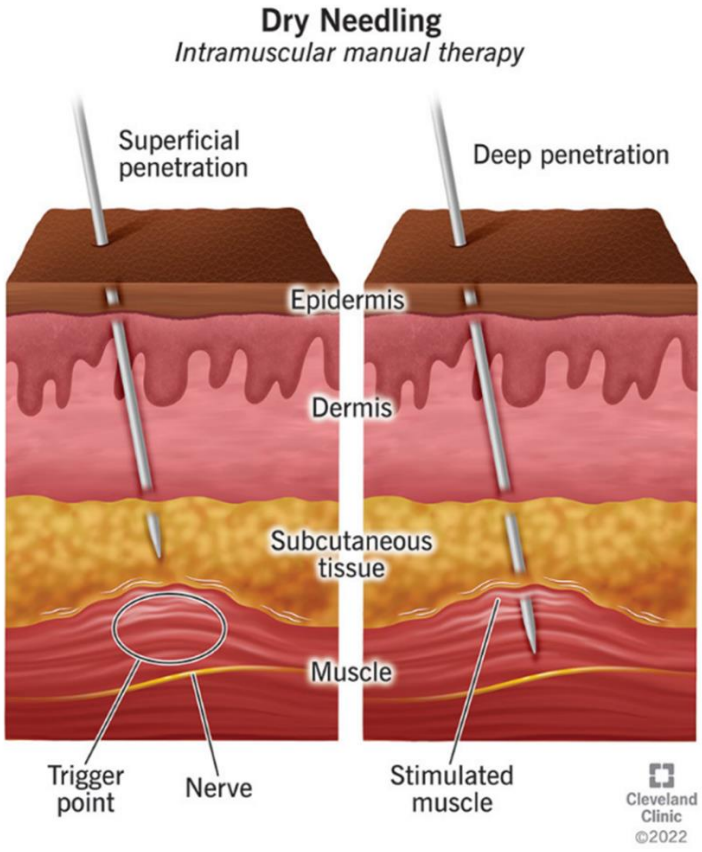
A. EFFECT OF PROPOSED CHANGES:

Background

Dry Needling

Dry needling is a technique that acupuncturists, physical therapists, and other trained healthcare providers use to treat musculoskeletal pain and movement issues. Healthcare providers may incorporate dry needling as a part of a larger pain management point that could include exercise, stretching, massage, and other techniques. With dry needling, a healthcare provider inserts thin, sharp needles through a patient's skin to treat underlying myofascial[1] trigger points. Trigger points are knotted, tender areas that develop in muscles which are highly sensitive and can be painful when touched.[2]

When health providers apply dry needling to muscles and tissues, needles may decrease tightness, increase blood flow, and reduce local and referred pain. Providers use solid needles that do not contain any kind of medication – hence "dry" needling. Dry needling may also be known as intramuscular stimulation. The visual graphic below illustrates how dry needling works.[3]



When a patient overexerts their muscle, the muscle experiences an energy crisis where the muscle fibers cannot access an adequate supply of blood. Without normal blood supply to the muscle, the muscle cannot get the oxygen and nutrients that allow the muscle to return to its normal resting state.

[1] In the word "myofascial," "myo" means "muscle." Fascia is the thin, white connective tissue that wraps around muscles.

[2] The Cleveland Clinic, *Dry Needling*, (last reviewed Feb. 20, 2023) https://my.clevelandclinic.org/health/treatments/16542-dry-needling (last visited Jan. 21, 2024).

[3] *Id*.

Dry needling may stimulate the trigger point to help draw normal blood supply back to flush out the area and release tension.[4]

Dry needling may help relieve pain and increase range of motion. Conditions that dry needling may treat include:[5]

- Joint issues.
- Disk issues.
- Tendonitis.
- Migraine and tension-type headaches.
- Jaw and mouth problems, such as temporomandibular joint (TMJ) disorders.
- Whiplash.
- Repetitive motion disorders, such as carpal tunnel syndrome.
- Spinal issues.
- Pelvic pain.
- Night cramps.
- Phantom limb pain.
- Postherpetic neuralgia, a complication of shingles.

There are certain groups of people who should not receive dry needling. Providers do not recommend the procedure for children under the age of 12 because it can be painful. Other groups who should consult with their physician before receiving dry needling include people who:[6]

- Are pregnant.
- Are not able to understand the treatment.
- Are very afraid of needles (trypanophobia).
- Have compromised immune systems.
- Have just had surgery.
- Are on blood thinners.

The most common side effect of dry needling is soreness during and after treatment. Other side effects are typically minor. They may include:[7]

- Stiffness.
- Bruising at or near the insertion site.
- Fainting.
- Fatigue.
- Risk of infection.

While both dry needling and acupuncture use needles to treat pain, acupuncture treats musculoskeletal pain and dry needling treats muscle tissue with the goal of pain mitigation, deactivating trigger points, and improving movement.[8] Depending on the state, dry needling is performed by licensed physical therapists, athletic trainers, chiropractors, or medical doctors who have been trained in the procedure.

On November 9, 2023, the Florida Board of Chiropractic Medicine convened a board meeting to discuss, in part, the Florida Chiropractic Association (FCA)'s petition for a declaratory statement[9] that asked whether dry needling is within the scope of practice for chiropractic physicians. The Florida Chiropractic Physician Association (FCPA) appeared in support of adding drying needling to the scope

[4] *Id*.
[5] *Id*.
[6] *Id*.
[7] *Id*.
[8] *Id*.
[9] *Florida Chiropractic Association's Petition for Declaratory Statement Before the Department of Health / Board of Chiropractic Medicine* (Oct. 30, 2023) https://www.fcachiro.org/wp-content/uploads/2023/08/Petition-for-Declaratory-Statement-dry-needling-1.pdf (last visited Jan. 21, 2024).

of practice. The Florida Chiropractic Society (FCS) appeared in opposition to adding dry needling to the scope of practice. After debate, the FCA withdrew their declaratory statement petition, and the Board suspended discussion of whether dry needling is within the scope of practice for chiropractic physicians.[10]

Chiropractic Medicine

The Practice of Chiropractic Medicine

Under current law s. 460.403, F.S., the practice of chiropractic medicine is a noncombative principle and practice consisting of the science, philosophy, and art of the adjustment, manipulation, and treatment of the human body. Specifically, chiropractic medicine targets vertebral subluxations and other malpositioned articulations and structures that interfere with the normal generation, transmission, and expression of nerve impulse between the brain, organs, and tissue cells of the body. Left untreated, these abnormalities may cause disease. To mitigate the occurrence of disease, chiropractors adjust, manipulate, and treat the human body to restore the normal flow of nerve impulse which produces normal function and consequent health. The practice of chiropractic medicine further contemplates that chiropractic physicians use specific chiropractic adjustment or manipulation techniques taught in chiropractic colleges accredited by the Council on Chiropractic Education. No person other than a licensed chiropractic physician may render chiropractic services, chiropractic adjustments, or chiropractic manipulations.[11]

Chiropractic physicians may adjust, manipulate, or treat the human body by:

- Manual, mechanical, electrical, or natural methods;
- The use of physical means or physiotherapy, including light, heat, water, or exercise;
- The use of acupuncture; or
- The administration of foods, food concentrates, food extracts, and items for which a prescription is not required.

In addition, chiropractic physicians may apply first aid and hygiene. However, chiropractic physicians are expressly prohibited from prescribing or administering to any person any legend drug except, in emergencies, prescription medical oxygen or topical anesthetics in aerosol form. Chiropractic physicians cannot perform any surgery or practice obstetrics.[12]

Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities which the chiropractic physician knows or has reason to know that she or he is not competent to perform constitutes grounds for denial of a license or disciplinary action.[13]

The Florida Board of Chiropractic Medicine

The Florida Board of Chiropractic Medicine (Board) ensures that every chiropractic physician practicing in Florida meets minimum requirements for safe practice. The Board is responsible for the licensure and quality control of chiropractic professionals to assure competency and safety.[14] The Board is a division of the Florida Department of Health (DOH) and consists of seven members appointed by the Governor and confirmed by the Senate.[15] Five board members must be licensed chiropractic physicians who are Florida residents and have practiced chiropractic medicine for at least 4 years. The other two board members must be Florida residents who are not, and never have been, licensed as

[10] Florida Board of Chiropractic Medicine, *Board Meeting Minutes, November 9, 2023*, Florida Department of Health (Nov. 9, 2023) https://ww10.doh.state.fl.us/pub/hcpr/Chiropractor/2023/Chiro%20Draft%20Minutes%2011.9.23.pdf (last visited Jan. 21, 2024).
[11] S. 460.403(9)(a), F.S.
[12] S. 460.403(9)(c), F.S.
[13] S. 460.413(1)(t), F.S.
[14] The Florida Board of Chiropractic Medicine, *Homepage*, Florida Department of Health, https://floridaschiropracticmedicine.gov/ (last visited Jan. 21, 2024).
[15] S. 460.404(1), F.S.

chiropractic physicians or members of any closely related profession. At least one board member must be 60 years of age or older.[16]

Any person desiring to be licensed as a chiropractic physician must apply to DOH to take the licensure examination. The nonrefundable application fee is capped at $100, and the National Board of Chiropractic Examiners (NBCE) administers the examination. The examination fee must not exceed $500 plus the actual per applicant cost to DOH for purchase of portions of the examination from NBCE.[17]

DOH examines each application whom the Board certifies has met all of the following criteria:[18]

- Completed the application form and remitted the appropriate fee.
- Submitted proof satisfactory to DOH that the applicant is not less than 18 years of age.
- Submitted proof satisfactory to DOH that the applicant is a graduate of a chiropractic college which is accredited by or has status with the Council on Chiropractic Education or its predecessor agency.
- Regarding matriculation at a chiropractic college, the following requirements apply:
    - Matriculation before 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.
    - Matriculation after July 1, 1990: granted a bachelor's degree, based upon 4 academic years of study, by a college or university accredited by an institutional accrediting agency that is a member of the Commission on Recognition of Postsecondary Accreditation.
    - Before matriculation effective July 1, 2000: completed 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. In addition, the applicant must have been granted a bachelor's degree from an institution holding accreditation for that degree from an institutional accrediting agency that is recognized by the United States Department of Education.[19]
- Passed the NBCE certification examination in parts I, II, III, and IV with a score approved by the Board.
- Passed the NBCE physiotherapy examination with a score approved by the Board.
- Submitted to DOH a set of fingerprints on a form and under procedures specified by DOH, along with payment in an amount equal to the costs incurred by DOH for the criminal background check of the applicant.

[16] S. 460.404(2), F.S.
[17] S. 460.406(1), F.S.
[18] S. 460.406(1), F.S.
[19] 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.

Effect of the Bill

The bill authorizes chiropractic physicians to adjust, manipulate, or treat the human body by the use of monofilament intramuscular stimulation, also known as dry needling, treatment for trigger points or myofascial pain.

Current law requires DOH to examine each applicant whom the Board certifies meets the necessary matriculation prerequisites. The bill gives The Board authority to recognize chiropractic physician applicants for licensure if they provide a credential evaluation report from a board-approved corporation that is equivalent to a bachelor's degree.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Amending s. 460.403, F.S., relating to definitions.
Section 2: Amending s. 460.406, F.S., relating to licensure by examination.
Section 3: Providing an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The Board has sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the practice of chiropractic medicine; amending s. 460.403, F.S.; authorizing chiropractic physicians to use dry needling treatments for specified purposes; amending s. 460.406, F.S.; requiring the Board of Chiropractic Medicine to certify certain applicants who provide a specified credential evaluation report; providing an effective date.

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

Section 1. Paragraph (c) of subsection (9) of section 460.403, Florida Statutes, is amended to read:

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

(9)

(c)1. Chiropractic physicians may adjust, manipulate, or treat the human body by manual, mechanical, electrical, or natural methods; by the use of physical means or physiotherapy, including light, heat, water, or exercise; by the use of acupuncture; by the use of monofilament intramuscular stimulation, also known as dry needling, treatment for trigger points or myofascial pain; or by the administration of foods, food concentrates, food extracts, and items for which a prescription is not required and may apply first aid and

hygiene, but chiropractic physicians are expressly prohibited from prescribing or administering to any person any legend drug except as authorized under subparagraph 2., from performing any surgery except as stated herein, or from practicing obstetrics.

2. Notwithstanding the prohibition against prescribing and administering legend drugs under subparagraph 1. or s. 499.83(2)(c), pursuant to board rule chiropractic physicians may order, store, and administer, for emergency purposes only at the chiropractic physician's office or place of business, prescription medical oxygen and may also order, store, and administer the following topical anesthetics in aerosol form:

a. Any solution consisting of 25 percent ethylchloride and 75 percent dichlorodifluoromethane.

b. Any solution consisting of 15 percent dichlorodifluoromethane and 85 percent trichloromonofluoromethane.

However, this paragraph does not authorize a chiropractic physician to prescribe medical oxygen as defined in chapter 499.

Section 2. Paragraph (d) of 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 the board certifies has met all of the following criteria:

(d)1. For an applicant who has matriculated in a chiropractic college before 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 or provides a credential evaluation report from a board-approved corporation that is equivalent to a bachelor's degree. However, before being certified by the board to sit for the examination, each applicant who has matriculated in a chiropractic college after July 1, 1990, must have been granted a bachelor's degree, based upon 4 academic years of study, by a college or university accredited by an institutional accrediting agency that is a member of the Commission on Recognition of Postsecondary Accreditation or provides a credential evaluation report from a board-approved corporation that is equivalent to a bachelor's

degree.

2. Effective July 1, 2000, completed, before 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 or provides a credential evaluation report from a board-approved corporation that is equivalent to a bachelor's degree. However, before being certified by the board to sit for the examination, each applicant who has matriculated in a chiropractic college after July 1, 2000, must have been granted a bachelor's degree from an institution holding accreditation for that degree from an institutional accrediting agency that 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 3. This act shall take effect July 1, 2024.

COMMITTEE/SUBCOMMITTEE ACTION

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

Committee/Subcommittee hearing bill: Healthcare Regulation Subcommittee

Representative Hunschofsky offered the following:

Amendment

Remove lines 66-112 and insert:

provides a credentials evaluation report from a board-approved organization that deems the applicant's education equivalent to a bachelor's degree. However, before being certified by the board to sit for the examination, each applicant who has matriculated in a chiropractic college after July 1, 1990, must have been granted a bachelor's degree, based upon 4 academic years of study, by a college or university accredited by an institutional accrediting agency that is a member of the Commission on Recognition of Postsecondary Accreditation or provides a credentials evaluation report from a board-approved

organization that deems the applicant’s education equivalent to a bachelor’s degree.

2. Effective July 1, 2000, completed, before 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 or provides a credentials evaluation report from a board-approved organization that deems the applicant’s education equivalent to a bachelor’s degree. However, before being certified by the board to sit for the examination, each applicant who has matriculated in a chiropractic college after July 1, 2000, must have been granted a bachelor's degree from an institution holding accreditation for that degree from an institutional accrediting agency that is recognized by the United States Department of Education or provides a credentials evaluation report from a board-approved organization that deems the applicant’s education equivalent to a bachelor’s degree. 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 3. This act shall take effect upon becoming law.

HB 1173

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1173 Dental Therapy
SPONSOR(S): Chaney
TIED BILLS: **IDEN./SIM. BILLS:** SB 1254

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Osborne	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The Board of Dentistry (BOD) regulates dental practice in Florida, including dentists, dental hygienists, and dental assistants under the Dental Practice Act. A dentist is licensed to examine, diagnose, treat, and care for conditions within the human oral cavity and its adjacent tissues and structures. A dental hygienist provides education, preventive and delegated therapeutic dental services. There are currently 17,193 dentists, 17,681 dental hygienists, and 8,371 dental radiographers with active licenses to practice in Florida. There are 41 out-of-state registered telehealth dentists.

Dental therapists are mid-level dental care providers; the role of dental therapists has been equated to that of physician assistants in medicine. Under dentist supervision, dental therapists provide preventative and routine restorative care, such as filling cavities, placing temporary crowns, and extracting badly diseased or loose teeth. There are currently 14 states in the US that authorize the practice of dental therapy to some extent. Florida does not currently issue licenses for dental therapists.

Current law limits the use of mobile dental units in Medicaid. Medicaid reimbursement is only available for dental services provided by mobile dental units owned or operated by, or under contract with, a county health department, FQHC, state-approved dental educational institution, or a mobile dental unit providing adult dental services at a nursing home.

HB 1173 establishes licensure criteria for dental therapists. The bill specifies the scope of practice for dental therapists and requires they operate under a written collaborative management agreement with a licensed dentist. The bill sets continuing education requirements for dental therapists.

The bill directs the BOD to establish a Council on Dental Therapy to advise the BOD on matters relating to the practice and regulation of dental therapy. The bill directs the chair of the BOD to appoint the members of Council 28 months after the first dental therapy license is granted by the BOD and sets requirements for the composition of the Council.

The bill allows Medicaid to provide reimbursement for dental services provided by a mobile dental unit owned by, operated by, or having a contractual relationship with a health access setting or similar program serving underserved populations.

The bill has a significant, indeterminant, negative fiscal impact on state government, and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Regulation of Dental Practice in Florida

The Board of Dentistry (BOD) regulates dental practice in Florida, including dentists, dental hygienists, and dental assistants under the Dental Practice Act.[1] Dentists and dental hygienists must receive specified education and training to be licensed and practice in their respective professions;[2] dental assistants are not a licensed profession and provide a narrow scope of services as authorized and supervised by a licensed dentist.[3]

There are currently 17,193 dentists and 17,681 dental hygienists with active licenses to practice in Florida. There are 41 out-of-state registered telehealth dentists.[4]

Dentists

A dentist is licensed to examine, diagnose, treat, and care for conditions within the human oral cavity and its adjacent tissues and structures.[5] Dentists may delegate certain tasks[6] to dental hygienists and dental assistants, but a patient's "dentist of record" retains primary responsibility for all dental treatment on the patient.[7]

Any person wishing to practice dentistry in this state must meet specified requirements and apply to the Department of Health (DOH) for licensure. Applicants must sit for and pass three examinations prior to licensure:[8]

- The National Board of Dental Examiners dental examination (NBDE);
- A practical examination, which is the American Dental Licensing Examination developed by the American Board of Dental Examiners, Inc.;[9] and
- A written examination on Florida laws and rules regulating the practice of dentistry and dental hygiene.

To qualify to take the Florida dental licensure examination, an applicant must be 18 years of age or older, be a graduate of a dental school accredited by the American Dental Association or be a student in the final year of a program at an accredited institution, and have successfully completed the NBDE dental examination.[10]

Dentists must maintain professional liability insurance or provide proof of professional responsibility. If the dentist obtains professional liability insurance, the coverage must be at least $100,000 per claim, with a minimum annual aggregate of at least $300,000.[11] Alternatively, a dentist may maintain an unexpired, irrevocable letter of credit in the amount of $100,000 per claim, with a minimum aggregate availability of credit of at least $300,000.[12] The professional liability insurance must provide coverage

[1] S. 466.004, F.S.
[2] S. 466.003(2) and (5), F.S.
[3] *See*, Rules 64B5-16.002 and 64B5-16.005, F.A.C.
[4] *See*, Department of Health *License Verification* web search. Available at https://mqa-internet.doh.state.fl.us/MQASearchServices/HealthCareProviders (last visited January 14, 2023).
[5] S. 466.003(2)-(3), F.S.
[6] S. 466.024, F.S.
[7] S. 466.018, F.S.
[8] S. 466.006, F.S.
[9] Rule 64B5-2.013, F.A.C.
[10] S. 466.006(2), F.S.
[11] Rule 64B5-17.011(1), F.A.C.
[12] Rule 64B5-17.011(2), F.A.C.

for the actions of any dental hygienist supervised by the dentist.[13] However, a dentist may be exempt from maintaining professional liability insurance if he or she:[14]

- Practices exclusively for the federal government or the State of Florida or its agencies or subdivisions;
- Is not practicing in this state;
- Practices only in conjunction with his or her teaching duties at an accredited school of dentistry or in its main teaching hospitals; or
- Demonstrates to the Board that he or she has no malpractice exposure in this state.

Dental Hygienists

A dental hygienist provides education, preventive and delegated therapeutic dental services under varying levels of supervision by a licensed dentist.[15] Any person wishing to be licensed as a dental hygienist must apply to DOH and meet the following qualifications:[16]

- Be 18 years of age or older;
- Be a graduate of an accredited dental hygiene college or school;[17] and
- Obtain a passing score on the:
    - Dental Hygiene National Board Examination;
    - Dental Hygiene Licensing Examination developed by the American Board of Dental Examiners, Inc., which is graded by a Florida-licensed dentist or dental hygienist employed by DOH for such purpose; and
    - A written examination on Florida laws and rules regulating the practice of dental hygiene.

A dental hygienist is not required to maintain professional liability insurance and must be covered by the supervising dentist's liability insurance.[18]

A supervising dentist may delegate certain tasks to a dental hygienist, such as removing calculus deposits, accretions, and stains from exposed surfaces of the teeth and from the gingival sulcus and the task of performing root planning and curettage.[19] A dental hygienist may also expose dental X-ray films, apply topical preventive or prophylactic agents, and delegated remediable tasks.[20] Remediable tasks are intra-oral tasks which do not create an unalterable change in the oral cavity or contiguous structures, are reversible, and do not expose a risk to the patient, including but not limited to:

- Fabricating temporary crowns or bridges inter-orally;
- Selecting and pre-sizing orthodontic bands;
- Preparing a tooth service by applying conditioning agents for orthodontic appliances;
- Removing and re-cementing properly contoured and fitting loose bands that are not permanently attached to any appliance;
- Applying bleaching solution, activating light source, and monitoring and removing in-office bleaching solution;
- Placing or removing rubber dams;
- Making impressions for study casts which are not being made for the purpose of fabricating any intra-oral appliances, restorations, or orthodontic appliances;
- Taking impressions for passive appliances, occlusal guards, space maintainers, and protective mouth guards; and

[13] Rule 64B5-17.011(4), F.A.C.
[14] Rule 64B5-17.011(3), F.A.C.
[15] S. 466.003(4)-(5), F.S.
[16] S. 466.007, F.S.
[17] If the school is not accredited, the applicant must have completed a minimum of 4 years of postsecondary dental education and received a dental school diploma which is comparable to a D.D.S. or D.M.
[18] *Supra,* note 13.
[19] S. 466.023, F.S.
[20] Ss. 466.023 and 466.024, F.S.

- Cementing temporary crowns and bridges with temporary cement.

A dental hygienist may perform additional remediable tasks as delegated by the supervising dentist if they have received additional training in a pre-licensure course, other formal training, or on-the-job training.[21] To administer local anesthesia, a dental hygienist obtain certification which requires the dental hygienist completes an accredited course of 30 hours of didactic training and 30 hours of clinical training and is certified in basic or advanced cardiac life support. Once certified, the dental hygienist may only administer local anesthesia to a non-sedated, adult patient.[22]

Dental Assistants

Dental assistants provide limited dental care services under the supervision and authorization of a licensed dentist.[23] Florida does not license dental assistants; however, dental assistants may choose to receive formal education in dental assisting and obtain a national certification.[24] Dental assistants who have graduated from a board-approved dental assisting school are eligible for certification as dental radiographers.[25]

The scope of practice for dental assistants is limited to the delegable tasks determined in Florida law and rule. The specific tasks that may be delegated to a dental assistant are dependent on the formal and on-the-job training the dental assistant has received.[26]

Access to Dental Care in Florida

Lack of dental care can lead to poor oral health and poor overall health outcomes. Poor oral health is associated with a variety of poor health outcomes including diabetes, heart and lung disease, as well as increased stroke risk and adverse birth outcomes including pre-term deliveries and low birth-weight.[27]

The US Department of Health and Human Services' Health Resources and Services Administration (HRSA) designates Health Professional Shortage Areas (HPSAs). A HPSA is a geographic area, population group, or health care facility that has been designated by the HRSA as having a shortage of health professionals. There are three categories of HPSA: primary care, dental health, and mental health.[28] HPSAs can be designated as geographic areas; areas with a specific group of people such as low-income populations, homeless populations, and migrant farmworker populations; or as a specific facility that serves a population or geographic area with a shortage of providers.[29]

As of September 30, 2023, there are 266 dental HPSAs designated within the state. It would take 1,317 dentists distributed accordingly to eliminate these shortage areas.[30] Most dentists are disproportionately

[21] *See*, ss. 466.023, 466.0235, and 466.024, F.S.; and Rule 64B5-16, F.A.C.
[22] S. 466.017(5), F.S.
[23] S. 466.003(6), F.S.
[24] *See*, Dental Assisting National Board, *Earn Dental Assistant Certification*. Available at https://www.danb.org/certification/earn-dental-assistant-certification (last visited January 18, 2024).
[25] Rule 64B5-9.011, F.A.C.; A dental assistant may also become eligible for certification as a dental radiographer through three continuous months of on-the-job training under the direct supervision of a dentist.
[26] For more information on the specific tasks which may be delegated to a dental assistant, and the required training for each task, *see*, rules 64B5-16.002 and 64B5-16.005, F.A.C.
[27] Mayo Clinic. *Oral Health: A Window to Your Overall Health* (2021). Available at https://www.mayoclinic.org/healthy-lifestyle/adult-health/in-depth/dental/art-20047475 (last visited January 20, 2024).
[28] National Health Service Corps, *Health Professional Shortage Areas (HPSAs) and Your Site*. Available at https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/workforce-shortage-areas/nhsc-hpsas-practice-sites.pdf, (last visited January 8, 2024).
[29] HRSA, *What is a Shortage Designation?*. Available at https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation#hpsas, (last visited January 8, 2024).
[30] Bureau of Health Workforce, Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services, *Designated Health Professional Shortage Areas Statistics, Fourth Quarter of Fiscal Year 2023* (Sept. 30, 2023), available at https://data.hrsa.gov/topics/health-workforce/health-workforce-shortage-areas?hmpgtile=hmpg-hlth-srvcs (last visited January 8, 2024). To generate the report, select "Designated HPSA Quarterly Summary."

concentrated in the more populous areas of the state. Two counties, Dixie and Glades, do not have any licensed dentists, while other counties have over 150 dentists per 100,000 residents.[31]

Dental Therapy

Dental therapists are mid-level dental care providers; the role of dental therapists has been equated to that of physician assistants in medicine. Under dentist supervision, dental therapists provide preventative and routine restorative care, such as filling cavities, placing temporary crowns, and extracting badly diseases or loose teeth. Dental therapists are part of a larger dental team, and allow dentists to be able to perform more advanced care and treat a larger number of patients.[32]

In 2015, the Commission on Dental Accreditations (CODA) established accreditation standards for dental therapy education programs.[33] To be accredited programs must, among other things:[34]

- Include at least 3 academic years of full-time instruction or its equivalent at the postsecondary college-level;
- Include content that is integrated with sufficient depth, scope, sequence of instruction, quality and emphasis to ensure achievement of the curriculum's defined competencies in the following three areas: general education, biomedical sciences, and dental sciences (didactic and clinical);
- Have content that includes oral and written communications, psychology, and sociology;
- Include biomedical instruction that ensures an understanding of basic biological principles, consisting of a core of information on the fundamental structures, functions and interrelationships of the body systems in each of the following areas:
    - Head and neck and oral anatomy;
    - Oral embryology and histology;
    - Physiology;
    - Chemistry;
    - Biochemistry;
    - Microbiology;
    - Immunology;
    - General pathology and/or pathophysiology;
    - Nutrition; and
    - Pharmacology;
- Include didactic dental sciences that ensures an understanding of basic dental principles, consisting of a core of information in each of the following areas within the scope of dental therapy:
    - Tooth morphology;
    - Oral pathology;
    - Oral medicine;
    - Radiology;
    - Periodontology;
    - Cariology;
    - Atraumatic restorative treatment;
    - Operative dentistry;
    - Pain management;
    - Dental materials;
    - Dental disease etiology and epidemiology;
    - Preventive counseling and health promotion;

[31] Department of Health, FL Health Charts: Dentists (DMD, DDS). Available at https://www.flhealthcharts.gov/ChartsDashboards/rdPage.aspx?rdReport=NonVitalIndNoGrp.Dataviewer (last visited January 20, 2024).
[32] American Dental Therapy Association. *Get the Facts*. Available at https://www.americandentaltherapyassociation.org/get-the-facts (last visited January 20, 2024).
[33] Commission on Dental Accreditation, *Accreditation Standards for Dental Therapy Education Programs* (2015). Available at https://coda.ada.org/-/media/project/ada-organization/ada/coda/files/dental_therapy_standards.pdf?rev=814980f6110140e7ba00659703cc3b3c&hash=81A3585FD5B1B478DA7D99065A9B75DE (last visited January 20, 2024).
[34] *Id.*

    - Patient management;
    - Pediatric dentistry;
    - Geriatric dentistry;
    - Medical and dental emergencies;
    - Oral surgery;
    - Prosthodontics; and
    - Infection and hazard control management; and
- Ensure that graduates are competent in their use of critical thinking and problem-solving, related to the scope of dental therapy practice.

Currently, three dental therapy programs in the US have received accreditation by CODA.[35] The accredited dental therapy programs are located in Minnesota, Alaska, and Washington state.

There are currently 14 states in the US that authorize the practice of dental therapy to some extent.[36] There has been some evidence indicating that authorizing the practice of dental therapists has improved access to oral health care.[37] Florida does not currently issue licenses for dental therapists.

Florida Medicaid – Dental Services

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of the federal and state governments established to provide coverage for health services for eligible persons. The program is administered by the Agency for Health Care Administration (AHCA) and financed by federal and state funds. AHCA delegates certain functions to other state agencies, including the Department of Children and Families (DCF), the Department of Health (DOH), the Agency for Persons with Disabilities, and the Department of Elderly Affairs (DOEA).

The structure of each state's Medicaid program varies and what states must pay for is largely determined by the federal government, as a condition of receiving federal funds.[38] Federal law sets the amount, scope, and duration of services offered in the program, among other requirements. The federal government sets the minimum mandatory populations to be included in every state Medicaid program. The federal government also sets the minimum mandatory benefits to be covered in every state Medicaid program. These benefits include physician services, hospital services, home health services, and family planning.[39] States can add benefits, with federal approval; Florida has added many optional benefits, including adult dental services.[40]

Dental Services

While most Medicaid services are provided by comprehensive, integrated, managed care plans, dental services are provided by separate, dental-only, plans. Medicaid covers dental benefits for both children[41] and adults. Medicaid covers full dental services for children.[42] Adult dental benefits are limited to emergency treatment and dentures, and do not include preventive services.[43] However,

[35] Commission on Dental Accreditation, *Search for Dental Programs*. Available at https://coda.ada.org/find-a-program/search-dental-programs#sort=%40codastatecitysort%20ascending&f:ProgramType=[Dental%20Therapy] (last visited January 20, 2024). Two of the three programs are fully accredited and operational; the third program is still in the process of obtaining full accreditation.
[36] Oral Health Workforce Research Center. *Authorization Status of Dental Therapists by State*. Available at https://oralhealthworkforce.org/authorization-status-of-dental-therapists-by-state/ (last visited January 20, 2024). These states include: Vermont, Washington, Michigan, Minnesota, Montana, Nevada, New Mexico, Oregon, Alaska, Arizona, Colorado, Connecticut, Idaho, and Maine. Some states only authorize dental therapy in the context of providing services for Native American Tribes. For more information on Tribal Dental Therapy, *see* National Indian Health Board, *Tribal Dental Therapy Legislation in the States*. Available at https://www.nihb.org/oralhealthinitiative/map.php (last visited January 20, 2024).
[37] Mertz, E., Kottek, A., Werts, M., Langelier, M., Surdu, S., & Moore, J. *Dental Therapists in the United States: Health Equity, Advancing*. (2021). Medical care, 59(Suppl 5), S441–S448. https://doi.org/10.1097/MLR.0000000000001608
[38] Title 42 U.S.C. §§ 1396-1396w-5; Title 42 C.F.R. Part 430-456 (§§ 430.0-456.725) (2016).
[39] S. 409.905, F.S.
[40] S. 409.906, F.S.
[41] Under the age of 21.
[42] S. 409.906(6), F.S.
[43] S. 409.906(1), F.S.

Medicaid dental plans provide expanded dental benefits to adults, including preventive and restorative dental services at no cost to the state.[44] The chart below indicates the covered dental services.[45]

Children		Adults
Ambulatory Surgical Center or Hospital-based Dental Services	Orthodontics	Dental Exams (emergencies and dentures only)
Dental Exams	Periodontics	Dental X-rays (limited)
Dental Screenings	Prosthodontics (dentures)	Prosthodontics (dentures)
Dental X-rays	Root Canals	Extractions
Extractions	Sealants	Sedation
Fillings and Crowns	Sedation	Ambulatory Surgical Center or Hospital-based Dental Services
Fluoride	Space Maintainers	
Oral Health Instructions	Teeth Cleanings	

Dental services under Medicaid may be provided by a:[46]

- Licensed dentist or dental hygienist;
- County health department administered by DOH;
- Federally qualified health center (FQHC);[47] or a
- Dental intern or a dental graduate temporarily certified to practice in a state operated hospital or a state or county government facility in accordance with s. 466.025, F.S.

Mobile Dental Units

Current law prohibits Medicaid reimbursement for dental services provided in a mobile dental unit except under specified circumstances. Medicaid may reimburse services provided in a mobile dental unit owned or operated by, or under contract with, a county health department, FQHC, state-approved dental educational institution, or a mobile dental unit providing adult dental services at a nursing home.[48] Current law does not authorize the reimbursement for dental services provided in a mobile dental unit owned by, operated by, or having a contractual agreement with a health access setting.[49]

The Sunrise Act and Sunrise Questionnaire

The Sunrise Act (Act), codified in s. 11.62, F.S., requires the Legislature to consider specific factors in determining whether to regulate a new profession or occupation.[50] The legislative intent in the Act provides that:[51]

[44] Agency for Healthcare Administration, *Agency Analysis of HB 1177 (2023).* On file with the Healthcare Regulation Subcommittee.
[45] Florida Medicaid, *Dental Services Coverage Policy* (August 2018). Available at https://ahca.myflorida.com/content/download/5945/file/59G-4.060_Dental_Coverage_Policy.pdf (last visited January 20, 2024).
[46] *Id.*
[47] A federally qualified health center is a federally funded nonprofit health center or clinic that serves medically underserved areas and populations regardless of an individual's ability to pay. *See* Federally Qualified Health Center, HealthCare.gov. Available at https://www.healthcare.gov/glossary/federally-qualified-health-center-fqhc/ (last visited January 20, 2024).
[48] S. 409.906(1)(c) and (6)(a)-(d), F.S.
[49] S. 466.003, F.S.; a health access setting is a program or an institution of the Department of Children and Families, the Department of Health, the Department of Juvenile Justice, a nonprofit community health center, a Head Start center, a federally qualified health center or look-alike as defined by federal law, a school-based prevention program, a clinic operated by an accredited college of dentistry, or an accredited dental hygiene program in this state if such community service program or institution immediately reports to the Board of Dentistry all violations of s. 466.027, s. 466.028, or other practice act or standard of care violations related to the actions or inactions of a dentist, dental hygienist, or dental assistant engaged in the delivery of dental care in such setting.
[50] *Id.*
[51] S. 11.62(2), F.S.

- No profession or occupation be subject to regulation unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage and that the state's police power be exercised only to the extent necessary for that purpose; and
- No profession or occupation be regulated in a manner that unnecessarily restricts entry into the practice of the profession or occupation or adversely affects the availability of the services to the public.

The Legislature must review all legislation proposing regulation of a previously unregulated profession or occupation and make a determination for regulation based on consideration of the following:[52]

- Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote;
- Whether the practice of the profession or occupation requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability;
- Whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment;
- Whether the public is or can be effectively protected by other means; and
- Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.

The act requires the proponents of legislation for the regulation of a profession or occupation to provide specific information in writing to the state agency that is proposed to have jurisdiction over the regulation and to the legislative committees of reference.[53] This required information is traditionally compiled in a "Sunrise Questionnaire."

Dental Therapist Sunrise Questionnaire

The Sunrise Questionnaire was completed on behalf of several National and Florida-based organizations seeking to advance the practice act for dental therapy. They include: The National Partnership for Dental Therapy, the National Coalition of Dentists for Health Equity, the American Dental Therapy Association, and Floridians for Dental Access.[54]

The questionnaire reflects that the licensure and regulation of dental therapists is being sought to address oral health access challenges. Existing law regulates the practice of dentistry in Florida.[55] The law prohibits anyone, other than dentists, to perform certain procedures that would be within the scope of practice for a dental therapist. The proposed legislation would authorize a dental therapist to practice dental therapy in Florida without violating the dental practice act. This is allowing a mid-level practitioner to provide some dental services that currently may only be provided by a dentist.[56]

Since dental therapist are not yet licensed, the public is already protected by the existing dental practice act. By licensing dental therapists, it will exclude unqualified practitioners from providing services, give official recognition to the field's scope of practice, extend professional opportunities for dental care professionals, and expand access to dental care.[57]

Effect of the Bill

HB 1173 creates a new licensed profession of "dental therapist," and defines "dental therapy."

[52] S. 11.62(3), F.S.
[53] S. 11.62(4), F.S.
[54] FLORIDA SENATE SUNRISE QUESTIONNAIRE, Submitted January 22, 2024. On file with the Healthcare Regulation Subcommittee.
[55] Chapter 466, F.S.
[56] *Supra*, note 54.
[57] *Id*.

Dental Therapist Licensure

The bill establishes licensure requirements for dental therapists. Under the bill, an applicant for licensure as a dental therapist must take the appropriate licensure exams, verify their application for licensure under oath, and include two personal photographs with the application. In order to be eligible for the licensure exams, an applicant must:

- Be at least 18 years of age;
- Have graduated from a CODA-accredited dental therapy school or program, or a program accredited by another entity recognized by the US Department of Education;
- Successfully complete a dental therapy practical or clinical exam produced by the American Board of Dental Examiners (ADEX) within three attempts;
- Not have been disciplined by the BOD with the exception of minor violations or citations;
- Not have been convicted, or pled nolo contendere to a misdemeanor or felony related to the practice of dental therapy; and
- Pass a written exam on the laws and rules regulating the practice of dental therapy.

The bill creates a process for licensure by endorsement for dental therapists who have been licensed in another US jurisdiction.

The bill requires dental therapists complete at least 24 hours of continuing education biennially. The continuing education must be approved by the BOD, and, in the opinion of the BOD, contribute directly to the dental education of the dental therapist.

The bill allows an individual licensed as both a dental therapist and dental hygienist to count two hours of continuing education toward the individual's total continuing education requirement. The bill allows the BOD to excuse the continuing education requirement due to an unusual circumstance, emergency, or hardship that prevented compliance. The bill gives the BOD rulemaking authority to establish the rules necessary to implement this section.

Dental Therapist Scope of Practice

The bill authorizes licensed dental therapists to perform specific dental therapy services under the general supervision of a dentist, to the extent authorized by the supervising dentist and provided for by the terms of a written collaborative management agreement signed by the dental therapist and supervising dentist.

Dental therapy services include:

- All services, treatments, and competencies identified by CODA in the Dental Therapy Accreditation Standards;[58]
- Evaluation radiographs;
- Placement of space maintainers;
- Pulpotomies on primary teeth;
- Dispensing and administering nonopioid analgesics; and
- Oral evaluation and assessment of dental disease.

The bill outlines specific content which must be included in the written collaborative management agreement entered into by the dental therapist and dentist. The agreement must include:

- Practice settings where the dental therapist may provide services and to what populations;
- Any limitations on the services that may be provided by the dental therapist;

[58] *See*, a complete list of services required for CODA Dental Therapy Accreditation Standards. Available at https://coda.ada.org/-/media/project/ada-organization/ada/coda/files/dental_therapy_standards.pdf?rev=814980f6110140e7ba00659703cc3b3c&hash=81A3585FD5B1B478DA7D99065A9B75DE (last visited January 20, 2024).

- Age-specific and procedure-specific practice protocols;
- A procedure for creating and maintaining dental records;
- A plan for managing medical emergencies in each relevant practice setting;
- A quality assurance plan;
- Protocols for the administration of medications;
- Criteria for the provision of care for patients with specific conditions or complex medical histories;
- Supervision criteria; and
- A plan for the provision of clinical resources and referrals in situations beyond the capabilities of the dental therapist.

The bill grants the supervising dentist the authority to limit the scope of practice of the individual dental therapist; the bill additionally allows the supervising dentist to establish a certain number of hours of direct and indirect supervision under which the dental therapist must practice prior to performing services under general supervision. The bill allows a dental therapist to perform services on a patient prior to the patient being seen by the supervising dentist.

The supervising dentist must be licensed and practicing in Florida. The supervising dentist is responsible for all services authorized and performed by the dental therapist pursuant to the collaborative management agreement and for arranging follow-up services that exceeded the dental therapist's scope of practice or authorization.

Council of Dental Therapy

The bill directs the establishment of a Council on Dental Therapy to advise the BOD on matters relating to the practice and regulation of dental therapy. The bill directs the chair of the BOD to appoint the members of Council 28 months after the first dental therapy license is granted by the BOD. The Council members shall consist of one BOD member to chair the council and three dental therapists actively engaged in the practice of dental therapy in Florida. The bill requires that the council must meet at least three times per year following its formal establishment, and at the request of the BOD chair, a majority of BOD members, or the Council chair.

The bill makes conforming changes throughout the Ch. 466, F.S.

Medicaid – Mobile Dental Units

The bill allows Medicaid to provide reimbursement for dental services provided by a mobile dental unit owned by, operated by, or having a contractual relationship with a health access setting or similar program serving underserved populations.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Amends s. 409.906, F.S., relating to optional Medicaid services.
Section 2: Amends s. 466.001, F.S., relating to Legislative purpose and intent.
Section 3: Amends s. 466.002, F.S., relating to persons exempt from operation of chapter.
Section 4: Amends s. 466.003, F.S., relating to definitions.
Section 5: Amends s. 466.004, F.S., relating to the Board of Dentistry.
Section 6: Amends s. 466.006, F.S., relating to examination of dentists.
Section 7: Amends s. 466.009, F.S., relating to reexamination.
Section 8: Amends s. 466.011, F.S., relating to licensure.
Section 9: Creates s. 466.0136, F.S., relating to continuing education; dental therapists.

Section 10: Amends s. 466.016, F.S., relating to license to be displayed.
Section 11: Amends s. 466.017, F.S., relating to prescription of drugs; anesthesia.
Section 12: Amends s. 466.018, F.S., relating to dentist of record; patient records.
Section 13: Creates s. 466.0225, F.S., relating to examination of dental therapists; licensing.
Section 14: Creates s. 466.0227, F.S., relating to dental therapists; scope and area of practice.
Section 15: Amends s. 466.026, F.S., relating to prohibitions; penalties.
Section 16: Amends s. 466.028, F.S., relating to grounds for disciplinary action; action by the board.
Section 17: Amends s. 466.0285, F.S., relating to proprietorship by nondentists.
Section 18: Creates an unnumbered section of law relating to a progress report and recommendations.
Section 19: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH will incur an indeterminate, recurring negative fiscal impact related to the licensure, regulation, and enforcement of a new dental profession, dental therapy.[59] The bill does not authorize DOH to collect application, licensure, or renewal fees.

   DOH will incur an insignificant, non-recurring negative fiscal impact related to rulemaking, updates to DOH's website, and the Licensing and Enforcement Information Database System (LEIDS), which current resources are adequate to absorb.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

[59] Department of Health, *Agency Legislative Analysis for House Bill 663 (2018)*, on file with the Healthcare Regulation Subcommittee.

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to dental therapy; amending s. 409.906, F.S.; authorizing Medicaid to reimburse for dental services provided in a mobile dental unit that is owned by, operated by, or contracted with a health access setting or another similar setting or program; amending s. 466.001, F.S.; revising legislative purpose and intent; amending s. 466.002, F.S.; providing applicability; reordering and amending s. 466.003, F.S.; defining the terms "dental therapist" and "dental therapy"; making technical changes; amending s. 466.004, F.S.; requiring the chair of the Board of Dentistry to appoint a Council on Dental Therapy, effective after a specified timeframe; providing for membership, meetings, and the purpose of the council; amending s. 466.006, F.S.; revising the definitions of the terms "full-time practice" and "full-time practice of dentistry within the geographic boundaries of this state within 1 year" to include full-time faculty members of certain dental therapy schools; amending s. 466.009, F.S.; requiring the Department of Health to allow any person who fails the dental therapy examination to retake the examination; providing that a person who fails a practical or clinical examination to practice dental therapy and

who has failed one part or procedure of the examination may be required to retake only that part or procedure to pass the examination; amending s. 466.011, F.S.; requiring the board to certify an applicant for licensure as a dental therapist; creating s. 466.0136, F.S.; requiring the board to require each licensed dental therapist to complete a specified number of hours of continuing education; requiring the board to adopt rules and guidelines; authorizing the board to excuse licensees from continuing education requirements in certain circumstances; amending s. 466.016, F.S.; requiring a practitioner of dental therapy to post and display her or his license in each office where she or he practices; amending s. 466.017, F.S.; requiring the board to adopt certain rules relating to dental therapists; authorizing a dental therapist under the general supervision of a dentist to administer local anesthesia and operate an X-ray machine, expose dental X-ray films, and interpret or read such films if specified requirements are met; correcting the spelling of a term; amending s. 466.018, F.S.; providing that a dentist of record remains primarily responsible for the dental treatment of a patient regardless of whether the treatment is provided by a

dental therapist; requiring that the initials of a dental therapist who renders treatment to a patient be placed in the record of the patient; creating s. 466.0225, F.S.; providing application requirements and examination and licensure qualifications for dental therapists; creating s. 466.0227, F.S.; authorizing a dental therapist to perform specified services under the general supervision of a dentist under certain conditions; specifying state-specific dental therapy services; requiring that a collaborative management agreement be signed by a supervising dentist and a dental therapist and to include certain information; requiring the supervising dentist to determine the number of hours of practice that a dental therapist must complete before performing certain authorized services; authorizing a supervising dentist to restrict or limit the dental therapist's practice in a collaborative management agreement; providing that a supervising dentist may authorize a dental therapist to provide dental therapy services to a patient before the dentist examines or diagnoses the patient under certain conditions; requiring a supervising dentist to be licensed and practicing in this state; specifying that the supervising dentist is responsible for certain services; amending s. 466.026, F.S.; providing

criminal penalties for practicing dental therapy without an active license, selling or offering to sell a diploma from a dental therapy school or college, falsely using a specified name or initials, or holding oneself out as an actively licensed dental therapist; amending s. 466.028, F.S.; revising grounds for denial of a license or disciplinary action to include the practice of dental therapy; amending s. 466.0285, F.S.; prohibiting persons other than licensed dentists from employing a dental therapist in the operation of a dental office and from controlling the use of any dental equipment or material in certain circumstances; requiring the department, in consultation with the board and the Agency for Health Care Administration, to provide reports to the Legislature by specified dates; requiring that certain information and recommendations be included in the reports; providing an effective date.

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

Section 1. Paragraph (c) of subsection (1) of section 409.906, Florida Statutes, is amended, and paragraph (e) is added to subsection (6) of that section, 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, 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:

(1) ADULT DENTAL SERVICES.—

(c) However, Medicaid will not provide reimbursement for dental services provided in a mobile dental unit, except for a mobile dental unit:

1. Owned by, operated by, or having a contractual agreement with the Department of Health and complying with Medicaid's county health department clinic services program specifications as a county health department clinic services provider.

2. Owned by, operated by, or having a contractual arrangement with a federally qualified health center and complying with Medicaid's federally qualified health center specifications as a federally qualified health center provider.

3. Rendering dental services to Medicaid recipients, 21 years of age and older, at nursing facilities.

4. Owned by, operated by, or having a contractual agreement with a state-approved dental educational institution.

5. Owned by, operated by, or having a contractual agreement with a health access setting as defined in s. 466.003 or a similar setting or program.

(6) CHILDREN'S DENTAL SERVICES.—The agency may pay for diagnostic, preventive, or corrective procedures, including orthodontia in severe cases, provided to a recipient under age 21, by or under the supervision of a licensed dentist. The agency may also reimburse a health access setting as defined in s. 466.003 for the remediable tasks that a licensed dental hygienist is authorized to perform under s. 466.024(2). Services provided under this program include treatment of the teeth and associated structures of the oral cavity, as well as treatment

of disease, injury, or impairment that may affect the oral or general health of the individual. However, Medicaid will not provide reimbursement for dental services provided in a mobile dental unit, except for a mobile dental unit:

(e) Owned by, operated by, or having a contractual agreement with a health access setting as defined in s. 466.003 or a similar setting or program.

Section 2. Section 466.001, Florida Statutes, is amended to read:

466.001 Legislative purpose and intent.—The legislative purpose for enacting this chapter is to ensure that every dentist, dental therapist, or dental hygienist practicing in this state meets minimum requirements for safe practice without undue clinical interference by persons not licensed under this chapter. It is the legislative intent that dental services be provided only in accordance with ~~the provisions of~~ this chapter and not be delegated to unauthorized individuals. It is the further legislative intent that dentists, dental therapists, and dental hygienists who fall below minimum competency or who otherwise present a danger to the public ~~shall~~ be prohibited from practicing in this state. All provisions of this chapter relating to the practice of dentistry, dental therapy, and dental hygiene shall be liberally construed to carry out such purpose and intent.

Section 3. Subsections (5) and (6) of section 466.002,

Florida Statutes, are amended to read:

466.002 Persons exempt from operation of chapter.—Nothing in this chapter shall apply to the following practices, acts, and operations:

(5) Students in Florida schools of dentistry, dental therapy, and dental hygiene or dental assistant educational programs, while performing regularly assigned work under the curriculum of such schools or programs.

(6) Instructors in Florida schools of dentistry, instructors in dental programs that prepare persons holding D.D.S. or D.M.D. degrees for certification by a specialty board and that are accredited in the United States by January 1, 2005, in the same manner as the board recognizes accreditation for Florida schools of dentistry that are not otherwise affiliated with a Florida school of dentistry, or instructors in Florida schools of dental hygiene or dental therapy or dental assistant educational programs, while performing regularly assigned instructional duties under the curriculum of such schools or programs. A full-time dental instructor at a dental school or dental program approved by the board may be allowed to practice dentistry at the teaching facilities of such school or program, upon receiving a teaching permit issued by the board, in strict compliance with such rules as are adopted by the board pertaining to the teaching permit and with the established rules and procedures of the dental school or program as recognized in

this section.

Section 4. Section 466.003, Florida Statutes, is reordered and amended to read:

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

(1) "Board" means the Board of Dentistry.

(7) ~~(2)~~ "Dentist" means a person licensed to practice dentistry pursuant to this chapter.

(8) ~~(3)~~ "Dentistry" means the healing art which is concerned with the examination, diagnosis, treatment planning, and care of conditions within the human oral cavity and its adjacent tissues and structures. It includes the performance or attempted performance of any dental operation, or oral or oral-maxillofacial surgery and any procedures adjunct thereto, including physical evaluation directly related to such operation or surgery pursuant to hospital rules and regulations. It also includes dental service of any kind gratuitously or for any remuneration paid, or to be paid, directly or indirectly, to any person or agency. The term "dentistry" ~~shall~~ also includes ~~include~~ the following:

(a) ~~The~~ Taking ~~of~~ an impression of the human tooth, teeth, or jaws directly or indirectly and by any means or method.

(b) Supplying artificial substitutes for the natural teeth or furnishing, supplying, constructing, reproducing, or repairing any prosthetic denture, bridge, appliance, or any other structure designed to be worn in the human mouth except on

the written work order of a duly licensed dentist.

(c) ~~The~~ Placing ~~of~~ an appliance or structure in the human mouth or the adjusting or attempting to adjust the same.

(d) Delivering the same to any person other than the dentist upon whose work order the work was performed.

(e) Professing to the public by any method to furnish, supply, construct, reproduce, or repair any prosthetic denture, bridge, appliance, or other structure designed to be worn in the human mouth.

(f) Diagnosing, prescribing, or treating or professing to diagnose, prescribe, or treat disease, pain, deformity, deficiency, injury, or physical condition of the human teeth or jaws or oral-maxillofacial region.

(g) Extracting or attempting to extract human teeth.

(h) Correcting or attempting to correct malformations of teeth or of jaws.

(i) Repairing or attempting to repair cavities in the human teeth.

(3)~~(4)~~ "Dental hygiene" means the rendering of educational, preventive, and therapeutic dental services pursuant to ss. 466.023 and 466.024 and any related extra-oral procedure required in the performance of such services.

(4)~~(5)~~ "Dental hygienist" means a person licensed to practice dental hygiene pursuant to this chapter.

(2)~~(6)~~ "Dental assistant" means a person, other than a

dental hygienist, who, under the supervision and authorization of a dentist, provides dental care services directly to a patient. This term does ~~shall~~ not include a certified registered nurse anesthetist licensed under part I of chapter 464.

(5) "Dental therapist" means a person licensed to practice dental therapy pursuant to s. 466.0225.

(6) "Dental therapy" means the rendering of services pursuant to s. 466.0227 and any related extraoral services or procedures required in the performance of such services.

(9)~~(7)~~ "Department" means the Department of Health.

(10)~~(8)~~ "Direct supervision" means supervision whereby a dentist diagnoses the condition to be treated, a dentist authorizes the procedure to be performed, a dentist remains on the premises while the procedures are performed, and a dentist approves the work performed before dismissal of the patient.

(13)~~(9)~~ "Indirect supervision" means supervision whereby a dentist authorizes the procedure and a dentist is on the premises while the procedures are performed.

(11)~~(10)~~ "General supervision" means supervision whereby a dentist authorizes the procedures which are being carried out but need not be present when the authorized procedures are being performed. The authorized procedures may also be performed at a place other than the dentist's usual place of practice. The issuance of a written work authorization to a commercial dental laboratory by a dentist does not constitute general supervision.

(14) ~~(11)~~ "Irremediable tasks" are those intraoral treatment tasks which, when performed, are irreversible and create unalterable changes within the oral cavity or the contiguous structures or which cause an increased risk to the patient. The administration of anesthetics other than topical anesthesia is considered to be an "irremediable task" for purposes of this chapter.

(16) ~~(12)~~ "Remediable tasks" are those intraoral treatment tasks which are reversible and do not create unalterable changes within the oral cavity or the contiguous structures and which do not cause an increased risk to the patient.

(15) ~~(13)~~ "Oral and maxillofacial surgery" means the specialty of dentistry involving diagnosis, surgery, and adjunctive treatment of diseases, injuries, and defects involving the functional and esthetic aspects of the hard and soft tissues of the oral and maxillofacial regions. This term may not be construed to apply to any individual exempt under s. 466.002(1).

(12) ~~(14)~~ "Health access setting" means a program or an institution of the Department of Children and Families, the Department of Health, the Department of Juvenile Justice, a nonprofit community health center, a Head Start center, a federally qualified health center or look-alike as defined by federal law, a school-based prevention program, a clinic operated by an accredited college of dentistry, or an accredited

dental hygiene program in this state if such community service program or institution immediately reports to the Board of Dentistry all violations of s. 466.027, s. 466.028, or other practice act or standard of care violations related to the actions or inactions of a dentist, dental hygienist, or dental assistant engaged in the delivery of dental care in such setting.

(17) ~~(15)~~ "School-based prevention program" means preventive oral health services offered at a school by one of the entities described ~~defined~~ in subsection (12) ~~(14)~~ or by a nonprofit organization that is exempt from federal income taxation under s. 501(a) of the Internal Revenue Code, and described in s. 501(c)(3) of the Internal Revenue Code.

Section 5. Subsection (2) of section 466.004, Florida Statutes, is amended to read:

466.004 Board of Dentistry.—

(2) To advise the board, it is the intent of the Legislature that councils be appointed as specified in paragraphs (a)-(d) ~~(a), (b), and (c)~~. The department shall provide administrative support to the councils and shall provide public notice of meetings and agendas ~~agenda~~ of the councils. Councils must ~~shall~~ include at least one board member, who shall serve as chair, ~~the council~~ and must ~~shall~~ include nonboard members. All council members shall be appointed by the board chair. Council members shall be appointed for 4-year terms, and

all members are ~~shall be~~ eligible for reimbursement of expenses in the manner of board members.

(a) A Council on Dental Hygiene shall be appointed by the board chair and shall include one dental hygienist member of the board, who shall chair the council, one dental member of the board, and three dental hygienists who are actively engaged in the practice of dental hygiene in this state. In making the appointments, the chair shall consider recommendations from the Florida Dental Hygiene Association. The council shall meet at the request of the board chair, a majority of the members of the board, or the council chair; however, the council must meet at least three times a year. The council is charged with the responsibility of and shall meet for the purpose of developing rules and policies for recommendation to the board, which the board shall consider, on matters pertaining to that part of dentistry consisting of educational, preventive, or therapeutic dental hygiene services; dental hygiene licensure, discipline, or regulation; and dental hygiene education. Rule and policy recommendations of the council must ~~shall~~ be considered by the board at its next regularly scheduled meeting in the same manner in which it considers rule and policy recommendations from designated subcommittees of the board. Any rule or policy proposed by the board pertaining to the specified part of dentistry identified ~~defined~~ by this subsection must ~~shall~~ be referred to the council for a recommendation before final action

by the board. The board may take final action on rules pertaining to the specified part of dentistry identified ~~defined~~ by this subsection without a council recommendation if the council fails to submit a recommendation in a timely fashion as prescribed by the board.

(b) A Council on Dental Assisting shall be appointed by the board chair and shall include one board member who shall chair the council and three dental assistants who are actively engaged in dental assisting in this state. The council shall meet at the request of the board chair or a majority of the members of the board. The council shall meet for the purpose of developing recommendations to the board on matters pertaining to that part of dentistry related to dental assisting.

(c) Effective 28 months after the first dental therapy license is granted by the board, the board chair shall appoint a Council on Dental Therapy, which must include one board member who shall chair the council and three dental therapists who are actively engaged in the practice of dental therapy in this state. The council shall meet at the request of the board chair, a majority of the members of the board, or the council chair; however, the council shall meet at least three times per year. The council is charged with the responsibility of, and shall meet for the purpose of, developing rules and policies for recommendation to the board on matters pertaining to that part of dentistry consisting of educational, preventive, or

therapeutic dental therapy services; dental therapy licensure, discipline, or regulation; and dental therapy education. Rule and policy recommendations of the council must be considered by the board at its next regularly scheduled meeting in the same manner in which it considers rule and policy recommendations from designated subcommittees of the board. Any rule or policy proposed by the board pertaining to the specified part of dentistry identified by this subsection must be referred to the council for a recommendation before final action by the board. The board may take final action on rules pertaining to the specified part of dentistry identified by this subsection without a council recommendation if the council fails to submit a recommendation in a timely fashion as prescribed by the board.

(d) With the concurrence of the State Surgeon General, the board chair may create and abolish other advisory councils relating to dental subjects, including, but not limited to: examinations, access to dental care, indigent care, nursing home and institutional care, public health, disciplinary guidelines, and other subjects as appropriate. Such councils shall be appointed by the board chair and shall include at least one board member who shall serve as chair.

Section 6. Paragraph (b) of subsection (4) and paragraph (b) of subsection (6) of section 466.006, Florida Statutes, are amended to read:

466.006 Examination of dentists.—

(4) Notwithstanding any other provision of law in chapter 456 pertaining to the clinical dental licensure examination or national examinations, to be licensed as a dentist in this state, an applicant must successfully complete both of the following:

(b) A practical or clinical examination, which must be the American Dental Licensing Examination produced by the American Board of Dental Examiners, Inc., or its successor entity, if any, that is administered in this state, provided that the board has attained, and continues to maintain thereafter, representation on the board of directors of the American Board of Dental Examiners, the examination development committee of the American Board of Dental Examiners, and such other committees of the American Board of Dental Examiners as the board deems appropriate by rule to assure that the standards established herein are maintained organizationally. A passing score on the American Dental Licensing Examination administered in this state is valid for 365 days after the date the official examination results are published.

1. As an alternative to such practical or clinical examination, an applicant may submit scores from an American Dental Licensing Examination previously administered in a jurisdiction other than this state after October 1, 2011, and such examination results must ~~shall~~ be recognized as valid for the purpose of licensure in this state. A passing score on the

American Dental Licensing Examination administered out of state is ~~shall be~~ the same as the passing score for the American Dental Licensing Examination administered in this state. The examination results are valid for 365 days after the date the official examination results are published. The applicant must have completed the examination after October 1, 2011. This subparagraph may not be given retroactive application.

2. If the date of an applicant's passing American Dental Licensing Examination scores from an examination previously administered in a jurisdiction other than this state under subparagraph 1. is older than 365 days, such scores are nevertheless valid for the purpose of licensure in this state, but only if the applicant demonstrates that all of the following additional standards have been met:

a. The applicant completed the American Dental Licensing Examination after October 1, 2011. This sub-subparagraph may not be given retroactive application;

b. The applicant graduated from a dental school accredited by the American Dental Association Commission on Dental Accreditation or its successor entity, if any, or any other dental accrediting organization recognized by the United States Department of Education. Provided, however, if the applicant did not graduate from such a dental school, the applicant may submit proof of having successfully completed a full-time supplemental general dentistry program accredited by the American Dental

Association Commission on Dental Accreditation of at least 2 consecutive academic years at such accredited sponsoring institution. Such program must provide didactic and clinical education at the level of a D.D.S. or D.M.D. program accredited by the American Dental Association Commission on Dental Accreditation. For purposes of this sub-subparagraph, a supplemental general dentistry program does not include an advanced education program in a dental specialty;

c. The applicant currently possesses a valid and active dental license in good standing, with no restriction, which has never been revoked, suspended, restricted, or otherwise disciplined, from another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico;

d. The applicant submits proof that he or she has never been reported to the National Practitioner Data Bank, the Healthcare Integrity and Protection Data Bank, or the American Association of Dental Boards Clearinghouse. This sub-subparagraph does not apply if the applicant successfully appealed to have his or her name removed from the data banks of these agencies;

e.(I)(A) The applicant submits proof of having been consecutively engaged in the full-time practice of dentistry in another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico in the 5 years

immediately preceding the date of application for licensure in this state; or

(B) If the applicant has been licensed in another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico for less than 5 years, the applicant submits proof of having been engaged in the full-time practice of dentistry since the date of his or her initial licensure.

(II) As used in this section, "full-time practice" is defined as a minimum of 1,200 hours per year for each and every year in the consecutive 5-year period or, when applicable, the period since initial licensure, and must include any combination of the following:

(A) Active clinical practice of dentistry providing direct patient care.

(B) Full-time practice as a faculty member employed by a dental, dental therapy, or dental hygiene school approved by the board or accredited by the American Dental Association Commission on Dental Accreditation.

(C) Full-time practice as a student at a postgraduate dental education program approved by the board or accredited by the American Dental Association Commission on Dental Accreditation.

(III) The board shall develop rules to determine what type of proof of full-time practice is required and to recoup the cost to the board of verifying full-time practice under this

section. Such proof must, at a minimum, be:

(A) Admissible as evidence in an administrative proceeding;

(B) Submitted in writing;

(C) Submitted by the applicant under oath with penalties of perjury attached;

(D) Further documented by an affidavit of someone unrelated to the applicant who is familiar with the applicant's practice and testifies with particularity that the applicant has been engaged in full-time practice; and

(E) Specifically found by the board to be both credible and admissible.

(IV) An affidavit of only the applicant is not acceptable proof of full-time practice unless it is further attested to by someone unrelated to the applicant who has personal knowledge of the applicant's practice. If the board deems it necessary to assess credibility or accuracy, the board may require the applicant or the applicant's witnesses to appear before the board and give oral testimony under oath;

f. The applicant submits documentation that he or she has completed, or will complete before he or she is licensed in this state, continuing education equivalent to this state's requirements for the last full reporting biennium;

g. The applicant proves that he or she has never been convicted of, or pled nolo contendere to, regardless of

adjudication, any felony or misdemeanor related to the practice of a health care profession in any jurisdiction;

h. The applicant has successfully passed a written examination on the laws and rules of this state regulating the practice of dentistry and the computer-based diagnostic skills examination; and

i. The applicant submits documentation that he or she has successfully completed the applicable examination administered by the Joint Commission on National Dental Examinations or its successor organization.

(6)

(b)1. As used in this section, "full-time practice of dentistry within the geographic boundaries of this state within 1 year" is defined as a minimum of 1,200 hours in the initial year of licensure, which must include any combination of the following:

a. Active clinical practice of dentistry providing direct patient care within the geographic boundaries of this state.

b. Full-time practice as a faculty member employed by a dental, dental therapy, or dental hygiene school approved by the board or accredited by the American Dental Association Commission on Dental Accreditation and located within the geographic boundaries of this state.

c. Full-time practice as a student at a postgraduate dental education program approved by the board or accredited by

the American Dental Association Commission on Dental Accreditation and located within the geographic boundaries of this state.

2. The board shall develop rules to determine what type of proof of full-time practice of dentistry within the geographic boundaries of this state for 1 year is required in order to maintain active licensure and shall develop rules to recoup the cost to the board of verifying maintenance of such full-time practice under this section. Such proof must, at a minimum:

a. Be admissible as evidence in an administrative proceeding;

b. Be submitted in writing;

c. Be submitted by the applicant under oath with penalties of perjury attached;

d. Be further documented by an affidavit of someone unrelated to the applicant who is familiar with the applicant's practice and testifies with particularity that the applicant has been engaged in full-time practice of dentistry within the geographic boundaries of this state within the last 365 days; and

e. Include such additional proof as specifically found by the board to be both credible and admissible.

3. An affidavit of only the applicant is not acceptable proof of full-time practice of dentistry within the geographic boundaries of this state within 1 year, unless it is further

attested to by someone unrelated to the applicant who has personal knowledge of the applicant's practice within the last 365 days. If the board deems it necessary to assess credibility or accuracy, the board may require the applicant or the applicant's witnesses to appear before the board and give oral testimony under oath.

Section 7. Subsection (1) of section 466.009, Florida Statutes, is amended, and subsection (4) is added to that section, to read:

466.009 Reexamination.—

(1) The department shall allow ~~permit~~ any person who fails an examination that ~~which~~ is required under s. 466.006, ~~or~~ s. 466.007, or s. 466.0225 to retake the examination. If the examination to be retaken is a practical or clinical examination, the applicant must ~~shall~~ pay a reexamination fee set by rule of the board in an amount not to exceed the original examination fee.

(4) If an applicant for a license to practice dental therapy fails the practical or clinical examination and she or he has failed only one part or procedure of such examination, she or he may be required to retake only that part or procedure to pass such examination. However, if any such applicant fails more than one part or procedure of any such examination, she or he must be required to retake the entire examination.

Section 8. Section 466.011, Florida Statutes, is amended

to read:

466.011 Licensure.—The board shall certify for licensure by the department any applicant who satisfies the requirements of s. 466.006, s. 466.0067, ~~or~~ s. 466.007, or s. 466.0225. The board may refuse to certify an applicant who has violated ~~any of the provisions of~~ s. 466.026 or s. 466.028.

Section 9. Section 466.0136, Florida Statutes, is created to read:

466.0136 Continuing education; dental therapists.—In addition to any other requirements for relicensure for dental therapists specified in this chapter, the board shall require each licensed dental therapist to complete at least 24 hours, but not more than 36 hours, biennially of continuing education in dental subjects in programs approved by the board or in equivalent programs of continuing education. Programs of continuing education approved by the board must be programs of learning which, in the opinion of the board, contribute directly to the dental education of the dental therapist. An individual who is licensed as both a dental therapist and a dental hygienist may use 2 hours of continuing education that is approved for both dental therapy and dental hygiene education to satisfy both dental therapy and dental hygiene continuing education requirements. The board shall adopt rules and guidelines to administer and enforce this section. The dental therapist shall retain in her or his records any receipts,

vouchers, or certificates necessary to document completion of the continuing education. Compliance with the continuing education requirements is mandatory for issuance of the renewal certificate. The board may excuse licensees, as a group or as individuals, from all or part of the continuing education requirements if an unusual circumstance, emergency, or hardship prevented compliance with this section.

Section 10. Section 466.016, Florida Statutes, is amended to read:

466.016 License to be displayed.—Every practitioner of dentistry, dental therapy, or dental hygiene within the meaning of this chapter shall post and keep conspicuously displayed her or his license in the office where ~~wherein~~ she or he practices, in plain sight of the practitioner's patients. Any dentist, dental therapist, or dental hygienist who practices at more than one location shall ~~be required to~~ display a copy of her or his license in each office where she or he practices.

Section 11. Present subsections (7) through (15) of section 466.017, Florida Statutes, are redesignated as subsections (8) through (16), respectively, a new subsection (7) is added to that section, and paragraphs (d) and (e) of subsection (3), subsection (4), and present subsections (7), (8), and (14) of that section are amended, to read:

466.017 Prescription of drugs; anesthesia.—

(3) The board shall adopt rules which:

(d) Establish further requirements relating to the use of general anesthesia or sedation, including, but not limited to, office equipment and the training of dental assistants, dental therapists, or dental hygienists who work with dentists using general anesthesia or sedation.

(e) Establish an administrative mechanism enabling the board to verify compliance with training, education, experience, equipment, or certification requirements of dentists, dental therapists, dental hygienists, and dental assistants adopted pursuant to this subsection. The board may charge a fee to defray the cost of verifying compliance with requirements adopted pursuant to this paragraph.

(4) A dentist, dental therapist, or dental hygienist who administers or employs the use of any form of anesthesia must possess a certification in either basic cardiopulmonary resuscitation for health professionals or advanced cardiac life support approved by the American Heart Association or the American Red Cross or an equivalent agency-sponsored course with recertification every 2 years. Each dental office that ~~which~~ uses any form of anesthesia must have immediately available and in good working order such resuscitative equipment, oxygen, and other resuscitative drugs as are specified by rule of the board in order to manage possible adverse reactions.

(7) A dental therapist, under the general supervision of a dentist, may administer local anesthesia, including intraoral

block anesthesia or soft tissue infiltration anesthesia if she or he has completed the course described in subsection (5) and presents evidence of current certification in basic or advanced cardiac life support.

(8) ~~(7)~~ A licensed dentist, or a dental therapist who is authorized by her or his supervising dentist, may operate ~~utilize~~ an X-ray machine, expose dental X-ray films, and interpret or read such films. Notwithstanding ~~The provisions of~~ part IV of chapter 468 ~~to the contrary notwithstanding~~, a licensed dentist, or a dental therapist who is authorized by her or his supervising dentist, may authorize or direct a dental assistant to operate such equipment and expose such films under her or his direction and supervision, pursuant to rules adopted by the board in accordance with s. 466.024 which ensure that the ~~said~~ assistant is competent by reason of training and experience to operate the X-ray ~~said~~ equipment in a safe and efficient manner. The board may charge a fee not to exceed $35 to defray the cost of verifying compliance with requirements adopted pursuant to this section.

(9) ~~(8)~~ Notwithstanding ~~The provisions of~~ s. 465.0276 ~~notwithstanding~~, a dentist need not register with the board or comply with the continuing education requirements of that section if the dentist confines her or his dispensing activity to the dispensing of fluorides and chlorhexidine ~~chlorohexidine~~ rinse solutions; provided that the dentist complies with and is

subject to all laws and rules applicable to pharmacists and pharmacies, including, but not limited to, chapters 465, 499, and 893, and all applicable federal laws and regulations, when dispensing such products.

(15) ~~(14)~~ As used in subsections (10)-(14) ~~(9)-(13)~~, the term "adverse incident" means any mortality that occurs during or as the result of a dental procedure, or an incident that results in a temporary or permanent physical or mental injury that requires hospitalization or emergency room treatment of a dental patient which occurs during or as a direct result of the use of general anesthesia, deep sedation, moderate sedation, pediatric moderate sedation, oral sedation, minimal sedation (anxiolysis), nitrous oxide, or local anesthesia.

Section 12. Subsection (1) of section 466.018, Florida Statutes, is amended to read:

466.018 Dentist of record; patient records.—

(1) Each patient must ~~shall~~ have a dentist of record. The dentist of record shall remain primarily responsible for all dental treatment on such patient regardless of whether the treatment is rendered by that ~~the~~ dentist or by another dentist, a dental therapist, a dental hygienist, or a dental assistant rendering such treatment in conjunction with, at the direction or request of, or under the supervision of such dentist of record. The dentist of record must ~~shall~~ be identified in the record of the patient. If treatment is rendered by a dentist

other than the dentist of record or by a dental hygienist, dental therapist, or dental assistant, the name or initials of such person must ~~shall~~ be placed in the record of the patient. In any disciplinary proceeding brought pursuant to this chapter or chapter 456, it must ~~shall~~ be presumed as a matter of law that treatment was rendered by the dentist of record unless otherwise noted on the patient record pursuant to this section. The dentist of record and any other treating dentist are subject to discipline pursuant to this chapter or chapter 456 for treatment rendered to the patient and performed in violation of such chapter. One of the purposes of this section is to ensure that the responsibility for each patient is assigned to one dentist in a multidentist practice of any nature and to assign primary responsibility to the dentist for treatment rendered by a dental hygienist, dental therapist, or dental assistant under her or his supervision. This section may ~~shall~~ not be construed to assign any responsibility to a dentist of record for treatment rendered pursuant to a proper referral to another dentist who does not ~~in~~ practice with the dentist of record or to prohibit a patient from voluntarily selecting a new dentist without permission of the dentist of record.

Section 13. Section 466.0225, Florida Statutes, is created to read:

466.0225 Examination of dental therapists; licensing.—

(1) Any person desiring to be licensed as a dental

therapist must apply to the department to take the licensure examinations and shall verify the information required on the application by oath. The application must include two recent photographs of the applicant.

(2) An applicant is entitled to take the examinations required under this section and receive licensure to practice dental therapy in this state if the applicant meets all of the following criteria:

(a) Is 18 years of age or older.

(b) Is a graduate of a dental therapy college or school accredited by the American Dental Association Commission on Dental Accreditation or its successor entity, if any, or any other dental therapy accrediting entity recognized by the United States Department of Education. For applicants applying for a dental therapy license before January 1, 2029, the board must approve the applicant's dental therapy education program if the program was administered by a college or school that operates an accredited dental or dental hygiene program and the college or school certifies to the board that the applicant's education substantially conformed to the education standards established by the American Dental Association Commission on Dental Accreditation or its successor entity.

(c) Has successfully completed a dental therapy practical or clinical examination produced by the American Board of Dental Examiners, Inc., (ADEX) or its successor entity, if any, if the

board finds that the successor entity's examination meets or exceeds the requirements of this section. If an applicant fails to pass such an examination after three attempts, the applicant is not eligible to retake the examination unless the applicant completes additional education requirements as specified by the board. If a dental therapy examination has not been established by ADEX, the board must administer or approve an alternative examination.

(d) Has not been disciplined by a board, except for citation offenses or minor violations.

(e) Has not been convicted of or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession.

(f) Has successfully completed a written examination on the laws and rules of this state regulating the practice of dental therapy.

(3) An applicant who meets the requirements of this section and who has successfully completed an examination identified in paragraph (2)(c) in a jurisdiction other than this state, or who has successfully completed a comparable examination administered or approved by the licensing authority in a jurisdiction other than this state, must be licensed to practice dental therapy in this state if the board determines that the other jurisdiction's examination is substantially similar to those identified in paragraph (2)(c).

Section 14. Section 466.0227, Florida Statutes, is created to read:

466.0227 Dental therapists; scope and area of practice.—

(1) Except as otherwise provided in this chapter, a dental therapist may perform the dental therapy services specified in subsection (2) under the general supervision of a dentist to the extent authorized by the supervising dentist and provided within the terms of a written collaborative management agreement signed by the dental therapist and the supervising dentist which meets the requirements of subsection (3).

(2) Dental therapy services include all of the following:

(a) All services, treatments, and competencies identified by the American Dental Association Commission on Dental Accreditation in the commission's Accreditation Standards for Dental Therapy Education Programs.

(b) The following state-specific services, if the dental therapist's education included curriculum content satisfying the American Dental Association Commission on Dental Accreditation criteria for state-specific dental therapy services:

1. Evaluating radiographs.

2. Placement of space maintainers.

3. Pulpotomies on primary teeth.

4. Dispensing and administering nonopioid analgesics, including nitrous oxide, anti-inflammatories, and antibiotics, as authorized by the supervising dentist and within the

parameters of the collaborative management agreement.

5. Oral evaluation and assessment of dental disease and formulation of an individualized treatment plan if authorized by the supervising dentist and subject to any conditions, limitations, and protocols specified by the supervising dentist in the collaborative management agreement.

(3) Before performing any of the services authorized in subsection (2), a dental therapist must enter into a written collaborative management agreement with a supervising dentist. The agreement must be signed by the dental therapist and the supervising dentist and must include all of the following information:

(a) Practice settings where services may be provided by the dental therapist and the populations to be served by the dental therapist.

(b) Any limitations on the services that may be provided by the dental therapist, including the level of supervision required by the supervising dentist. This may include telehealth.

(c) Age-specific and procedure-specific practice protocols for the dental therapist, including case selection criteria, assessment guidelines, and imaging frequency.

(d) A procedure for creating and maintaining dental records for the patients who are treated by the dental therapist.

(e) A plan to manage medical emergencies in each practice setting where the dental therapist provides care.

(f) A quality assurance plan for monitoring care provided by the dental therapist, including patient care review, referral follow-up, and a quality assurance chart review.

(g) Protocols for the dental therapist to administer and dispense medications, including the specific conditions and circumstances under which the medications are to be dispensed and administered.

(h) Criteria relating to the provision of care by the dental therapist to patients with specific medical conditions or complex medication histories, including requirements for consultation before the initiation of care.

(i) Supervision criteria of dental therapists.

(j) A plan for the provision of clinical resources and referrals in situations that are beyond the capabilities of the dental therapist.

(4) A supervising dentist shall determine the number of hours of practice that a dental therapist must complete under direct or indirect supervision of the supervising dentist before the dental therapist may perform any of the services authorized in subsection (2) under general supervision.

(5) A supervising dentist may restrict or limit the dental therapist's practice in the written collaborative management agreement to be less than the full scope of practice for dental

therapists which is authorized in subsection (2).

(6) A supervising dentist may authorize a dental therapist to provide dental therapy services to a patient before the supervising dentist examines or diagnoses the patient if the authority, conditions, and protocols are established in a written collaborative management agreement and if the patient is subsequently referred to a dentist for any needed additional services that exceed the dental therapist's scope of practice or authorization under the collaborative management agreement.

(7) A supervising dentist must be licensed and practicing in this state. The supervising dentist is responsible for all services authorized and performed by the dental therapist pursuant to the collaborative management agreement and for providing or arranging follow-up services to be provided by a dentist for any additional services that exceed the dental therapist's scope of practice or authorization under the collaborative management agreement.

Section 15. Section 466.026, Florida Statutes, is amended to read:

466.026 Prohibitions; penalties.—

(1) Each of the following acts constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084:

(a) Practicing dentistry, dental therapy, or dental hygiene unless the person has an appropriate, active license

issued by the department pursuant to this chapter.

(b) Using or attempting to use a license issued pursuant to this chapter which license has been suspended or revoked.

(c) Knowingly employing any person to perform duties outside the scope allowed such person under this chapter or the rules of the board.

(d) Giving false or forged evidence to the department or board for the purpose of obtaining a license.

(e) Selling or offering to sell a diploma conferring a degree from a dental college, ~~or~~ dental hygiene school or college, or dental therapy school or college, or a license issued pursuant to this chapter, or procuring such diploma or license with intent that it will ~~shall~~ be used as evidence of that which the document stands for, by a person other than the one upon whom it was conferred or to whom it was granted.

(2) Each of the following acts constitutes a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083:

(a) Using the name or title "dentist," the letters "D.D.S." or "D.M.D.", or any other words, letters, title, or descriptive matter which in any way represents a person as being able to diagnose, treat, prescribe, or operate for any disease, pain, deformity, deficiency, injury, or physical condition of the teeth or jaws or oral-maxillofacial region unless the person has an active dentist's license issued by the department

pursuant to this chapter.

(b) Using the name "dental hygienist" or the initials "R.D.H." or otherwise holding herself or himself out as an actively licensed dental hygienist or implying to any patient or consumer that she or he is an actively licensed dental hygienist unless that person has an active dental hygienist's license issued by the department pursuant to this chapter.

(c) Using the name "dental therapist" or the initials "D.T." or otherwise holding herself or himself out as an actively licensed dental therapist or implying to any patient or consumer that she or he is an actively licensed dental therapist unless that person has an active dental therapist's license issued by the department pursuant to this chapter.

(d) Presenting as her or his own the license of another.

(e) ~~(d)~~ Knowingly concealing information relative to violations of this chapter.

(f) ~~(e)~~ Performing any services as a dental assistant as defined herein, except in the office of a licensed dentist, unless authorized by this chapter or by rule of the board.

Section 16. Paragraphs (b), (c), (g), (s), and (t) of subsection (1) of section 466.028, Florida Statutes, are amended to read:

466.028 Grounds for disciplinary action; action by the board.—

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

license or disciplinary action, as specified in s. 456.072(2):

(b) Having a license to practice dentistry, dental therapy, or dental hygiene revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of another state, territory, or country.

(c) Being convicted or found guilty of or entering a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of dentistry, dental therapy, or dental hygiene. A plea of nolo contendere creates ~~shall create~~ a rebuttable presumption of guilt to the underlying criminal charges.

(g) Aiding, assisting, procuring, or advising any unlicensed person to practice dentistry, dental therapy, or dental hygiene contrary to this chapter or to a rule of the department or the board.

(s) Being unable to practice her or his profession with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition. In enforcing this paragraph, the department ~~shall have~~, upon a finding of the State Surgeon General or her or his designee that probable cause exists to believe that the licensee is unable to practice dentistry, dental therapy, or dental hygiene because of the reasons stated in this paragraph, has the authority to issue an order to compel a licensee to submit to a mental or physical

examination by physicians designated by the department. If the licensee refuses to comply with such order, the department's order directing such examination may be enforced by filing a petition for enforcement in the circuit court where the licensee resides or does business. The licensee against whom the petition is filed may ~~shall~~ not be named or identified by initials in any public court records or documents, and the proceedings must ~~shall~~ be closed to the public. The department is ~~shall be~~ entitled to the summary procedure provided in s. 51.011. A licensee affected under this paragraph must ~~shall~~ at reasonable intervals be afforded an opportunity to demonstrate that she or he can resume the competent practice of her or his profession with reasonable skill and safety to patients.

(t) Fraud, deceit, or misconduct in the practice of dentistry, dental therapy, or dental hygiene.

Section 17. Paragraphs (a) and (b) of subsection (1) of section 466.0285, Florida Statutes, are amended to read:

466.0285 Proprietorship by nondentists.—

(1) No person other than a dentist licensed pursuant to this chapter, nor any entity other than a professional corporation or limited liability company composed of dentists, may:

(a) Employ a dentist, a dental therapist, or a dental hygienist in the operation of a dental office.

(b) Control the use of any dental equipment or material

while such equipment or material is being used for the provision of dental services, whether those services are provided by a dentist, a dental therapist, a dental hygienist, or a dental assistant.

Any lease agreement, rental agreement, or other arrangement between a nondentist and a dentist whereby the nondentist provides the dentist with dental equipment or dental materials shall contain a provision whereby the dentist expressly maintains complete care, custody, and control of the equipment or practice.

Section 18. The Department of Health, in consultation with the Board of Dentistry and the Agency for Health Care Administration, shall submit a progress report to the President of the Senate and the Speaker of the House of Representatives by July 1, 2027, and a final report 4 years after the first dental therapy license is issued. The reports must include all of the following information and recommendations:

(1) The progress that has been made in this state to implement dental therapy training programs, licensing, and Medicaid reimbursement.

(2) Data demonstrating the effects of dental therapy in this state on all of the following:

(a) Patient access to dental services.

(b) Costs to dental providers, patients, dental insurance

carriers, and the state.

(c) The quality and safety of dental services.

(3) Specific recommendations for any necessary legislative, administrative, or regulatory reform relating to the practice of dental therapy.

(4) Any other information the department deems appropriate.

Section 19. This act shall take effect July 1, 2024.

HB 1441

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1441 Department of Health
SPONSOR(S): Anderson
TIED BILLS: **IDEN./SIM. BILLS:** SB 1582

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Osborne	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

HB 1441 makes numerous changes to the programs under the Department of Health (DOH).

Environmental health professionals (EHPs) are certified by DOH to perform evaluations of environmental or sanitary conditions in two environmental health program areas: food hygiene and onsite sewage treatment and disposal. The bill creates an environmental health technician certification for candidates to work under the supervision of a certified EHP.

The Legislature established the Rare Disease Advisory Council (RDAC) in 2021 to assist DOH in providing recommendations to improve health outcomes for individuals with rare diseases residing in the state. In the United States, a rare disease is any condition that nationally affects fewer than 200,000 people. There may be as many as 7,000 rare diseases impacting the lives of 25-30 million Americans and their families. The bill creates the Andrew John Anderson Pediatric Rare Disease Grant Program within DOH with the purpose of advancing the progress of research and cures for rare pediatric diseases through the award of grants by a competitive, peer-reviewed process. Grants shall be awarded by DOH, after consultation with the RDAC.

Sickle cell disease is a rare disease affecting approximately 100,000 Americans. In 2023, the Legislature directed DOH to partner with a community-based sickle cell disease medical treatment and research center to establish and maintain a registry to track outcome measures of newborns who are identified as carrying a sickle cell hemoglobin variant. The bill revises certain requirements for the registry related to who may be included in the registry, and the process by which parents can opt their newborns out of the registry.

The Florida Newborn Screening Program (NSP) promotes the screening of all newborns for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect. The NSP also promotes the identification and screening of all newborns in the state and their families for environmental risk factors. The bill revises the certain aspects of the NSP to specify the responsibilities of relevant health care practitioners and delete obsolete provisions.

Newborns are also required to undergo hearing screening before they are discharged from the hospital. The bill standardizes hearing screening practices for newborns born in licensed birth facilities.

In 2021, the Legislature created the Telehealth Minority Maternity Care Pilot Program in Duval and Orange counties to increase positive maternal health outcomes in racial and ethnic minority populations. The bill authorizes DOH to expand the program to other counties dependent upon available funding.

The bill has an insignificant, negative fiscal impact on DOH, which current resources are adequate to absorb. The bill has no fiscal impact on local governments.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Environmental Health Professionals

Current Situation

Environmental health professionals (EHPs) are certified by the Department of Health (DOH) to perform evaluations of environmental or sanitary conditions in two environmental health program areas: food hygiene and onsite sewage treatment and disposal.[1]

DOH currently employs 448 certified EHPs, most of which are housed in county health departments to perform health evaluations at public food establishments and sanitary evaluations on private and business properties where onsite wastewater treatment and disposal systems are in use.[2]

EHPs must be certified by DOH to perform evaluations of environmental or sanitary conditions in food hygiene or onsite sewage treatment and disposal. Current law requires an EHP to have graduated from an accredited four-year college or university with a degree or major coursework in public health, environmental health, environmental science, or a physical or biological science to be certified.[3] According to DOH, county health departments are experiencing a shortage of qualified applicants to the food hygiene and onsite sewage treatment and disposal programs due to the requirement for a four-year degree.[4]

In 2020, the Legislature transferred the Onsite Sewage Program from DOH to the Department of Environmental Protection (DEP). In establishing the transfer, the Legislature also required that the agencies enter into an interagency agreement for a period of no less than five years in order to coordinate the logistics relating to collaboration with the county health departments and the transfer or shared use of buildings or facilities owned by DOH.[5]

Effect of Proposed Changes – Environmental Health Professionals

The bill creates a certification for environmental health technicians who will be authorized to conduct septic tank inspections under the supervision of an environmental health professional who is certified in onsite sewage treatment and disposal.

The bill directs DOH, in conjunction with DEP, to adopt rules to establish standards for environmental health technicians, as well as, relevant administrative processes. To obtain and maintain certification as an environmental health technician, one must:

- Be certified by examination to be knowledgeable in the area of onsite sewage treatment and disposal;
- Have a high school diploma, or its equivalent;
- Be employed by a department as defined in s. 20.03;
- Complete supervised field inspection work as prescribed by rule before examination;
- Renew certification biennially by completing at least 24 contact hours of continuing education; and
- Notify the department within 60 days after any change of name or address.

[1] S. 381.0101(4), F.S.
[2] Department of Health, *Agency Analysis of HB 1441* (2024). On file with the Healthcare Regulation Subcommittee. This excludes establishments licensed under Ch. 509, F.S., which operate under separate standards.
[3] S. 381.0101(4)(e), F.S.
[4] *Supra*, note 2.
[5] Ch. 2020-150, L.O.F.

Rare Diseases

Current Situation

In the United States, a rare disease is any condition that nationally affects fewer than 200,000 people. There may be as many as 7,000 rare diseases impacting the lives of 25-30 million Americans and their families.[6] So, while the individual diseases may be rare, the total number of people impacted by a rare disease is large.

Rare diseases include genetic disorders, infectious diseases, cancers, and various other pediatric and adult conditions. A rare disease can affect anyone at any point in their life, and can be acute or chronic. It is estimated that 80 percent or more of rare diseases are genetic. For genetic rare diseases, genetic testing is often the only way to make a definitive diagnosis. Rare diseases present a fundamentally different array of challenges compared to those of more common diseases; often patients are set on a "diagnostic odyssey," in order to determine the cause of their symptoms as they seek treatment in health care settings where their condition may have never been seen before.[7]

In 2023, the Legislature allocated $500,000 in non-recurring funds in the General Appropriations Act for pediatric rare disease research grants.[8]

Rare Disease Advisory Council

The Legislature established the Rare Disease Advisory Council (RDAC) in 2021 to assist DOH in providing recommendations to improve health outcomes for individuals with rare diseases residing in the state.[9]

The establishment of RDACs across the country is an initiative spearheaded by the National Organization for Rare Disorders (NORD),[10] a national nonprofit group advocating for individuals and families affected by rare diseases.[11] Florida was the 19th state to establish a RDAC through legislation.[12]

Florida's RDAC is directed to:[13]

- Consult with experts on rare diseases and solicit public comment to assist in developing recommendations on improving the treatment of rare diseases in Florida;
- Develop recommended strategies for academic research institutions in Florida to facilitate continued research on rare diseases;
- Develop recommended strategies for health care providers to be informed on how to more efficiently recognize and diagnose rare diseases in order to effectively treat patients; and
- Provide input and feedback in writing to DOH, the Medicaid program, and other state agencies on matters that affect people who have been diagnosed with rare diseases.

Rare Disease Registries – Sickle Cell Disease

[6] National Organization for Rare Diseases, *Rare Disease Day: Frequently Asked Questions*. Available at https://rarediseases.org/wp-content/uploads/2019/01/RDD-FAQ-2019.pdf (last visited January 19, 2024).
[7] Department of Health, *Rare Disease Advisory Council: Legislative Report, Fiscal Year 2022-2023* (2023). Available at https://www.floridahealth.gov/provider-and-partner-resources/rdac/_documents/RDACLegislativeReport2023Final_Draft.pdf (last visited January 20, 2024).
[8] Ch. 2023-239, L.O.F., line item 539A; *See also*, Department of Health, *Agency Analysis of HB 1441* (2024). On file with the Healthcare Regulation Subcommittee
[9] S. 381.99, F.S.
[10] National Organization for Rare Disorders (NORD). *Project RDAC Year One* (2021). Available at https://rarediseases.org/wp-content/uploads/2021/11/NRD-2200-RDAC-Year1-Highlights_FNL.pdf (last visited January 20, 2024).
[11] National Organization for Rare Disorders (NORD). About Us. Available at https://rarediseases.org/about-us/ (last visited January 20, 2024).
[12] *Supra*, note 7.
[13] S. 381.99(4), F.S.; *See also*, the Rare Disease Advisory Council's 2nd Legislative Report at: https://www.floridahealth.gov/provider-and-partner-resources/rdac/_documents/RDACLegislativeReport2023Final_Draft.pdf

In addition to the diagnostic challenges presented by rare diseases, difficulties abound in the research of rare diseases. Due to the inherently small population affected by each rare disease, gathering sufficient sample sizes to conduct clinical trials is difficult. Patient data is scarce, and small sample sizes limit research possibilities. Patient registries are a means of overcoming some of the research limitations that exist due to the nature of rare diseases. Patient registries are organized systems that allow for the use of observational study methods to collect uniform data and evaluate specified outcomes for a population defined by a particular disease.[14]

Sickle cell disease (SCD) affects approximately 100,000 Americans, well within the definition of a rare disease, and is also the most prevalent inherited blood disorder in the US.[15] SCD affects mostly, but not exclusively, Americans of African ancestry. SCD is a group of inherited disorders in which abnormal hemoglobin cause red blood cells to buckle into the iconic sickle shape; the deformed red blood cells damage blood vessels and over time contribute to a cascade of negative health effects beginning in infancy, such as intense vaso-occlusive pain episodes, strokes, organ failure, and recurrent infections.[16] The severity of complications generally worsens as people age, but treatment and prevention strategies can mitigate complications and lengthen the lives of people with SCD.[17]

A person who carries a single gene for SCD has sickle cell trait. People with sickle cell trait do not have SCD, and under normal conditions they are generally asymptomatic. However, they are carriers of SCD and have an increased likelihood of having a child with SCD. It is estimated that 8 to 10 percent of African Americans carry sickle cell trait.[18]

While SCD is the most common inherited blood disorder in the US and is often diagnosed at birth through newborn screening programs,[19] patients with SCD experience many of the other trials associated with treating a rare disease. Until recently there was very little research development in the areas of managing, treating, or curing SCD, and a lack of understanding of SCD persists among many health care professionals.[20]

In 2023, the Legislature directed DOH to partner with a community-based sickle cell disease medical treatment and research center to establish and maintain a registry to track outcome measures of newborns who are identified as carrying a sickle cell hemoglobin variant.[21] DOH has since contracted with the Foundation for Sickle Cell Research for the implementation of the registry.[22] Under current law, only newborns who have been detected as carrying a sickle cell hemoglobin variant through the Newborn Screening Program are included in the registry. Parents may choose to have their child removed from the registry by submitting a form provided by DOH.[23] There is not a mechanism under current law for adults with SCD to be included in the registry.

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[14] Hageman, I.C., van Rooij, I.A., de Blaauw, I., et al. *A systematic overview of rare disease patient registries: challenges in design, quality management, and maintenance* (2023). Orphanet Journal of Rare Diseases 18, 106. https://doi.org/10.1186/s13023-023-02719-0

[15] National Heart, Lung, and Blood Institute, *What is Sickle Cell Disease?*, Available at https://www.nhlbi.nih.gov/health/sickle-cell-disease (last visited June 26, 2023).

[16] Centers for Disease Control and Prevention, *What is Sickle Cell Disease?* Available at https://www.cdc.gov/ncbddd/sicklecell/facts.html (last visited June 26, 2023). See also, AHCA (2023) *Florida Medicaid Study of Enrollees with Sickle Cell Disease*. Available at https://ahca.myflorida.com/content/download/20771/file/Florida_Medicaid_Study_of_Enrollees_with_Sickle_Cell_Disease.pdf (last visited June 26, 2023).

[17] Centers for Disease Control and Prevention, *Complications of Sickle Cell Disease*. Available at https://www.cdc.gov/ncbddd/sicklecell/complications.html (last visited March 24, 2023).

[18] American Society of Hematology. ASH Position on Sickle Cell Trait (2021). Available at https://www.hematology.org/advocacy/policy-news-statements-testimony-and-correspondence/policy-statements/2021/ash-position-on-sickle-cell-trait (last visited January 20, 2024).

[19] Centers for Disease Control and Prevention. *Newborn Screening (NBS) Data* (2023). Available at https://www.cdc.gov/ncbddd/hemoglobinopathies/scdc-state-data/newborn-screening/index.html#:~:text=Newborn%20screening%20(NBS)%20for%20sickle,SCD%20living%20in%20a%20state. (last visited January 20, 2024).

[20] *See*, American Society of Hematology. *ASH Sickle Cell Disease Initiative*. Available at https://www.hematology.org/advocacy/sickle-cell-disease-initiative (last visited January 20, 2024).

[21] S. 383.147, F.S.

[22] Department of Health. *Contract Summary: Contract # CMO28*. On file with the Healthcare Regulation Subcommittee.

[23] S. 383.147, F.S.

Current law also directs the newborn's primary care physician to provide the parent or guardian of the newborn with information regarding the availability and benefits of genetic counseling.

Effect of Proposed Changes – Rare Diseases

Andrew John Anderson Pediatric Rare Disease Grant Program

HB 1441 establishes the Andrew John Anderson Pediatric Rare Disease Grant Program within DOH with the purpose of advancing the progress of research and cures for rare pediatric diseases through the award of grants through a competitive, peer-reviewed process. Grants are awarded by DOH, after consultation with the Rare Disease Advisory Council (RDAC).

Grants are awarded to universities or established research institutes in the state for scientific and clinical research to further the search for new diagnostics, treatments, and cures for rare pediatric diseases. The bill establishes a preference for grant proposals which foster collaboration among institutions, researchers, and community practitioners.

The bill directs DOH to appoint peer review panels of independent, scientifically qualified individuals to review the scientific merit of each proposal, and to share the results of such reviews with the RDAC which are to be considered in the recommendations for funding. The RDAC and peer review panels are to establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflicts of interest.

Sickle Cell Disease Registry

HB 1441 creates a process through which parents may opt-out of their child's inclusion in the registry through a proactive process, rather than retroactively removing a child from the registry upon the parent's request. Parents may opt-out through a form obtained from DOH, or otherwise indicating their objection to DOH in writing.

The bill transfers the responsibility of informing parents of the availability and benefits of genetic counseling from the infant's primary care physician to DOH.

The bill also creates a mechanism for adults with SCD who are Florida residents to choose to be included in the registry. The bill directs DOH to prescribe by rule the process for an adult to opt into the registry.

Florida Newborn Screening Program

Current Situation

The Legislature created the Florida Newborn Screening Program (NSP) within DOH, to promote the screening of all newborns for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect.[24] The NSP also promotes the identification and screening of all newborns in the state and their families for environmental risk factors such as low income, poor education, maternal and family stress, emotional instability, substance abuse, and other high-risk conditions associated with increased risk of infant mortality and morbidity to provide early intervention, remediation, and prevention services.[25]

The NSP involves coordination across several entities, including the Bureau of Public Health Laboratories Newborn Screening Laboratory in Jacksonville (state laboratory), DOH Children's Medical Services (CMS) Newborn Screening Follow-up Program in Tallahassee, referral centers, birthing centers, and physicians throughout the state.[26] Health care providers in hospitals, birthing centers,

[24] S. 383.14(1), F.S.
[25] *Id*.
[26] S. 383.14, F.S.

perinatal centers, county health departments, and school health programs provide screening as part of the multilevel NSP screening process.[27] This includes a risk assessment for prenatal women, and risk factor analysis and screening for postnatal women and newborns as well as laboratory screening for select disorders in newborns.[28] The NSP attempts to screen all newborns for hearing impairment and to identify, diagnose, and manage newborns at risk for select disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death.[29] The NSP is intended to screen all prenatal women and newborns, however, parents and guardians may choose to decline the screening.[30]

Health care providers perform non-laboratory NSP screening, such as hearing and risk factor analysis, and report the results to the Office of Vital Statistics. If necessary, health care providers refer patients to the appropriate health, education, and social services.[31] Health care providers in hospitals and birthing centers perform specimen collection for laboratory NSP screening by collecting a few drops of blood from the newborn's heel on a standardized specimen collection card. [32] The specimen card is then sent to the state laboratory for testing and the results are released to the newborn's health care provider. In the event that a newborn screen has an abnormal result, the newborn's health care practitioner,[33] or a nurse or specialist from NSP's Follow-up Program provides follow-up services and referrals for the child and his or her family.[34]

To administer the NSP, DOH is authorized to charge and collect a fee not to exceed $15 per live birth occurring in a hospital or birth center.[35] DOH must calculate the annual assessment for each hospital and birth center, and then quarterly generate and mail each hospital and birth center a statement of the amount due.[36] DOH bills hospitals and birth centers quarterly using vital statistics data to determine the amount to be billed.[37] DOH is authorized to bill third-party payers for the NSP tests and bills insurers directly for the cost of the screening.[38] DOH does not bill families that do not have insurance coverage.[39]

The Legislature established the Florida Genetics and Newborn Screening Advisory Council to advise DOH on disorders to be included in the NSP panel of screened disorders and the procedures for collecting and transmitting specimens.[40] Florida's NSP currently screens for 58 conditions, 55 of which are screened through the collection of blood spots. Screening of the other three conditions – hearing screening, critical congenital heart defect (CCHD) or pulse oximetry, and congenital cytomegalovirus (CCMV) targeted screening—are completed at the birthing facility through point-of-care testing.[41]

Newborn Hearing Screening

Section 383.145, F.S., requires a newborn hearing screening for all newborns in hospitals before discharge. The newborn hearing screening program (NBHS) is housed within DOH, which is

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[27] *Id.*
[28] *Id*.
[29] Florida Department of Health, *Florida Newborn Screening Guidelines*. Available at https://floridanewbornscreening.com/wp-content/uploads/NBS-Protocols-2022-FINAL.pdf (last visited December 27, 2023).
[30] S. 383.14(4), F.S.; Rule 64C-7.008, F.A.C.; The health care provider must attempt to get a written statement of objection to be placed in the medical record.
[31] *Id*.
[32] Florida Newborn Screening, *What is Newborn Screening?* Available at https://floridanewbornscreening.com/parents/what-is-newborn-screening/ (last visited December 27, 2023). *See also,* Florida Newborn Screening, *Specimen Collection Card*, http://floridanewbornscreening.com/wp-content/uploads/Order-Form.png (last visited December 27, 2023).
[33] Current law allows for the screening results to be released to specified health care practitioners including: allopathic and osteopathic physicians and physician assistants licensed under chs. 458 and 459, F.S., advanced practice registered nurses, registered nurses, and licensed practical nurses licensed under ch. 464, F.S., a midwife licensed under ch. 467, F.S., a speech-language pathologist or audiologist licensed under part I of ch. 468, F.S., or a dietician or nutritionist licensed under part X of ch. 468, F.S.
[34] *Id*.
[35] S. 383.145(3)(g)1., F.S.
[36] *Id.*
[37] S. 383.145(3)(g), F.S.
[38] S. 383.145(3)(h), F.S.
[39] *Supra*, note 26.
[40] S. 383.14(5), F.S.
[41] Department of Health, *Agency Analysis of HB 1441* (2024). On file with the Healthcare Regulation Subcommittee.

responsible for coordinating the statewide hearing screening and follow-up referral system. The NBHS program is funded through donations trust and federal grants from the Centers for Disease Control and Prevention and the Health Resources and Services Administration (HRSA).[42]

Before a newborn is discharged from a hospital or other state-licensed birthing facility, and unless objected to by the parent or legal guardian, the newborn must be screened for the detection of hearing loss to prevent the consequences of unidentified disorders.[43] For births occurring in a non-hospital setting, specifically a licensed birth center or private home, the facility or attending health care provider is responsible for providing a referral to an audiologist, a hospital, or other newborn hearing screening provider within 7 days after the birth or discharge from the facility.[44]

All screenings must be conducted by a licensed audiologist, a licensed physician, or appropriately supervised individual who has completed documented training specifically for newborn hearing screening.[45] When ordered by the treating physician, screening of a newborn's hearing must include auditory brainstem responses, or evoked otoacoustic emissions, or appropriate technology as approved by the United States Food and Drug Administration (FDA).[46]

NBHS staff provide follow-up to parents of infants who do not pass the newborn hearing screen to ensure timely diagnosis and enrollment in early intervention for children diagnosed with hearing loss.[47] A child who is diagnosed as having a permanent hearing impairment must be referred by the licensee or individual who conducted the screening to the primary care physician for medical management, treatment, and follow-up services. Furthermore, any child from birth to 36 months of age who is diagnosed as having a hearing impairment that requires ongoing special hearing services must be referred to the Children's Medical Services Early Intervention Program by the licensee or individual who conducted the screening serving the geographical area in which the child resides.

Hearing loss is one of the most common birth defects in the United States, with approximately 2 newborns per 1,000 born having hearing loss each year. It is estimated that only half of early childhood hearing loss is detected through newborn hearing screening. To further support early identification of hearing loss prior to school entry to prevent the consequences of unidentified disorders, the HRSA federal grant requires collection of hearing screening data for infants and toddlers up to age 36 months.[48]

In 2020, 98% of newborns in Florida received a hearing screen. In 2020, 9,500 infants did not pass the hearing screening, and 261 infants were diagnosed with hearing loss. It is estimated that 71% (814) of infants born in birthing centers in 2020 did not receive a hearing screen.[49]

Effect of Proposed Changes – Florida Newborn Screening Program

HB 1441 expressly states that the health care practitioner present at birth, or responsible for primary care during the neonatal period, has the responsibility for administering the newborn screenings. The bill requires that health care practitioners responsible for administering newborn screenings shall prepare and send all specimen cards to the State Public Health Laboratory. The bill provides DOH rulemaking authority to implement these provisions.

The bill adds genetic counselors to the list of health care practitioners to whom the state laboratory may release NBS results.

[42] *Id*.
[43] S. 383.145(3), F.S. If the screening is not completed before discharge due to scheduling or temporary staffing limitations, the screening must be completed within 21 days after the birth.
[44] S. 383.145(3)(d), F.S.
[45] S. 383.145(3)(f), F.S.
[46] S. 383.145(3)(i), F.S.
[47] *Supra*, note 42.
[48] *Supra*, note 42.
[49] *Supra*, note 42.

The bill deletes several obsolete provisions related to the NBS program, including:

- The requirement that the NBS program and Healthy Start to coordinate with the Florida Department of Education;
- Statutory references to a specific disease, phenylketonuria, which is included in the NBS program regimen;
- The requirement for DOH's Office of Inspector General to certify the financial operations of the NBS program;[50]
- The requirement for DOH to furnish physicians, county health departments, perinatal centers, birth centers, and hospitals with forms related in NBS.

Environmental Risk Screening

The bill removes current language relating to environmental risk screening from the NBS program and creates a separate section of law wherein the requirements for environmental risk screening are outlined. The requirements for environmental risk screening under the bill are consistent with current law.

Newborn Hearing Screening

The bill requires licensed birth centers to conduct newborn screenings before the newborn is discharged, rather than requiring the newborn be referred for testing outside of the birth center. The bill also requires that all newborns who do not pass the hearing screening are, within seven days of birth, referred for congenital cytomegalovirus testing to occur before the infant is 21 days of age.

The bill defines "toddler," as a child from 12 months to 36 months of age. Under current law, a physician-ordered hearing screening of a newborn must include auditory brainstem responses, or evoked otoacoustic emissions, or appropriate technology as approved by the US Food and Drug Administration. The bill expands these requirements to apply to physician-ordered screenings for infants and toddlers. The results of such tests must be reported to DOH within seven days of the receipt of test results.

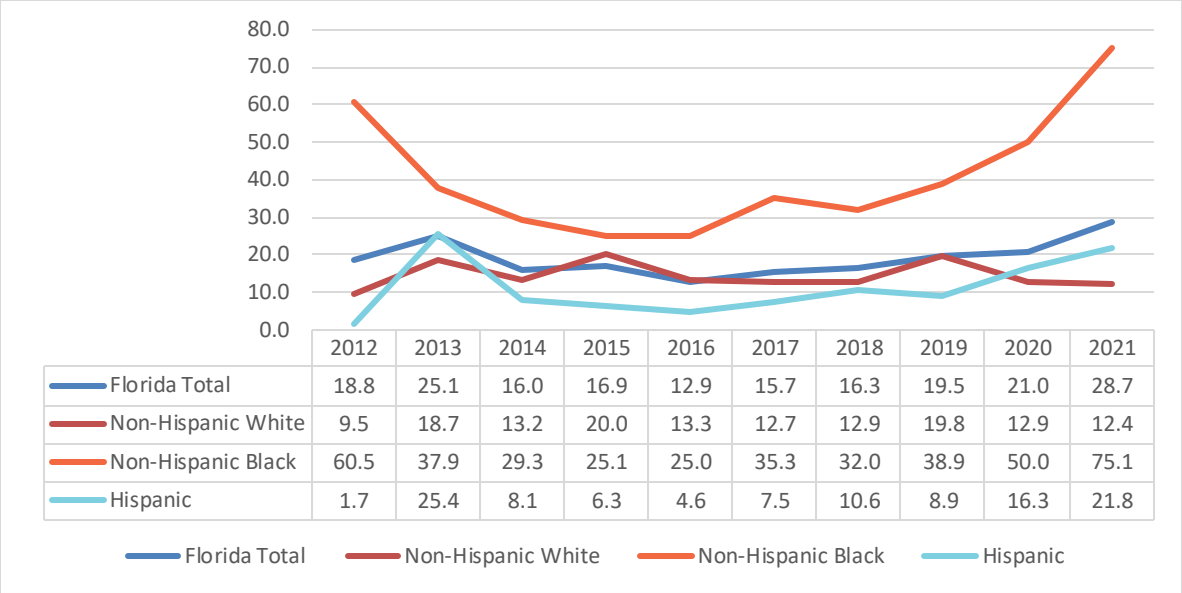
Maternal Health Outcomes

Current Situation

Maternal mortality refers to deaths occurring during pregnancy or within 42 days of the end of pregnancy, regardless of the duration of the pregnancy, from any cause related to or aggravated by the pregnancy, but not from accidental or incidental causes.[51] In 2021, more than 1,200 women died of maternal causes in the United States compared with 861 in 2020 and 754 in 2019.[52] The national maternal mortality rate for 2021 was 32.9 deaths per 100,000 live births.[53] Racial and ethnic gaps exist between non-Hispanic black, non-Hispanic white, and Hispanic women. The maternal mortality rate of these groups is 69.9, 26.6, and 28.0 deaths per 100,000 live births, respectively.[54] The overall number and rate of maternal deaths increased in 2020 and 2021 during the COVID-19 pandemic.[55]

[50] According to DOH, this current process is duplicative as NBS program funds are placed in a state trust fund subject to the rules governing state trust funds. *See*, Department of Health, *Agency Analysis for HB 1441* (2024). On file with the Healthcare Regulation Subcommittee.
[51] U.S. Department of Health and Human Services, *The Surgeon General's Call to Action to Improve Maternal Health*, (Dec. 2020), available at https://www.hhs.gov/sites/default/files/call-to-action-maternal-health.pdf (last visited December 5, 2023).
[52] Donna L. Hoyert, Ph.D., Division of Vital Statistics, National Center for Health Statistics, *Maternal Mortality Rates in the United States, 2021,* (2023). Available at https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.pdf https://www.cdc.gov/reproductivehealth/maternal-mortality/index.html (last visited January 8, 2024).
[53] *Id.*
[54] *Id.*
[55] United States Government Accountability Office, *Maternal Health Outcomes Worsened and Disparities Persisted During the Pandemic*, (Oct. 2022), available at https://www.gao.gov/assets/gao-23-105871.pdf (last visited December 5, 2023).

Although Florida's maternal mortality rate is lower than the national rate, it has been increasing in recent years. As of 2021, the maternal mortality rate in Florida is 28.7 deaths per 100,000 live births, an increase from a low of 12.9 deaths per 100,000 live births in 2016.[56] Similar to the national trend, racial and ethnic disparities exist in the maternal mortality rates in Florida as evidenced in the following chart:



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Florida Total	18.8	25.1	16.0	16.9	12.9	15.7	16.3	19.5	21.0	28.7
Non-Hispanic White	9.5	18.7	13.2	20.0	13.3	12.7	12.9	19.8	12.9	12.4
Non-Hispanic Black	60.5	37.9	29.3	25.1	25.0	35.3	32.0	38.9	50.0	75.1
Hispanic	1.7	25.4	8.1	6.3	4.6	7.5	10.6	8.9	16.3	21.8

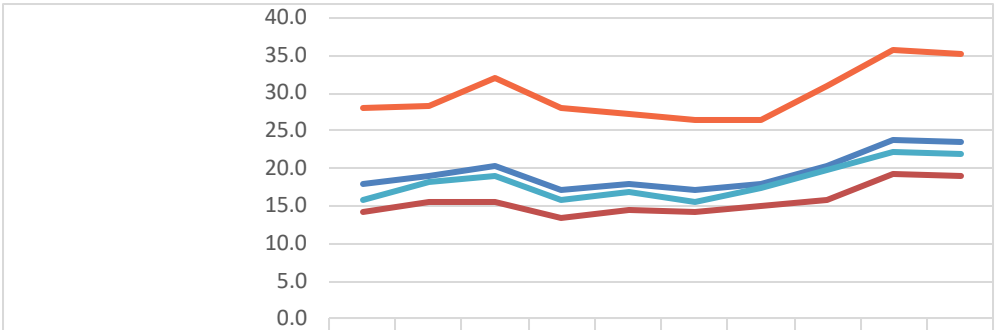
For every maternal death, 100 women suffer a severe obstetric morbidity, a life-threatening diagnosis, or undergo a lifesaving procedure during their delivery hospitalization.[57] Severe maternal morbidity (SMM) includes unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman's health. SMM has been steadily increasing in recent years.[58]

The consequences of the increasing SMM prevalence, in addition to the health effects for the woman, are wide-ranging and include increased medical costs and longer hospitalization stays.[59] The leading causes of SMM in 2021 were:

- Blood transfusion;
- Disseminated intravascular coagulation;
- Acute renal failure;
- Sepsis;
- Adult respiratory distress syndrome;
- Hysterectomy;
- Shock;
- Ventilation; and
- Eclampsia.[60]

[56] Presentation by Kenneth Scheppke, M.d., F.A.E.M.S., Deputy Sec'y for Health, DOH, before the Senate Committee on Health Policy (Nov. 14, 2023), available at https://www.flsenate.gov/Committees/Show/HP/MeetingPacket/5979/10504_MeetingPacket_5979_4.pdf (last visited January 8, 2024).
[57] Elizabeth A. Howell, MD, MPP, *Reducing Disparities in Severe Maternal Morbidity and Mortality*, 61(2) CLINICAL OBSTETRICS AND GYNECOLOGY 387 (June 2018). Available at https://journals.lww.com/clinicalobgyn/abstract/2018/06000/reducing_disparities_in_severe_maternal_morbidity.22.aspx (last visited January 8, 2024).
[58] *Id.,* and CDC, *Severe Maternal Morbidity in the United States*, (last rev. July 3, 2023). Available at https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html (last visited January 8, 2024).
[59] CDC, *Severe Maternal Morbidity in the United States*, (last rev. July 3, 2023). Available at https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html (last visited January 8, 2024).
[60] Florida Perinatal Quality Collaborative, *Opportunities for Florida Hospital Participation*, (Aug. 23, 2022), available at https://health.usf.edu/-/media/Files/Public-Health/Chiles-Center/FPQC/FPQC-Informational-Webinar-FINAL-23-AUG-22.ashx?la=en&hash=93B16B88819045E16DA5C84EEE3A6C416B3E457A (last visited January 8, 2024).

From 2013 to 2022, there were 51,454 cases of SMM among delivery hospitalization in Florida.[61] Similar to maternal mortality rates, rates of SMM are higher in racial and ethnic minority women.[62] The following figure shows the trend over time for SMM rates in Florida per 1,000 delivery hospitalizations:[63]



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Florida Total	17.9	19.1	20.2	17.0	18.0	17.2	18.0	20.4	23.8	23.6
Non-Hispanic White	14.1	15.6	15.6	13.3	14.5	14.3	15.0	15.9	19.3	19.1
Non-Hispanic Black	28.0	28.3	32.0	28.0	27.2	26.3	26.4	31.0	35.6	35.3
Hispanic	15.7	18.2	19.1	15.8	16.9	15.4	17.5	19.7	22.2	22.0

Telehealth Minority Maternity Care Pilot Program

In 2021, the Legislature created the Telehealth Minority Maternity Care Pilot Program in Duval and Orange counties to increase positive maternal health outcomes in racial and ethnic minority populations.[64]

DOH received funding in the 2023-2024 FY[65] to expand the pilot program to an additional 18 counties.[66] The additional counties are Brevard, Broward, Collier, Escambia, Hillsborough, Lake, Lee, Leon, Manatee, Marion, Miami-Dade, Palm Beach, Pasco, Pinellas, Polk, Sarasota, Seminole, and Volusia.

The pilot programs use telehealth to coordinate with prenatal home visiting programs to provide the following services and education to eligible pregnant women[67] up to the last day of their postpartum period:

- Referrals to Healthy Start's[68] coordinated intake and referral program to offer families prenatal home visiting services;

[61] Presentation by Kenneth Scheppke, M.D., F.A.E.M.S., Deputy Sec'y for Health, DOH, before the Senate Committee on Health Policy (Nov. 14, 2023), available at https://www.flsenate.gov/Committees/Show/HP/MeetingPacket/5979/10504_MeetingPacket_5979_4.pdf (last visited January 8, 2024).
[62] Elizabeth A. Howell, MD, MPP, *Reducing Disparities in Severe Maternal Morbidity and Mortality*, 61(2) CLINICAL OBSTETRICS AND GYNECOLOGY 387 (June 2018), available at https://journals.lww.com/clinicalobgyn/abstract/2018/06000/reducing_disparities_in_severe_maternal_morbidity.22.aspx (last visited January 8, 2024).
[63] *Id.*
[64] Chapter 2021-238, Laws of Florida, codified at s. 381.2163, F.S.
[65] Chapter 2023-239, Laws of Florida, line item 435.
[66] Florida Department of Health, Office of Minority Health, *Request for Applications: Programs to Reduce Severe Maternal Morbidity through Telehealth (SMMT) in Florida, RFA #22-002*, (April 19, 2023), available at https://www.floridahealth.gov/about/administrative-functions/purchasing/grant-funding-opportunities/RFA22-002.pdf#Open%20in%20new%20window (last visited January 8, 2024).
[67] An "eligible pregnant woman" is a pregnant woman who is receiving, or is eligible to receive, maternal or infant services from the DOH under ch. 381, F.S. or ch. 383, F.S.
[68] Healthy Start is a free home visiting program that provides education and care coordination to pregnant women and families of children under the age of three. The goal of the program is to lower risks factors associated with preterm birth, low birth weight, infant mortality, and poor development outcomes. *See* DOH, *Healthy Start*, available at https://www.floridahealth.gov/programs-and-services/childrens-health/healthy-start/index.html (last visited January 8, 2024).

- Services and education addressing social determinants of health;[69]
- Evidence-based health literacy and pregnancy, childbirth, and parenting education for women in prenatal and postpartum periods;
- For women during their pregnancies through the postpartum periods, connection to support from doulas and other perinatal health workers; and
- Medical devices for prenatal women to conduct key components of maternal wellness checks.[70]

The pilot programs also provide training to participating health care practitioners on:

- Implicit and explicit biases, racism, and discrimination in the provision of maternity care and how to eliminate these barriers;
- The use of remote patient monitoring tools;
- How to screen for social determinants of health risks in prenatal and postpartum periods;
- Best practices to screen for, evaluate, and treat mental health conditions and substance use disorders, as needed; and
- Collection of information, recording, and evaluation activities for program and patient evaluations.[71]

According to DOH, since the program's implementation, it has served more than 2,500 women in Duval and Orange counties, and 95 percent of the participants have reported that the program addressed an unmet social need.[72] The five most prevalent critical factors were food scarcity, childcare, paid work opportunities, affordability and access to utilities such as the Internet, and access to stable housing.

Additionally, 71 percent of the enrolled women in Duval County and 85 percent of enrolled women in Orange County reported high satisfaction with the implementation of the technology in the pilot program.[73] The enrolled women were provided blood pressure cuffs, scales, and glucose monitors to remotely screen and treat common pregnancy-related complications.

Effect of Proposed Changes – Telehealth Minority Maternity Care Pilot Program

The bill authorizes DOH to expand the Telehealth Minority Maternity Care Program statewide, contingent on funding. The bill allows DOH to implement local programs through community-based organizations.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.0101, F.S., relating to environmental health professionals.
Section 2: Creates s. 381.991, F.S., relating to the Andrew John Anderson Pediatric Rare Disease Grant Program.
Section 3: Amends s. 383.14, F.S., relating to screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.
Section 4: Amends s. 383.145, F.S., relating to newborn and infant hearing screening.
Section 5: Amends s. 383.147, F.S., relating to newborn and infant screenings for sickle cell hemoglobin variants; registry.
Section 6: Creates s. 383.148, F.S., relating to environmental risk screening.
Section 7: Amends s. 383.2163, F.S., relating to telehealth minority maternity care pilot programs.
Section 8: Amends s. 383.318, F.S., relating to postpartum care for birth center clients and infants.

[69] Social determinants of health refer to the conditions in the places where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality of life outcomes and risks. They are grouped into five domains: economic stability, education access and quality, health care access and quality, neighborhood and built environments, and social and community context. *See* U.S. Dep't of Health and Human Services, Office of Disease Prevention and Health Promotion, *Social Determinants of Health*, available at https://health.gov/healthypeople/priority-areas/social-determinants-health (last visited January 8, 2024).
[70] Section 383.2163(3), F.S.
[71] Section 383.2163(4), F.S.
[72] Department of Health, Office of Minority Health and Health Equity. *Pilot Programs to Reduce Racial and Ethnic Disparities in Severe Maternal Morbidity through Telehealth: Final Report* (2023). On file with the Healthcare Regulation Subcommittee.
[73] *Id.*

Section 9: Amends s. 395.1053, F.S., relating to postpartum education.
Section 10: Amends s. 456.0496, F.S., relating to provision of information on eye and vision disorders to parents during planned out-of-hospital births.
Section 11: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill has an indeterminant, negative fiscal impact on DOH.

   The provisions of Section 2 (the Andrew John Anderson Pediatric Rare Disease Grant Program) and Section 7 (the Telehealth Minority Maternity Care Programs) of the bill are subject to appropriation. The bill does not currently include an appropriation for these provisions.[74]

   See *fiscal comments*.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Private research institutions who are eligible for the Andrew John Anderson Pediatric Rare Disease Grant Program may experience a positive fiscal impact from access to this additional funding.

D. FISCAL COMMENTS:

Andrew John Anderson Pediatric Rare Disease Grant Program

According to DOH, the $500,000 that was allocated in the 2023 General Appropriations Act to fund research grants for pediatric rare diseases is intended fund the inaugural year of the Andrew John Anderson Pediatric Rare Disease Grant Program.[75]

Telehealth Minority Maternity Care Program

DOH estimates that a statewide expansion of the telehealth minority maternity care program will cost approximately $23,357,876.[76]

The breakdown for the $23,357,876 by category:

Expense (050310): $46,613/Non-Recurring; $133,087/Recurring
Contracted Services (050310): $22,500,000/Recurring

[74] *Supra*, note 41.
[75] *Id*.
[76] *Id*.

Salary/Fringe (010000): $675,658/Recurring
HR Outsourcing (107040): $2,518/Recurring

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the Department of Health; amending s. 381.0101, F.S.; defining the term "environmental health technician"; exempting environmental health technicians from certain certification requirements under certain circumstances; requiring the department, in conjunction with the Department of Environmental Protection, to adopt rules that establish certain standards for environmental health technician certification; requiring the Department of Health to adopt by rule certain standards for environmental health technician certification; revising provisions related to exemptions and fees to conform to changes made by the act; creating s. 381.991, F.S.; creating the Andrew John Anderson Rare Pediatric Disease Grant Program within the department for a specified purpose; subject to an appropriation by the Legislature, requiring the program to award grants for certain scientific and clinical research; specifying entities eligible to apply for the grants; specifying the types of applications that may be considered for grant funding; providing for a competitive, peer-reviewed application and selection process; providing that the remaining balance of appropriations for the program as of a specified date may be carried forward for a

specified timeframe under certain circumstances; amending s. 383.14, F.S.; providing that any health care practitioner present at a birth or responsible for primary care during the neonatal period has the primary responsibility of administering certain screenings; defining the term "health care practitioner"; deleting identification and screening requirements for newborns and their families for certain environmental and health risk factors; deleting certain related duties of the department; revising the definition of the term "health care practitioner" to include licensed genetic counselors; requiring that blood specimens for screenings of newborns be collected before a specified age; requiring that newborns have a blood specimen collected for newborn screenings, rather than only a test for phenylketonuria, before a specified age; deleting certain rulemaking authority of the department; deleting a requirement that the department furnish certain forms to specified entities; deleting the requirement that such entities report the results of certain screenings to the department; making technical and conforming changes; deleting a requirement that the department submit certain certifications as part of its legislative budget

request; requiring certain health care practitioners to prepare and send all newborn screening specimen cards to the State Public Health Laboratory; defining the term "health care practitioner"; amending s. 383.145, F.S.; defining the term "toddler"; revising hearing loss screening requirements to include infants and toddlers; revising hearing loss screening requirements for licensed birth centers; revising the timeframe in which a newborn's primary health care provider must refer a newborn for congenital cytomegalovirus screening after the newborn fails the hearing loss screening; requiring licensed birth centers to complete newborn hearing loss screenings before discharge, with an exception; amending s. 383.147, F.S.; revising sickle cell disease and sickle cell trait screening requirements; requiring screening providers to notify a newborn's parent or guardian, rather than the newborn's primary care physician, of certain information; authorizing the parents or guardians of a newborn to opt out of the newborn's inclusion in the sickle cell registry; specifying the manner in which a parent or guardian may opt out; authorizing certain persons other than newborns who have been identified as having sickle cell disease or carrying a sickle cell trait to choose to be included

in the registry; creating s. 383.148, F.S.; requiring the department to promote the screening of pregnant women and infants for specified environmental risk factors; requiring the department to develop a multilevel screening process for prenatal and postnatal risk screenings; specifying requirements for such screening processes; providing construction; requiring persons who object to a screening to give a written statement of such objection to the physician or other person required to administer and report the screening; amending s. 383.2163, F.S.; expanding the telehealth minority maternity care pilot program to a full program available in any county in this state, contingent upon available funding; making conforming changes; revising the source of funding for the program; amending ss. 383.318, 395.1053, and 456.0496, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Present subsections (5), (6), and (7) of section 381.0101, Florida Statutes, are redesignated as subsections (6), (7), and (8), respectively, a new subsection (5) is added to that section, and subsections (1), (2), and (4)

and present subsections (5) and (6) of that section are amended, to read:

381.0101 Environmental health professionals.—

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

(a) "Board" means the Environmental Health Professionals Advisory Board.

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

(d) ~~(c)~~ "Environmental health" means that segment of public health work which deals with the examination of those factors in the human environment which may impact adversely on the health status of an individual or the public.

(e) ~~(d)~~ "Environmental health professional" means a person who is employed or assigned the responsibility for assessing the environmental health or sanitary conditions, as defined by the department, within a building, on an individual's property, or within the community at large, and who has the knowledge, skills, and abilities to carry out these tasks. Environmental health professionals may be either field, supervisory, or administrative staff members.

(b) ~~(e)~~ "Certified" means a person who has displayed competency to perform evaluations of environmental or sanitary conditions through examination.

(f) "Environmental health technician" means a person who is employed or assigned the responsibility for conducting septic inspections under the supervision of a certified environmental

health professional. An environmental health technician must have completed training approved by the department and have the knowledge, skills, and abilities to carry out these tasks.

(h) ~~(f)~~ "Registered sanitarian," "R.S.," "Registered Environmental Health Specialist," or "R.E.H.S." means a person who has been certified by either the National Environmental Health Association or the Florida Environmental Health Association as knowledgeable in the environmental health profession.

(g) "Primary environmental health program" means those programs determined by the department to be essential for providing basic environmental and sanitary protection to the public. At a minimum, these programs shall include food protection program work.

(2) CERTIFICATION; EXEMPTIONS ~~REQUIRED~~.—A person may not perform environmental health or sanitary evaluations in any primary program area of environmental health without being certified by the department as competent to perform such evaluations. This section does not apply to any of the following:

(a) Persons performing inspections of public food service establishments licensed under chapter 509.~~; or~~

(b) Persons performing site evaluations in order to determine proper placement and installation of onsite wastewater treatment and disposal systems who have successfully completed a

department-approved soils morphology course and who are working under the direct responsible charge of an engineer licensed under chapter 471.

(c) Environmental health technicians employed by a department as defined in s. 20.03 who are assigned the responsibility for conducting septic tank inspections under the supervision of an environmental health professional certified in onsite sewage treatment and disposal.

(4) STANDARDS FOR CERTIFICATION.—The department shall adopt rules that establish definitions of terms and minimum standards of education, training, or experience for those persons subject to this subsection ~~section~~. The rules must also address the process for application, examination, issuance, expiration, and renewal of certification and ethical standards of practice for the profession.

(a) Persons employed as environmental health professionals shall exhibit a knowledge of rules and principles of environmental and public health law in Florida through examination. A person may not conduct environmental health evaluations in a primary program area unless he or she is currently certified in that program area or works under the direct supervision of a certified environmental health professional.

1. All persons who begin employment in a primary environmental health program on or after September 21, 1994,

must be certified in that program within 6 months after employment.

2. Persons employed in the primary environmental health program of a food protection program or an onsite sewage treatment and disposal system prior to September 21, 1994, shall be considered certified while employed in that position and shall be required to adhere to any professional standards established by the department pursuant to paragraph (b), complete any continuing education requirements imposed under paragraph (d), and pay the certificate renewal fee imposed under subsection (7) ~~(6)~~.

3. Persons employed in the primary environmental health program of a food protection program or an onsite sewage treatment and disposal system prior to September 21, 1994, who change positions or program areas and transfer into another primary environmental health program area on or after September 21, 1994, must be certified in that program within 6 months after such transfer, except that they will not be required to possess the college degree required under paragraph (e).

4. Registered sanitarians shall be considered certified and shall be required to adhere to any professional standards established by the department pursuant to paragraph (b).

(b) At a minimum, the department shall establish standards for professionals in the areas of food hygiene and onsite sewage treatment and disposal.

(c) Those persons conducting primary environmental health evaluations shall be certified by examination to be knowledgeable in any primary area of environmental health in which they are routinely assigned duties.

(d) Persons who are certified shall renew their certification biennially by completing not less than 24 contact hours of continuing education for each program area in which they maintain certification, subject to a maximum of 48 hours for multiprogram certification.

(e) Applicants for certification shall have graduated from an accredited 4-year college or university with a degree or major coursework in public health, environmental health, environmental science, or a physical or biological science.

(f) A certificateholder shall notify the department within 60 days after any change of name or address from that which appears on the current certificate.

(5) STANDARDS FOR ENVIRONMENTAL HEALTH TECHNICIAN CERTIFICATION.—The department, in conjunction with the Department of Environmental Protection, shall adopt rules that establish definitions of terms and minimum standards of education, training, and experience for those persons subject to this subsection. The rules must also address the process for application, examination, issuance, expiration, and renewal of certification, and ethical standards of practice for the profession.

(a) At a minimum, the department shall establish standards for technicians in the areas of onsite sewage treatment and disposal.

(b) A person conducting septic inspections must be certified by examination to be knowledgeable in the area of onsite sewage treatment and disposal.

(c) An applicant for certification as an environmental health technician must, at a minimum, have received a high school diploma or its equivalent.

(d) An applicant for certification as an environmental health technician must be employed by a department as defined in s. 20.03.

(e) An applicant for certification as an environmental health technician must complete supervised field inspection work as prescribed by department rule before examination.

(f) A certified environmental health technician must renew his or her certification biennially by completing at least 24 contact hours of continuing education for each program area in which he or she maintains certification, subject to a maximum of 48 hours for multiprogram certification.

(g) A certified environmental health technician shall notify the department within 60 days after any change of name or address from that which appears on the current certificate.

(6)~~(5)~~ EXEMPTIONS.—A person who conducts primary environmental evaluation activities and maintains a current

registration or certification from another state agency which examined the person's knowledge of the primary program area and requires comparable continuing education to maintain the certificate shall not be required to be certified by this section. ~~Examples of persons not subject to certification are physicians, registered dietitians, certified laboratory personnel, and nurses.~~

(7)~~(6)~~ FEES.—The department shall charge fees in amounts necessary to meet the cost of providing environmental health professional certification. Fees for certification shall be not less than $10 or more than $300 and shall be set by rule. Application, examination, and certification costs shall be included in this fee. Fees for renewal of a certificate shall be no less than $25 nor more than $150 per biennium.

Section 2. Section 381.991, Florida Statutes, is created to read:

381.991 Andrew John Anderson Pediatric Rare Disease Grant Program.—

(1)(a) There is created within the Department of Health the Andrew John Anderson Rare Pediatric Disease Grant Program. The purpose of the program is to advance the progress of research and cures for rare pediatric diseases by awarding grants through a competitive, peer-reviewed process.

(b) Subject to an annual appropriation by the Legislature, the program shall award grants for scientific and clinical

research to further the search for new diagnostics, treatments, and cures for rare pediatric diseases.

(2)(a) Applications for grants for rare pediatric disease research may be submitted by any university or established research institute in the state. All qualified investigators in the state, regardless of institutional affiliation, shall have equal access and opportunity to compete for the research funding. Preference may be given to grant proposals that foster collaboration among institutions, researchers, and community practitioners, as such proposals support the advancement of treatments and cures of rare pediatric diseases through basic or applied research. Grants shall be awarded by the department, after consultation with the Rare Disease Advisory Council, pursuant to s. 381.99, on the basis of scientific merit, as determined by the competitive, peer-reviewed process to ensure objectivity, consistency, and high quality. The following types of applications may be considered for funding:

1. Investigator-initiated research grants.

2. Institutional research grants.

3. Collaborative research grants, including those that advance the finding of treatment and cures through basic or applied research.

(b) To ensure appropriate and fair evaluation of grant applications based on scientific merit, the department shall appoint peer review panels of independent, scientifically

qualified individuals to review the scientific merit of each proposal and establish its priority score. The priority scores shall be forwarded to the council and must be considered in determining which proposals shall be recommended for funding.

(c) The council and the peer review panels shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflicts of interest. A member of the council or panel may not participate in any discussion or decision of the council or panel with respect to a research proposal by any firm, entity, or agency that the member is associated with as a member of the governing body or as an employee or with which the member has entered into a contractual arrangement.

(d) Notwithstanding s. 216.301 and pursuant to s. 216.351, the balance of any appropriation from the General Revenue Fund for the Andrew John Anderson Pediatric Rare Disease Grant Program that is not disbursed but that is obligated pursuant to contract or committed to be expended by June 30 of the fiscal year in which the funds are appropriated may be carried forward for up to 5 years after the effective date of the original appropriation.

Section 3. Present subsection (5) of section 383.14, Florida Statutes, is redesignated as subsection (6), a new subsection (5) is added to that section, and subsections (1), (2), and (3) of that section are amended, to read:

383.14 Screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.—

(1) SCREENING REQUIREMENTS.—To help ensure access to the maternal and child health care system, the Department of Health shall promote the screening of all newborns born in Florida for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect, as screening programs accepted by current medical practice become available and practical in the judgment of the department. Any health care practitioner present at a birth or responsible for primary care during the neonatal period has the primary responsibility of administering screenings as required in ss. 383.14 and 383.145. As used in this subsection, the term "health care practitioner" means a physician or physician assistant licensed under chapter 458, an osteopathic physician or physician assistant licensed under chapter 459, an advanced practice registered nurse licensed under part I of chapter 464, or a midwife licensed under chapter 467 ~~The department shall also promote the identification and screening of all newborns in this state and their families for environmental risk factors such as low income, poor education, maternal and family stress, emotional instability, substance abuse, and other high-risk conditions associated with increased risk of infant mortality and morbidity to provide early intervention, remediation, and prevention services, including, but not limited to, parent support and~~

~~training programs, home visitation, and case management. Identification, perinatal screening, and intervention efforts shall begin prior to and immediately following the birth of the child by the attending health care provider. Such efforts shall be conducted in hospitals, perinatal centers, county health departments, school health programs that provide prenatal care, and birthing centers, and reported to the Office of Vital Statistics.~~

~~(a) *Prenatal screening.*—The department shall develop a multilevel screening process that includes a risk assessment instrument to identify women at risk for a preterm birth or other high-risk condition. The primary health care provider shall complete the risk assessment instrument and report the results to the Office of Vital Statistics so that the woman may immediately be notified and referred to appropriate health, education, and social services.~~

~~(b) *Postnatal screening.*—A risk factor analysis using the department's designated risk assessment instrument shall also be conducted as part of the medical screening process upon the birth of a child and submitted to the department's Office of Vital Statistics for recording and other purposes provided for in this chapter. The department's screening process for risk assessment shall include a scoring mechanism and procedures that establish thresholds for notification, further assessment, referral, and eligibility for services by professionals or~~

~~paraprofessionals consistent with the level of risk. Procedures for developing and using the screening instrument, notification, referral, and care coordination services, reporting requirements, management information, and maintenance of a computer-driven registry in the Office of Vital Statistics which ensures privacy safeguards must be consistent with the provisions and plans established under chapter 411, Pub. L. No. 99-457, and this chapter. Procedures established for reporting information and maintaining a confidential registry must include a mechanism for a centralized information depository at the state and county levels. The department shall coordinate with existing risk assessment systems and information registries. The department must ensure, to the maximum extent possible, that the screening information registry is integrated with the department's automated data systems, including the Florida On-line Recipient Integrated Data Access (FLORIDA) system~~.

(a) *Blood specimens for newborn screenings.*—Newborn ~~Tests and~~ screenings must be performed by the State Public Health Laboratory, in coordination with Children's Medical Services, at such times and in such manner as is prescribed by the department after consultation with the Genetics and Newborn Screening Advisory Council ~~and the Department of Education~~.

(b) ~~(c)~~ *Release of screening results.*—Notwithstanding any law to the contrary, the State Public Health Laboratory may release, directly or through the Children's Medical Services

program, the results of a newborn's ~~hearing and metabolic tests or~~ screenings to the newborn's health care practitioner, the newborn's parent or legal guardian, the newborn's personal representative, or a person designated by the newborn's parent or legal guardian. As used in this paragraph, the term "health care practitioner" means a physician or physician assistant licensed under chapter 458; an osteopathic physician or physician assistant licensed under chapter 459; an advanced practice registered nurse, registered nurse, or licensed practical nurse licensed under part I of chapter 464; a midwife licensed under chapter 467; a speech-language pathologist or audiologist licensed under part I of chapter 468; ~~or~~ a dietician or nutritionist licensed under part X of chapter 468; or a genetic counselor licensed under part III of chapter 483.

(2) RULES.—

(a) After consultation with the Genetics and Newborn Screening Advisory Council, the department shall adopt and enforce rules requiring that every newborn in this state shall:

1. Before becoming 1 week of age, have a blood specimen collected for newborn screenings ~~be subjected to a test for phenylketonuria~~;

2. Be tested for any condition included on the federal Recommended Uniform Screening Panel which the council advises the department should be included under the state's screening program. After the council recommends that a condition be

included, the department shall submit a legislative budget request to seek an appropriation to add testing of the condition to the newborn screening program. The department shall expand statewide screening of newborns to include screening for such conditions within 18 months after the council renders such advice, if a test approved by the United States Food and Drug Administration or a test offered by an alternative vendor is available. If such a test is not available within 18 months after the council makes its recommendation, the department shall implement such screening as soon as a test offered by the United States Food and Drug Administration or by an alternative vendor is available; and

3. At the appropriate age, be tested for such other metabolic diseases and hereditary or congenital disorders as the department may deem necessary ~~from time to time~~.

~~(b) After consultation with the Department of Education, the department shall adopt and enforce rules requiring every newborn in this state to be screened for environmental risk factors that place children and their families at risk for increased morbidity, mortality, and other negative outcomes.~~

(b) ~~(c)~~ The department shall adopt such additional rules as are found necessary for the administration of this section and ss. 383.145 and 383.148 ~~s. 383.145~~, including rules providing definitions of terms, rules relating to the methods used and time or times for testing as accepted medical practice

indicates, rules relating to charging and collecting fees for the administration of the newborn screening program authorized by this section, rules for processing requests and releasing test and screening results, and rules requiring mandatory reporting of the results of tests and screenings for these conditions to the department.

(3) DEPARTMENT OF HEALTH; POWERS AND DUTIES.—The department shall administer and provide certain services to implement the provisions of this section and shall:

(a) Assure the availability and quality of the necessary laboratory tests and materials.

(b) ~~Furnish all physicians, county health departments, perinatal centers, birthing centers, and hospitals forms on which environmental screening and the results of tests for phenylketonuria and such other disorders for which testing may be required from time to time shall be reported to the department.~~

~~(c)~~ Promote education of the public about the prevention and management of metabolic, hereditary, and congenital disorders ~~and dangers associated with environmental risk factors~~.

(c)~~(d)~~ Maintain a confidential registry of cases, including information of importance for the purpose of follow-up ~~followup~~ services to prevent intellectual disabilities, to correct or ameliorate physical disabilities, and for

epidemiologic studies, if indicated. Such registry shall be exempt from the provisions of s. 119.07(1).

(d) ~~(c)~~ Supply the necessary dietary treatment products where practicable for diagnosed cases of ~~phenylketonuria and other~~ metabolic diseases for as long as medically indicated when the products are not otherwise available. Provide nutrition education and supplemental foods to those families eligible for the Special Supplemental Nutrition Program for Women, Infants, and Children as provided in s. 383.011.

(e) ~~(f)~~ Promote the availability of genetic studies, services, and counseling in order that the parents, siblings, and affected newborns may benefit from detection and available knowledge of the condition.

(f) ~~(g)~~ Have the authority to charge and collect fees for the administration of the newborn screening program. ~~authorized in this section, as follows:~~

~~1.~~ A fee not to exceed $15 will be charged for each live birth, as recorded by the Office of Vital Statistics, occurring in a hospital licensed under part I of chapter 395 or a birth center licensed under s. 383.305 ~~per year~~. The department shall calculate the ~~annual~~ assessment for each hospital and birth center, and this assessment must be paid ~~in equal amounts~~ quarterly. ~~Quarterly,~~ The department shall generate and issue ~~mail to~~ each hospital and birth center a statement of the amount due.

~~2. As part of the department's legislative budget request prepared pursuant to chapter 216, the department shall submit a certification by the department's inspector general, or the director of auditing within the inspector general's office, of the annual costs of the uniform testing and reporting procedures of the newborn screening program. In certifying the annual costs, the department's inspector general or the director of auditing within the inspector general's office shall calculate the direct costs of the uniform testing and reporting procedures, including applicable administrative costs. Administrative costs shall be limited to those department costs which are reasonably and directly associated with the administration of the uniform testing and reporting procedures of the newborn screening program.~~

(g) ~~(h)~~ Have the authority to bill third-party payors for newborn screening tests.

(h) ~~(i)~~ Create and make available electronically a pamphlet with information on screening for, and the treatment of, preventable infant and childhood eye and vision disorders, including, but not limited to, retinoblastoma and amblyopia.

All provisions of this subsection must be coordinated with the provisions and plans established under this chapter, chapter 411, and Pub. L. No. 99-457.

(5) SUBMISSION OF NEWBORN SCREENING SPECIMEN CARDS.—Any

health care practitioner whose duty it is to administer screenings under this section shall prepare and send all newborn screening specimen cards to the State Public Health Laboratory in accordance with rules adopted under this section. As used in this subsection, the term "health care practitioner" means a physician or physician assistant licensed under chapter 458, an osteopathic physician or physician assistant licensed under chapter 459, an advanced practice registered nurse licensed under part I of chapter 464, or a midwife licensed under chapter 467.

Section 4. Paragraph (k) is added to subsection (2) of Section 383.145, Florida Statutes, and subsection (3) of that section is amended, to read:

383.145 Newborn, ~~and~~ infant, and toddler hearing screening.—

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

(k) "Toddler" means a child from 12 months to 36 months of age.

(3) REQUIREMENTS FOR SCREENING OF NEWBORNS, INFANTS, AND TODDLERS; INSURANCE COVERAGE; REFERRAL FOR ONGOING SERVICES.—

(a) Each hospital or other state-licensed birth ~~birthing~~ facility that provides maternity and newborn care services shall ensure that all newborns are, before discharge, screened for the detection of hearing loss to prevent the consequences of unidentified disorders. If a newborn fails the screening for the

detection of hearing loss, the hospital or other state-licensed birth ~~birthing~~ facility must administer a test approved by the United States Food and Drug Administration or another diagnostically equivalent test on the newborn to screen for congenital cytomegalovirus before the newborn becomes 21 days of age or before discharge, whichever occurs earlier.

(b) Each licensed birth center that provides maternity and newborn care services shall ensure that all newborns are, before discharge, screened for the detection of hearing loss. Within 7 days after the birth, the licensed birth center must ensure that all newborns who do not pass the hearing screening are referred for ~~to~~ an appointment ~~audiologist, a hospital, or another newborn hearing screening provider~~ for a test to screen for congenital cytomegalovirus before the newborn becomes 21 days of age ~~screening for the detection of hearing loss to prevent the consequences of unidentified disorders. The referral for appointment must be made within 7 days after discharge~~. Written documentation of the referral must be placed in the newborn's medical chart.

(c) If the parent or legal guardian of the newborn objects to the screening, the screening must not be completed. In such case, the physician, midwife, or other person attending the newborn shall maintain a record that the screening has not been performed and attach a written objection that must be signed by the parent or guardian.

(d) For home births, the health care provider in attendance is responsible for coordination and referral to an audiologist, a hospital, or another newborn hearing screening provider. The health care provider in attendance must make the referral for appointment within 7 days after the birth. In cases in which the home birth is not attended by a health care provider, the newborn's primary health care provider is responsible for coordinating the referral.

(e) For home births and births in a licensed birth center, if a newborn is referred to a newborn hearing screening provider and the newborn fails the screening for the detection of hearing loss, the newborn's primary health care provider must refer the newborn for administration of a test approved by the United States Food and Drug Administration or another diagnostically equivalent test on the newborn to screen for congenital cytomegalovirus before the newborn becomes 21 days of age.

(f) All newborn and infant hearing screenings must be conducted by an audiologist, a physician, or an appropriately supervised individual who has completed documented training specifically for newborn hearing screening. Every hospital that provides maternity or newborn care services shall obtain the services of an audiologist, a physician, or another newborn hearing screening provider, through employment or contract or written memorandum of understanding, for the purposes of appropriate staff training, screening program supervision,

monitoring the scoring and interpretation of test results, rendering of appropriate recommendations, and coordination of appropriate follow-up services. Appropriate documentation of the screening completion, results, interpretation, and recommendations must be placed in the medical record within 24 hours after completion of the screening procedure.

(g) The screening of a newborn's hearing must be completed before the newborn is discharged from the hospital or licensed birth center. However, if the screening is not completed before discharge due to scheduling or temporary staffing limitations, the screening must be completed within 21 days after the birth. Screenings completed after discharge or performed because of initial screening failure must be completed by an audiologist, a physician, a hospital, or another newborn hearing screening provider.

(h) Each hospital shall formally designate a lead physician responsible for programmatic oversight for newborn hearing screening. Each birth center shall designate a licensed health care provider to provide such programmatic oversight and to ensure that the appropriate referrals are being completed.

(i) When ordered by the treating physician, screening of a newborn's, infant's, or toddler's hearing must include auditory brainstem responses, or evoked otoacoustic emissions, or appropriate technology as approved by the United States Food and Drug Administration.

(j) The results of any test conducted pursuant to this section, including, but not limited to, newborn hearing loss screening, congenital cytomegalovirus testing, and any related diagnostic testing, must be reported to the department within 7 days after receipt of such results.

(k) The initial procedure for screening the hearing of the newborn or infant and any medically necessary follow-up reevaluations leading to diagnosis shall be a covered benefit for Medicaid patients covered by a fee-for-service program. For Medicaid patients enrolled in HMOs, providers shall be reimbursed directly by the Medicaid Program Office at the Medicaid rate. This service may not be considered a covered service for the purposes of establishing the payment rate for Medicaid HMOs. All health insurance policies and health maintenance organizations as provided under ss. 627.6416, 627.6579, and 641.31(30), except for supplemental policies that only provide coverage for specific diseases, hospital indemnity, or Medicare supplement, or to the supplemental policies, shall compensate providers for the covered benefit at the contracted rate. Nonhospital-based providers are eligible to bill Medicaid for the professional and technical component of each procedure code.

(l) A child who is diagnosed as having permanent hearing loss must be referred to the primary care physician for medical management, treatment, and follow-up services. Furthermore, in

accordance with Part C of the Individuals with Disabilities Education Act, Pub. L. No. 108-446, Infants and Toddlers with Disabilities, any child from birth to 36 months of age who is diagnosed as having hearing loss that requires ongoing special hearing services must be referred to the Children's Medical Services Early Intervention Program serving the geographical area in which the child resides.

Section 5. Section 383.147, Florida Statutes, is amended to read:

383.147 ~~Newborn and infant screenings for~~ Sickle cell disease and sickle cell trait ~~hemoglobin variants;~~ registry.—

(1) If ~~a screening provider detects that~~ a newborn as ~~or an infant, as those terms are~~ defined in s. 383.145(2)~~,~~ is identified as having sickle cell disease or carrying a sickle cell trait through the newborn screening program as described in s. 383.14, the department ~~hemoglobin variant, it~~ must:

(a) Notify the parent or guardian of the newborn and provide information regarding the availability and benefits of genetic counseling. ~~primary care physician of the newborn or infant and~~

(b) Submit the results of such screening ~~to the Department of Health~~ for inclusion in the sickle cell registry established under paragraph (2)(a), unless the parent or guardian of the newborn provides an opt-out form obtained from the department, or otherwise indicates in writing to the department his or her

objection to having the newborn included in the sickle cell registry. ~~The primary care physician must provide to the parent or guardian of the newborn or infant information regarding the availability and benefits of genetic counseling.~~

(2)(a) The Department of Health shall contract with a community-based sickle cell disease medical treatment and research center to establish and maintain a registry for individuals ~~newborns and infants~~ who are identified as having sickle cell disease or carrying a sickle cell trait ~~hemoglobin variant~~. The sickle cell registry must track sickle cell disease outcome measures, except as provided in paragraph (1)(b). ~~A parent or guardian of a newborn or an infant in the registry may request to have his or her child removed from the registry by submitting a form prescribed by the department by rule.~~

(b) In addition to newborns identified and included in the registry under subsection (1), persons living in this state who have been identified as having sickle cell disease or carrying a sickle cell trait may choose to be included in the registry by providing the department with notification as prescribed by rule.

(c) The Department of Health shall also establish a system to ensure that the community-based sickle cell disease medical treatment and research center notifies the parent or guardian of a child who has been included in the registry that a follow-up consultation with a physician is recommended. Such notice must

be provided to the parent or guardian of such child at least once during early adolescence and once during late adolescence. The department shall make every reasonable effort to notify persons included in the registry who are 18 years of age that they may request to be removed from the registry by submitting a form prescribed by the department by rule. The department shall also provide to such persons information regarding available educational services, genetic counseling, and other beneficial resources.

(3) The Department of Health shall adopt rules to implement this section.

Section 6. Section 383.148, Florida Statutes, is created to read:

383.148 ENVIRONMENTAL RISK SCREENING.—

(1) RISK SCREENING.—To help ensure access to the maternal and child health care system, the Department of Health shall promote the screening of all pregnant women and infants in this state for environmental risk factors, such as low income, poor education, maternal and family stress, mental health, substance use disorder, and other high-risk conditions, and promote education of the public about the dangers associated with environmental risk factors.

(2) PRENATAL RISK SCREENING REQUIREMENTS.—The department shall develop a multilevel screening process that includes a risk assessment instrument to identify women at risk for a

preterm birth or other high-risk condition.

(a) A primary health care provider must complete the risk screening at a pregnant woman's first prenatal visit using the form and in the manner prescribed by rules adopted under this section, so that the woman may immediately be notified and referred to appropriate health, education, and social services.

(b) This subsection does not apply if the pregnant woman objects to the screening in a manner prescribed by department rule.

(3) POSTNATAL RISK SCREENING REQUIREMENTS.—The department shall develop a multilevel screening process that includes a risk assessment instrument to identify factors associated with increased risk of infant mortality and morbidity to provide early intervention, remediation, and prevention services, including, but not limited to, parent support and training programs, home visitation, and case management.

(a) A hospital or birth center must complete the risk screening immediately following the birth of the infant, before discharge from the hospital or birth center, using the form and in the manner prescribed by rules adopted under this section.

(b) This subsection does not apply if a parent or guardian of the newborn objects to the screening in a manner prescribed by department rule.

Section 7. Section 383.2163, Florida Statutes, is amended to read:

383.2163 Telehealth minority maternity care program ~~pilot programs~~.~~—By July 1, 2022,~~ The department shall establish a telehealth minority maternity care ~~pilot~~ program ~~in Duval County and Orange County~~ which uses telehealth to expand the capacity for positive maternal health outcomes in racial and ethnic minority populations. The department shall ~~direct and assist the county health departments in Duval County and Orange County to~~ implement local ~~the~~ programs contingent upon available funding.

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

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

(b) "Eligible pregnant woman" means a pregnant woman who is receiving, or is eligible to receive, maternal or infant care services from the department under chapter 381 or this chapter.

(c) "Health care practitioner" has the same meaning as in s. 456.001.

(d) "Health professional shortage area" means a geographic area designated as such by the Health Resources and Services Administration of the United States Department of Health and Human Services.

(e) "Indigenous population" means any Indian tribe, band, or nation or other organized group or community of Indians recognized as eligible for services provided to Indians by the United States Secretary of the Interior because of their status as Indians, including any Alaskan native village as defined in 43 U.S.C. s. 1602(c), the Alaska Native Claims Settlement Act,

as that definition existed on the effective date of this act.

(f) "Maternal mortality" means a death occurring during pregnancy or the postpartum period which is caused by pregnancy or childbirth complications.

(g) "Medically underserved population" means the population of an urban or rural area designated by the United States Secretary of Health and Human Services as an area with a shortage of personal health care services or a population group designated by the United States Secretary of Health and Human Services as having a shortage of such services.

(h) "Perinatal professionals" means doulas, personnel from Healthy Start and home visiting programs, childbirth educators, community health workers, peer supporters, certified lactation consultants, nutritionists and dietitians, social workers, and other licensed and nonlicensed professionals who assist women through their prenatal or postpartum periods.

(i) "Postpartum" means the 1-year period beginning on the last day of a woman's pregnancy.

(j) "Severe maternal morbidity" means an unexpected outcome caused by a woman's labor and delivery which results in significant short-term or long-term consequences to the woman's health.

(k) "Technology-enabled collaborative learning and capacity building model" means a distance health care education model that connects health care professionals, particularly

specialists, with other health care professionals through simultaneous interactive videoconferencing for the purpose of facilitating case-based learning, disseminating best practices, and evaluating outcomes in the context of maternal health care.

(2) PURPOSE.—The purpose of the program ~~pilot programs~~ is to:

(a) Expand the use of technology-enabled collaborative learning and capacity building models to improve maternal health outcomes for the following populations and demographics:

1. Ethnic and minority populations.

2. Health professional shortage areas.

3. Areas with significant racial and ethnic disparities in maternal health outcomes and high rates of adverse maternal health outcomes, including, but not limited to, maternal mortality and severe maternal morbidity.

4. Medically underserved populations.

5. Indigenous populations.

(b) Provide for the adoption of and use of telehealth services that allow for screening and treatment of common pregnancy-related complications, including, but not limited to, anxiety, depression, substance use disorder, hemorrhage, infection, amniotic fluid embolism, thrombotic pulmonary or other embolism, hypertensive disorders relating to pregnancy, diabetes, cerebrovascular accidents, cardiomyopathy, and other cardiovascular conditions.

(3) TELEHEALTH SERVICES AND EDUCATION.—The program ~~pilot programs~~ shall adopt the use of telehealth or coordinate with prenatal home visiting programs to provide all of the following services and education to eligible pregnant women up to the last day of their postpartum periods, as applicable:

(a) Referrals to Healthy Start's coordinated intake and referral program to offer families prenatal home visiting services.

(b) Services and education addressing social determinants of health, including, but not limited to, all of the following:

1. Housing placement options.

2. Transportation services or information on how to access such services.

3. Nutrition counseling.

4. Access to healthy foods.

5. Lactation support.

6. Lead abatement and other efforts to improve air and water quality.

7. Child care options.

8. Car seat installation and training.

9. Wellness and stress management programs.

10. Coordination across safety net and social support services and programs.

(c) Evidence-based health literacy and pregnancy, childbirth, and parenting education for women in the prenatal

and postpartum periods.

(d) For women during their pregnancies through the postpartum periods, connection to support from doulas and other perinatal health workers.

(e) Tools for prenatal women to conduct key components of maternal wellness checks, including, but not limited to, all of the following:

1. A device to measure body weight, such as a scale.

2. A device to measure blood pressure which has a verbal reader to assist the pregnant woman in reading the device and to ensure that the health care practitioner performing the wellness check through telehealth is able to hear the reading.

3. A device to measure blood sugar levels with a verbal reader to assist the pregnant woman in reading the device and to ensure that the health care practitioner performing the wellness check through telehealth is able to hear the reading.

4. Any other device that the health care practitioner performing wellness checks through telehealth deems necessary.

(4) TRAINING.—The program ~~pilot programs~~ shall provide training to participating health care practitioners and other perinatal professionals on all of the following:

(a) Implicit and explicit biases, racism, and discrimination in the provision of maternity care and how to eliminate these barriers to accessing adequate and competent maternity care.

(b) The use of remote patient monitoring tools for pregnancy-related complications.

(c) How to screen for social determinants of health risks in the prenatal and postpartum periods, such as inadequate housing, lack of access to nutritional foods, environmental risks, transportation barriers, and lack of continuity of care.

(d) Best practices in screening for and, as needed, evaluating and treating maternal mental health conditions and substance use disorders.

(e) Information collection, recording, and evaluation activities to:

1. Study the impact of the ~~pilot~~ program;

2. Ensure access to and the quality of care;

3. Evaluate patient outcomes as a result of the pilot program;

4. Measure patient experience; and

5. Identify best practices for the future expansion of the ~~pilot~~ program.

(5) FUNDING.—The program ~~pilot programs~~ shall be funded using funds appropriated by the Legislature ~~for the Closing the Gap grant program~~. The department's Division of Community Health Promotion and Office of Minority Health and Health Equity shall also work in partnership to apply for federal funds that are available to assist the department in accomplishing the program's purpose and successfully implementing the program

through community-based organizations ~~pilot programs~~.

(6) RULES.—The department may adopt rules to implement this section.

Section 8. Paragraph (i) of subsection (3) of section 383.318, Florida Statutes, is amended to read:

383.318 Postpartum care for birth center clients and infants.—

(3) The birth center shall provide a postpartum evaluation and followup care that includes all of the following:

(i) Provision of the informational pamphlet on infant and childhood eye and vision disorders created by the department pursuant to s. 383.14(3)(h) ~~s. 383.14(3)(i)~~.

Section 9. Section 395.1053, Florida Statutes, is amended to read:

395.1053 Postpartum education.—A hospital that provides birthing services shall incorporate information on safe sleep practices and the possible causes of Sudden Unexpected Infant Death into the hospital's postpartum instruction on the care of newborns and provide to each parent the informational pamphlet on infant and childhood eye and vision disorders created by the department pursuant to s. 383.14(3)(h) ~~s. 383.14(3)(i)~~.

Section 10. Section 456.0496, Florida Statutes, is amended to read:

456.0496 Provision of information on eye and vision disorders to parents during planned out-of-hospital births.—A

health care practitioner who attends an out-of-hospital birth must ensure that the informational pamphlet on infant and childhood eye and vision disorders created by the department pursuant to s. 383.14(3)(h) ~~s. 383.14(3)(i)~~ is provided to each parent after such a birth.

Section 11. This act shall take effect July 1, 2024.

HB 1561

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1561 Office Surgeries
SPONSOR(S): Busatta Cabrera
TIED BILLS: **IDEN./SIM. BILLS:** SB 1188

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Guzzo	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The bill provides additional enforcement authority to the Department of Health (DOH) over offices in which physicians perform certain liposuction procedures including gluteal fat grafting procedures.

Current law requires a physician to register their office with DOH if they perform liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed. The bill requires them to register if the fat is temporarily or permanently removed, thus removing a loophole from registration because gluteal fat grafting procedures involve removing (temporarily) and then reinserting the fat in the patient.

The bill requires physicians to register their office with DOH if they perform gluteal fat grafting procedures. Additionally, the bill requires a physician to register their office with DOH if they perform a liposuction procedure in which the patient is rotated 180 degrees or more during the procedure.

Further, the bill requires physicians who have already registered their offices prior to July 1, 2024, to reregister their offices, in accordance with a schedule developed by DOH, if they perform gluteal fat grafting procedures, or if they perform liposuction procedures in which the patient is rotated 180 degrees or more. If during the reregistration process, DOH determines that the procedures being performed in such an office create a significant risk to patient safety and that the office should be licensed and regulated as an ASC, DOH must notify the Agency for Health Care Administration (AHCA) and AHCA must inspect the office to confirm that the office should be licensed as an ASC. If AHCA determines that the office should be licensed as an ASC, they must notify the office and DOH and the office must cease performing procedures that require registration. The office is prohibited from performing such procedures until it relinquishes its registration and obtains an ASC license. The bill requires DOH to complete reregistration by December 1, 2024.

Current law authorizes DOH to impose a fine of $5,000 per day on an unregistered physician office for performing a procedure that requires registration. The bill changes the fine to $5,000 per incident to allow DOH to fine a physician for multiple offenses committed during the same day.

The bill has an unknown, yet likely insignificant, negative fiscal impact on AHCA and no impact on local government.

The bill provides an effective date of “upon becoming a law.”

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Gluteal Fat Grafting

Gluteal fat grafting, commonly known as a "Brazilian butt lift" or BBL, is the fastest-growing plastic surgery procedure in the U.S. The procedure involves liposuction in areas where fat removal will improve the contour of the body. Typically, fat is harvested from two or more regions which may include the flanks (love handles), abdomen, or back. The harvested fat is purified to optimize the viability of fat cells and stem cells before it is injected into the subcutaneous layer (below the skin, but above the muscle) of the buttocks.[1]

The rate of fatal complications from gluteal fat grafting is higher than any other cosmetic procedure.[2] South Florida carries the highest BBL mortality rate by far in the nation with 25 deaths occurring between 2010 and 2022.[3] According to a study on the deaths that occurred in South Florida, the surgical setting and the short surgical times for these cases were the most significant contributing factors to the deaths.[4] Of the 25 deaths, 23 of the surgeries were performed at high-volume, low budget clinics. These clinics employ a practice model based on high-volume and minimal-patient-interaction. All of the deaths resulted from pulmonary fat embolism, which occurs when a vein wall is injured during the injection process allowing fat to enter the pulmonary vessels.[5]

Regulation of Office Surgeries

The Board of Medicine and the Board of Osteopathic Medicine (collectively, boards) have authority to adopt rules to regulate practice of medicine and osteopathic medicine, respectively.[6] The boards have authority to establish, by rule, standards of practice and standards of care for particular settings.[7] Such standards may include education and training, assistance of and delegation to other personnel, sterilization, performance of complex or multiple procedures, records, informed consent, and policy and procedures manuals.[8]

The boards establish the standards of care that must be met for office surgeries. An office surgery is any surgery that is performed outside a facility licensed under ch. 390, F.S., or ch. 395, F.S.[9] There are several levels of office surgeries governed by rules adopted by the boards, which establish the scope of each level of office surgeries, the equipment and medications that must be available, and the training requirements for personnel present during the surgery.

Registration

[1] O'Neill RC, Abu-Ghname A, Davis MJ, Chamata E, Rammos CK, Winocour SJ. *The Role of Fat Grafting in Buttock Augmentation*, Seminars in Plastic Surgery (February 15, 2020) available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7023974/#:~:text=First%2C%20fat%20is%20harvested%20from,figure%20with%20an%20augmented%20buttock (last visited January 18, 2024).
[2] Pat Pazmiño, Onelio Garcia, *Brazilian Butt Lift–Associated Mortality: The South Florida Experience*, Aesthetic Surgery Journal, Volume 43, Issue 2, February 2023, Pages 162–178, https://doi.org/10.1093/asj/sjac224 (last visited January 18, 2024).
[3] *Id.*
[4] *Id.*
[5] *Id.*
[6] Chapter 458, F.S., regulates the practice of allopathic medicine, and ch. 459, F.S., regulates the practice of osteopathic medicine.
[7] Ss. 458.331(v) and 459.015(z), F.S.
[8] *Id.*
[9] Rules 64B8-9.009(1)(d) and 64B15-14.007(1)(d), F.A.C. Abortion clinics are licensed under ch. 390, F.S., and facilities licensed under ch. 395, F.S., include hospitals, ASCs, mobile surgical facilities, and certain intensive residential treatment programs. Office surgery is a surgery performed at an office that primarily serves as the doctor's office where he or she regularly performs consultations, presurgical exams, and postoperative observation and care, and where patient medical records are maintained and available.

A physician is required to register their office with DOH to perform liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, a level II office surgery, or a level III office surgery.[10]

Each registered office must designate a physician who is responsible for complying with all laws and regulations establishing safety requirements for such offices.[11] The designated physician is required to notify DOH within 10 days of hiring any new recovery or surgical team personnel.[12] The office must notify DOH within 10 calendar days after the termination of a designated physician relationship.[13]

DOH must inspect any office where office surgeries will be done before the office is registered.[14] If the office refuses such inspection, it will not be registered until the inspection can be completed. If an office that has already been registered with DOH refuses inspection its registration will be immediately suspended and remain suspended until the inspection is completed, and the office must close for 14 days.[15]

DOH must inspect each registered office annually unless the office is accredited by a nationally recognized accrediting agency approved by the respective board. Such inspections may be unannounced.[16]

Currently, there are 723 offices registered with DOH.[17]

Standards of Care

Prior to performing any surgery, a physician must evaluate the risk of anesthesia and of the surgical procedure to be performed.[18] A physician must maintain a complete record of each surgical procedure, including the anesthesia record, if applicable, and written informed consent.[19] The written consent must reflect the patient's knowledge of identified risks, consent to the procedure, type of anesthesia and anesthesia provider, and that a choice of anesthesia provider exists.[20]

Physicians performing office surgeries must maintain a log of all liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed and Level II and Level III surgical procedures performed,[21] which includes:[22]

- A confidential patient identifier;
- The time the patient arrives in the operating suite;
- The name of the physician who provided medical clearance;
- The surgeon's name;
- The diagnosis;

[10] Ss. 458.328(1) and 459.0138(1), F.S.
[11] Rule 64B8-9.0091(1) and 64B15-14.0076(1), F.A.C.
[12] *Id.*
[13] *Id.*
[14] *Supra* note 10.
[15] *Id.*
[16] *Id.*
[17] Department of Health, *License Verification – Office Surgery Registration, Practicing Statuses Only*, March 21, 2023, available at https://mqa-internet.doh.state.fl.us/MQASearchServices/HealthCareProviders (last visited January 18, 2024).
[18] Rules 64B8-9.009(2) and 64B15-14.007(2), F.A.C.
[19] *Id.* A physician does not need to obtain written informed consent for minor Level I procedures limited to the skin and mucosa.
[20] *Id.* A patient may use an anesthesiologist, anesthesiologist assistant, another appropriately trained physician, certified registered nurse anesthetist, or physician assistant.
[21] Level I office surgeries involves the most minor of surgeries, which require minimal sedation or local or topical anesthesia, and have a remote chance of complications requiring hospitalization. Level II office surgeries involve moderate sedation and require the physician office to have a transfer agreement with a licensed hospital that is no more than 30 minutes from the office. Level IIA office surgeries are those Level II surgeries with a maximum planned duration of 5 minutes or less and in which chances of complications requiring hospitalization are remote. Level III office surgeries are the most complex and require deep sedation or general anesthesia. Rules 64B8-9.009(3)-(6) and 64B15-14.007(3)-(6), F.A.C.
[22] Rules 64B8-9.009(2)(c) and 64B15-14.007(2)(c), F.A.C.

- The CPT Codes for the procedures performed;
- The patient's ASA classification;
- The type of procedure performed;
- The level of surgery;
- The anesthesia provider;
- The type of anesthesia used;
- The duration of the procedure;
- The type of post-operative care;
- The duration of recovery;
- The disposition of the patient upon discharge;
- A list of medications used during surgery and recovery; and
- Any adverse incidents.

Such log must be maintained for at least six years from the last patient contact and must be provided to DOH investigators upon request.[23]

For elective cosmetic and plastic surgery procedures performed in a physician's office:[24]

- The maximum planned duration of all planned procedures cannot exceed eight hours.
- A physician must discharge the patient within 24 hours, and overnight stay may not exceed 23 hours and 59 minutes.
- The overnight stay is strictly limited to the physician's office.
- If the patient has not sufficiently recovered to be safely discharged within the 24-hour period, the patient must be transferred to a hospital for continued post-operative care.

Office surgeries are prohibited from:

- Resulting in blood loss greater than 10 percent of blood volume in a patient with normal hemoglobin;
- Requiring major or prolonged intracranial, intrathoracic, abdominal, or joint replacement procedures, excluding laparoscopy;
- Involving a major blood vessel with direct visualization by open exposure of the vessel, not including percutaneous endovascular treatment[25]; or
- Being emergent or life threatening.

Adverse Incident Reporting

A physician must report any adverse incident that occurs in an office practice setting to DOH within 15 days after the occurrence any adverse incident.[26] An adverse incident in an office setting is defined as an event over which the physician or licensee could exercise control and which is associated with a medical intervention and results in one of the following patient injuries:[27]

- The death of a patient;
- Brain or spinal damage to a patient;
- The performance of a surgical procedure on the wrong patient;
- If the procedure results in death; brain or spinal damage; permanent disfigurement; the fracture or dislocation of bones or joints; a limitation of neurological, physical, or sensory functions; or any condition that required the transfer of a patient, the performance of:
    - A wrong-site surgical procedure;
    - A wrong surgical procedure; or

[23] Id.
[24] Rules 64B8-9.009(2)(g) and 64B15-14.007(2)(g), F.A.C.
[25] Such treatment addresses conditions such as peripheral artery disease and other arterial blockages.
[26] Ss. 458.351 and 459.026, F.S.
[27] Ss. 458.351(4) and 459.026(4), F.S.

    - A surgical repair of damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented through the informed consent process;
- A procedure to remove unplanned foreign objects remaining from a surgical procedure; or
- Any condition that required the transfer of a patient to a hospital from an ASC or any facility or any office maintained by a physician for the practice of medicine which is not licensed under ch. 395, F.S.

DOH must review each adverse incident report to determine if discipline against the practitioner's license is warranted.[28]

Office Surgeries – Gluteal Fat Procedures

Current law establishes standards of practice for physicians performing gluteal fat grafting procedures in office surgery settings.

A physician providing gluteal fat grafting procedures must adhere to the standards of practice in statute and in rule. A physician or osteopathic physician performing such procedures must conduct an in-person exam of the patient, while physically present in the same room as the patient, no later than the day before the procedure.

Any duty delegated by the physician and performed during the gluteal fat grafting procedure must be completed under the direct supervision of the physician. Gluteal fat injections and fat extraction may not be delegated. Gluteal fat injections must be done under ultrasound guidance, or guidance with other technology authorized by rule that equals or exceeds the quality of ultrasound, to ensure the fat is injected into the subcutaneous space. Gluteal fat may only be injected into the subcutaneous space and may not cross the fascia covering gluteal muscle. Intramuscular and submuscular fat injections are prohibited.

Enforcement Authority

DOH may deny or revoke an office registration if any of its physicians, owners, or operators do not comply with any office surgery laws or rules. Also, DOH may deny a person applying for a facility registration if he or she was named in the registration document of an office whose registration is revoked for five years after the revocation date.

DOH may impose penalties on the designated physician if the registered office is not in compliance with safety requirements, including:[29]

- Suspension or permanent revocation of a license;
- Restriction of license;
- Imposition of 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, or the department if there is no board, must impose a fine of $10,000 per count or offense.;
- Issuance of a reprimand or letter of concern.
- Placement of the licensee on probation for a period of time and subject to such conditions as the board;
- Corrective action;
- Imposition of an administrative fine in accordance with s. 381.0261 for violations regarding patient rights;
- Refund of fees billed and collected from the patient or a third party on behalf of the patient; or
- Requirement that the licensee undergo remedial education.

[28] Ss. 458.351(5) and 459.026(5), F.S.
[29] S. 456.072(2), F.S.

DOH can also issue an emergency order suspending or restricting the registration of a facility if there is probable cause that:

- The office or its physicians are not in compliance with the board rule on the standards of practice; or
- The licensee or registrant is practicing or offering to practice beyond the scope allowed by law or beyond his or her competence to perform; and
- Such noncompliance constitutes an immediate danger to the public.

The boards must adopt rules establishing the standards of practice for physicians who perform office surgery. The boards must fine physicians who perform office surgeries in an unregistered facility $5,000 per day. Lastly, performing office surgery in a facility that is not registered with DOH is grounds for disciplinary action against a physician's license.

In 2023, the Legislature provided further enforcement authority to DOH and the boards to regulate offices in which certain liposuction procedures and office surgeries.[30]

Ambulatory Surgical Centers

An ambulatory surgical center (ASC) is a facility, that is not a part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within 24 hours.[31] If a provider anticipates or knows that they will be discharging patients beyond 24 hours, they must self-designate as an ASC by applying for ASC licensure with the Agency for Health Care Administration (AHCA).[32]

ASCs are licensed and regulated by AHCA under the same regulatory framework as hospitals.[33] Currently, there are 520 licensed ASCs in Florida.[34]

Effect of the Bill

Current law requires a physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed to register his or her office with DOH. The bill requires physicians to register if the fat is temporarily or permanently removed, thus removing a loophole from registration because gluteal fat grafting procedures involve temporarily removing the fat and then reinserting it into the patient.

The bill requires physicians to register their office with DOH if they perform gluteal fat grafting procedures. Additionally, the bill requires a physician to register their office with DOH if they perform a liposuction procedure in which the patient is rotated 180 degrees or more during the procedure.

Further, the bill requires physicians who have already registered their offices prior to July 1, 2024, to reregister their offices, in accordance with a schedule developed by DOH, if they perform gluteal fat grafting procedures, or if they perform liposuction procedures in which the patient is rotated 180 degrees or more. The bill requires DOH to complete reregistration by December 1, 2024.

If during the reregistration process, DOH determines that the procedures being performed in such an office create a significant risk to patient safety and that the office should be licensed and regulated as an ASC, DOH must notify AHCA and AHCA must inspect the office to confirm whether the office should be licensed as an ASC. If AHCA determines that the office should be licensed as an ASC, they must notify the office and DOH and the office must cease performing procedures that require registration. The office is prohibited from performing such procedures until it relinquishes its registration and obtains an ASC license.

[30] Ch.23-307, Laws of Fla.
[31] S. 395.002(3), F.S.
[32] Agency for Health Care Administration, Agency Analysis of HB 1561 (Jan. 18, 2024).
[33] SS. 395.001-.1065, F.S., and Part II, Chapter 408, F.S.
[34] *Supra* note 32.

Current law authorizes DOH to impose a fine of $5,000 per day on an unregistered physician office for performing a procedure that requires registration. The bill changes the fine to $5,000 per incident to allow DOH to fine a physician for multiple offenses committed during the same day.

The bill provides an effective date of "upon becoming a law."

B. SECTION DIRECTORY:

Section 1: Amends s. 458.328, F.S., relating to office surgeries.
Section 2: Amends s. 459.0138, F.S., relating to office surgeries.
Section 3: In an unnumbered section of law, requires DOH to develop a schedule for reregistration of medical offices affected by the bill, to be completed by a specified date.
Section 4: Provides an effective date of "upon becoming a law."

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill has an unknown, yet likely insignificant, negative fiscal impact on AHCA for additional staff to conduct survey inspections of physician offices. According to AHCA, the number of additional surveys is unknown, so it is unknown if additional staff would be needed to cover the workload.[35]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

[35] *Id.*

DOH has sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to office surgeries; amending ss. 458.328 and 459.0138, F.S.; revising the types of procedures for which a medical office must register with the Department of Health to perform office surgeries; deleting obsolete language; making technical and clarifying changes; revising standards of practice for office surgeries; requiring medical offices already registered with the department to perform certain office surgeries as of a specified date to reregister if such offices perform specified procedures; specifying notification and inspection procedures for the department and the Agency for Health Care Administration in the event that, during the reregistration process, the department determines that the performance of specified procedures in an office creates a risk of patient safety such that the office should instead be regulated as an ambulatory surgical center; requiring an office to cease performing the specified procedures and relinquish its office surgery registration and instead seek licensure as an ambulatory surgical center under such circumstances; requiring the department to develop a schedule for reregistration of medical offices affected by this act, to be completed by a specified

date; providing an effective date.

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

Section 1. Paragraphs (a), (b), and (h) of subsection (1) and subsection (2) of section 458.328, Florida Statutes, are amended, and subsection (4) is added to that section, to read:

458.328 Office surgeries.—

(1) REGISTRATION.—

(a)1. An office in which a physician performs a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is temporarily or permanently removed, a liposuction procedure in which the patient is rotated 180 degrees or more during the procedure, a gluteal fat grafting procedure, a Level II office surgery, or a Level III office surgery must register with the department. ~~unless the office is licensed as~~ A facility licensed under chapter 390 or chapter 395 may not be registered under this section.

2. The department must complete an inspection of any office seeking registration under this section before the office may be registered.

(b) ~~By January 1, 2020,~~ Each office registered under this section or s. 459.0138 must designate a physician who is responsible for the office's compliance with the office health and safety requirements of this section and rules adopted

hereunder. A designated physician must have a full, active, and unencumbered license under this chapter or chapter 459 and shall practice at the office for which he or she has assumed responsibility. Within 10 calendar days after the termination of a designated physician relationship, the office must notify the department of the designation of another physician to serve as the designated physician. The department may suspend the registration of an office if the office fails to comply with the requirements of this paragraph.

~~(h) A physician may only perform a procedure or surgery identified in paragraph (a) in an office that is registered with the department. The board shall impose a fine of $5,000 per day on a physician who performs a procedure or surgery in an office that is not registered with the department.~~

(2) STANDARDS OF PRACTICE.—

(a) A physician may not perform any surgery or procedure identified in paragraph (1)(a) in a setting other than an office registered under this section or a facility licensed under chapter 390 or chapter 395, as applicable. The board shall impose a fine of $5,000 per incident on a physician who violates this paragraph ~~performing a gluteal fat grafting procedure in an office surgery setting shall adhere to standards of practice pursuant to this subsection and rules adopted by the board~~.

(b) Office surgeries may not:

1. Be a type of surgery that generally results in blood

loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin level;

2. Require major or prolonged intracranial, intrathoracic, abdominal, or joint replacement procedures, except for laparoscopic procedures;

3. Involve major blood vessels and be performed with direct visualization by open exposure of the major blood vessel, except for percutaneous endovascular intervention; or

4. Be emergent or life threatening.

(c) A physician performing a gluteal fat grafting procedure in an office surgery setting shall adhere to standards of practice under this subsection and rules adopted by the board, which include, but are not limited to, all of the following:

1. A physician performing a gluteal fat grafting procedure must conduct an in-person examination of the patient while physically present in the same room as the patient no later than the day before the procedure.

2. Before a physician may delegate any duties during a gluteal fat grafting procedure, the patient must provide written, informed consent for such delegation. Any duty delegated by a physician during a gluteal fat grafting procedure must be performed under the direct supervision of the physician performing such procedure. Fat extraction and gluteal fat injections must be performed by the physician and may not be

delegated.

3. Fat may only be injected into the subcutaneous space of the patient and may not cross the fascia overlying the gluteal muscle. Intramuscular or submuscular fat injections are prohibited.

4. When the physician performing a gluteal fat grafting procedure injects fat into the subcutaneous space of the patient, the physician must use ultrasound guidance, or guidance with other technology authorized under board rule which equals or exceeds the quality of ultrasound, during the placement and navigation of the cannula to ensure that the fat is injected into the subcutaneous space of the patient above the fascia overlying the gluteal muscle. Such guidance with the use of ultrasound or other technology is not required for other portions of such procedure.

5. An office in which a physician performs gluteal fat grafting procedures must at all times maintain a ratio of one physician to one patient during all phases of the procedure, beginning with the administration of anesthesia to the patient and concluding with the extubation of the patient. After a physician has commenced, and while he or she is engaged in, a gluteal fat grafting procedure, the physician may not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.

(d) If a procedure in an office surgery setting results in

hospitalization, the incident must be reported as an adverse incident pursuant to s. 458.351.

~~(c) An office in which a physician performs gluteal fat grafting procedures must at all times maintain a ratio of one physician to one patient during all phases of the procedure, beginning with the administration of anesthesia to the patient and concluding with the extubation of the patient. After a physician has commenced, and while he or she is engaged in, a gluteal fat grafting procedure, the physician may not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.~~

(4) REREGISTRATION.—An office that registered under this section before July 1, 2024, in which a physician performs liposuction procedures that include a patient being rotated 180 degrees or more during the procedure or in which a physician performs gluteal fat grafting procedures must seek reregistration with the department consistent with the parameters of initial registration under subsection (1) according to a schedule developed by the department. During the reregistration process, if the department determines that the performance of such procedures in the office creates a significant risk to patient safety and that the interests of patient safety would be better served if such procedures were instead regulated under the requirements of ambulatory surgical center licensure under chapter 395:

(a) The department must notify the Agency for Health Care Administration of its determination;

(b) The agency must inspect the office and determine, in the interest of patient safety, whether the office is a candidate for ambulatory surgical center licensure notwithstanding the office's failure to meet all requirements associated with such licensure at the time of inspection and notwithstanding the exceptions provided under s. 395.002(3).

If the agency determines that an office is a candidate for ambulatory surgical center licensure under paragraph (b), the agency must notify the office and the department, and the office must cease performing procedures described in this subsection. The office may not recommence performing such procedures without first relinquishing its registration under this section and attaining ambulatory surgery center licensure under chapter 395.

Section 2. Paragraphs (a), (b), and (h) of subsection (1) and subsection (2) of section 459.0138, Florida Statutes, are amended, and subsection (4) is added to that section, to read:

459.0138 Office surgeries.—

(1) REGISTRATION.—

(a)1. An office in which a physician performs a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is temporarily or permanently removed, a liposuction procedure in which the patient is rotated 180

degrees or more during the procedure, a gluteal fat grafting procedure, a Level II office surgery, or a Level III office surgery must register with the department. ~~unless the office is licensed as~~ A facility licensed under chapter 390 or chapter 395 may not be registered under this section.

2. The department must complete an inspection of any office seeking registration under this section before the office may be registered.

(b) ~~By January 1, 2020,~~ Each office registered under this section or s. 458.328 must designate a physician who is responsible for the office's compliance with the office health and safety requirements of this section and rules adopted hereunder. A designated physician must have a full, active, and unencumbered license under this chapter or chapter 458 and shall practice at the office for which he or she has assumed responsibility. Within 10 calendar days after the termination of a designated physician relationship, the office must notify the department of the designation of another physician to serve as the designated physician. The department may suspend a registration for an office if the office fails to comply with the requirements of this paragraph.

~~(h) A physician may only perform a procedure or surgery identified in paragraph (a) in an office that is registered with the department. The board shall impose a fine of $5,000 per day on a physician who performs a procedure or surgery in an office~~

~~that is not registered with the department.~~

(2) STANDARDS OF PRACTICE.—

(a) A physician may not perform any surgery or procedure identified in paragraph (1)(a) in a setting other than an office registered under this section or a facility licensed under chapter 390 or chapter 395, as applicable. The board shall impose a fine of $5,000 per incident on a physician who violates this paragraph ~~performing a gluteal fat grafting procedure in an office surgery setting shall adhere to standards of practice pursuant to this subsection and rules adopted by the board~~.

(b) Office surgeries may not:

1. Be a type of surgery that generally results in blood loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin level;

2. Require major or prolonged intracranial, intrathoracic, abdominal, or joint replacement procedures, except for laparoscopic procedures;

3. Involve major blood vessels and be performed with direct visualization by open exposure of the major blood vessel, except for percutaneous endovascular intervention; or

4. Be emergent or life threatening.

(c) A physician performing a gluteal fat grafting procedure in an office surgery setting shall adhere to standards of practice under this subsection and rules adopted by the board, which include, but are not limited to, all of the

following:

1. A physician performing a gluteal fat grafting procedure must conduct an in-person examination of the patient while physically present in the same room as the patient no later than the day before the procedure.

2. Before a physician may delegate any duties during a gluteal fat grafting procedure, the patient must provide written, informed consent for such delegation. Any duty delegated by a physician during a gluteal fat grafting procedure must be performed under the direct supervision of the physician performing such procedure. Fat extraction and gluteal fat injections must be performed by the physician and may not be delegated.

3. Fat may only be injected into the subcutaneous space of the patient and may not cross the fascia overlying the gluteal muscle. Intramuscular or submuscular fat injections are prohibited.

4. When the physician performing a gluteal fat grafting procedure injects fat into the subcutaneous space of the patient, the physician must use ultrasound guidance, or guidance with other technology authorized under board rule which equals or exceeds the quality of ultrasound, during the placement and navigation of the cannula to ensure that the fat is injected into the subcutaneous space of the patient above the fascia overlying the gluteal muscle. Such guidance with the use of

ultrasound or other technology is not required for other portions of such procedure.

5. An office in which a physician performs gluteal fat grafting procedures must at all times maintain a ratio of one physician to one patient during all phases of the procedure, beginning with the administration of anesthesia to the patient and concluding with the extubation of the patient. After a physician has commenced, and while he or she is engaged in, a gluteal fat grafting procedure, the physician may not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.

(d) If a procedure in an office surgery setting results in hospitalization, the incident must be reported as an adverse incident pursuant to s. 458.351.

~~(e) An office in which a physician performs gluteal fat grafting procedures must at all times maintain a ratio of one physician to one patient during all phases of the procedure, beginning with the administration of anesthesia to the patient and concluding with the extubation of the patient. After a physician has commenced, and while he or she is engaged in, a gluteal fat grafting procedure, the physician may not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.~~

(4) REREGISTRATION.—An office that registered under this section before July 1, 2024, in which a physician performs

liposuction procedures that include a patient being rotated 180 degrees or more during the procedure or in which a physician performs gluteal fat grafting procedures must seek reregistration with the department consistent with the parameters of initial registration under subsection (1) according to a schedule developed by the department. During the reregistration process, if the department determines that the performance of such procedures in the office creates a significant risk to patient safety and that the interests of patient safety would be better served if such procedures were instead regulated under the requirements of ambulatory surgical center licensure under chapter 395:

(a) The department must notify the Agency for Health Care Administration of its determination;

(b) The agency must inspect the office and determine, in the interest of patient safety, whether the office is a candidate for ambulatory surgical center licensure notwithstanding the office's failure to meet all requirements associated with such licensure at the time of inspection and notwithstanding the exceptions provided under s. 395.002(3).

If the agency determines that an office is a candidate for ambulatory surgical center licensure under paragraph (b), the agency must notify the office and the department, and the office must cease performing procedures described in this subsection.

The office may not recommence performing such procedures without first relinquishing its registration under this section and attaining ambulatory surgery center licensure under chapter 395.

Section 3. The Department of Health shall develop a schedule for reregistration of offices affected by the amendments made to s. 458.328(1) or s. 459.0138(1), Florida Statutes, by this act. Registration of all such offices must be completed by December 1, 2024.

Section 4. This act shall take effect upon becoming a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1609 Pregnancy Support Services
SPONSOR(S): Stevenson
TIED BILLS: **IDEN./SIM. BILLS:** SB 1442

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Osborne	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Social determinants of health are the external factors of a person's life that impact their health. These are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. Housing is an important social determinant of health.

The US is in the midst of a housing affordability crisis. Income growth has not kept up with rising housing costs, and the overall housing market has not responded adequately to the need for affordable housing. The national crisis is being acutely felt in Florida, with low-income renters being especially vulnerable to the rising cost of housing.

In 2022, there were 224,611 recorded births in Florida. Healthy pregnancies and childbirth are foundational to healthy families and communities. Nonetheless, pregnancy remains an essential but often dangerous experience with the potential for many avoidable complications. Maternal and infant health outcomes are an important marker of the overall health of a society. Florida's expecting mothers are not exempt from the state's affordable housing crisis. While the long-term effects of housing instability are detrimental to all who experience it, the impact on pregnant women is especially acute. Homelessness during pregnancy poses significant health risks for mothers and infants.

HB 1609 creates the Florida State Maternity Housing Grant Program within the Department of Health (DOH). The bill states the intent of the Legislature to provide housing resources to resident women and families during the prenatal period, regardless of age or marital status, whose financial resources have been determined inadequate to meet residential costs.

The bill outlines expenses which grant funds may be allocated toward, and directs DOH to make rules for the implementation of the grant. The bill specifies that the total amount of grants awarded by DOH may not exceed the funding appropriated for the grant program.

The bill grants DOH rulemaking authority to adopt rules necessary for the administration of the program.

The provisions of the bill are subject to appropriation; the bill has an indeterminant, negative fiscal impact on DOH. The bill has no fiscal impact on local governments.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Social Determinants of Health

Social determinants of health (SDOH) are the external factors of a person's life that impact their health. These are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

There are five main categories of SDOH:[1]

- Economic stability;
- Education access and quality;
- Health care access and quality;
- Neighborhood and built environment; and
- Social and community context.

SDOH influence a persons' health in several ways. Some SDOH have causal relationships that are clear and relatively direct; for example, the presence of mold, or poor air and water quality, are part of the built environment that a person lives in and while consequences may be delayed, the causal relationship is easily established.[2] Living in such environmental conditions are often influenced by other SDOH, such as economic stability and community context where the connections to health outcomes are evident, but less easily conceptualized.[3]

Some aspects of health are especially sensitive to the environments that a person find themselves in.

Housing Insecurity

Housing is an important social determinant of health. The lack of housing, or poor-quality housing, negatively affects a person's health and well-being. Tangible housing defects resulting from damp and mold, unregulated indoor temperatures, overcrowding, and safety factors have a clear impact on physical and mental health. There are also pronounced psychosocial benefits to the concept of "home," which are tied to the social values of housing as reflecting stability, control, autonomy, status, and empowerment. Such qualities have a significant impact on a person's mental health and long-term stability.[4]

The US is in the midst of a housing affordability crisis.[5] Income growth has not kept up with rising housing costs, and the overall housing market has not responded adequately to the need for affordable housing. The national crisis is being acutely felt in Florida, with one survey showing that 25 percent of Floridians identifying "housing costs," as the most important problem facing Florida today.[6]

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[1] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, *Social Determinants of Health*. Available at https://health.gov/healthypeople/priority-areas/social-determinants-health (last visited January 21, 2024).
[2] Braubach, M., Jacobs, D.E., & Ormandy, D. *Environmental burden of disease associated with inadequate housing: a method guide to the quantification of health effects of selected housing risks in the WHO European Region*. (2011). World Health Organization. Regional Office for Europe. https://iris.who.int/handle/10665/108587
[3] Braveman, P., & Gottlieb, L. *The social determinants of health: it's time to consider the causes of the causes*. (2014) Public health reports, *129:2*, 19–31. https://doi.org/10.1177/00333549141291S206
[4] Rolfe, S., Garnham, L., Godwin, J. et al. *Housing as a social determinant of health and wellbeing: developing an empirically-informed realist theoretical framework* (2020). BMC Public Health 20, 1138. https://doi.org/10.1186/s12889-020-09224-0
[5] Desmond, M. *Unaffordable America: Poverty, Housing, and Eviction* (2022). American Journal of Sociology. In The Affordable Housing Reader (pp. 389-395). https://doi.org/10.4324/9780429299377-34
[6] University of North Florida, Public Opinion Research Lab, *Florida Republican Presidential Primary Polling* (2023). Available at https://www.unfporl.org/uploads/1/4/4/5/144559024/unf_mar_statewide_2023_ada.pdf (last visited January 21, 2024).

The precise cause of the shortage of affordable housing is complex and multi-faceted, but it is an issue felt by would-be homebuyers and renters alike. In Florida, the median single-family home prices are approaching the boom-era costs of the mid-2000s; between 2011 and 2022, the median home price has risen 91 percent. Meanwhile, the situation in the rental market is dire for low-income renters. The state has added hundreds of thousands of rental units in the last decade, but simultaneously lost "affordable"[7] rental units.[8] Many low-income renters pay more than 40 percent of their income for housing, and there are only 26 affordable and available rental units for every 100 households with an extremely low income.[9]

As a result, more families and individuals are finding themselves in precarious housing situations.[10] Nationally, 5.52 million renter households reported being behind on their rent payment, with 1.87 million fearing imminent eviction in August 2023.[11]

While the majority of people experiencing homelessness are men, women and families constitute the fastest-growing segment of the homeless population.[12] Black and Hispanic women, particularly single mothers with children, are at the highest risk for housing insecurity. Women experiencing housing insecurity report barriers to health care generally, and as such tend to lack access to adequate contraceptive methods.[13]

Pregnancy Outcomes

In 2022, there were 224,611 recorded births in Florida.[14] Healthy pregnancies and childbirth are foundational to healthy families and communities. Nonetheless, pregnancy remains an essential but often dangerous experience with the potential for many avoidable complications.[15] Maternal and infant health outcomes are an important marker of the overall health of a society.

Maternal Health Outcomes

Maternal mortality refers to deaths occurring during pregnancy or within 42 days of the end of pregnancy, regardless of the duration of the pregnancy, from any cause related to or aggravated by the pregnancy, but not from accidental or incidental causes.[16] In 2021, more than 1,200 women died of maternal causes in the United States compared with 861 in 2020 and 754 in 2019.[17] The national maternal mortality rate for 2021 was 32.9 deaths per 100,000 live births.[18] Racial and ethnic gaps exist between non-Hispanic black, non-Hispanic white, and Hispanic women. The maternal mortality rate of these groups is 69.9, 26.6, and 28.0 deaths per 100,000 live births, respectively.[19]

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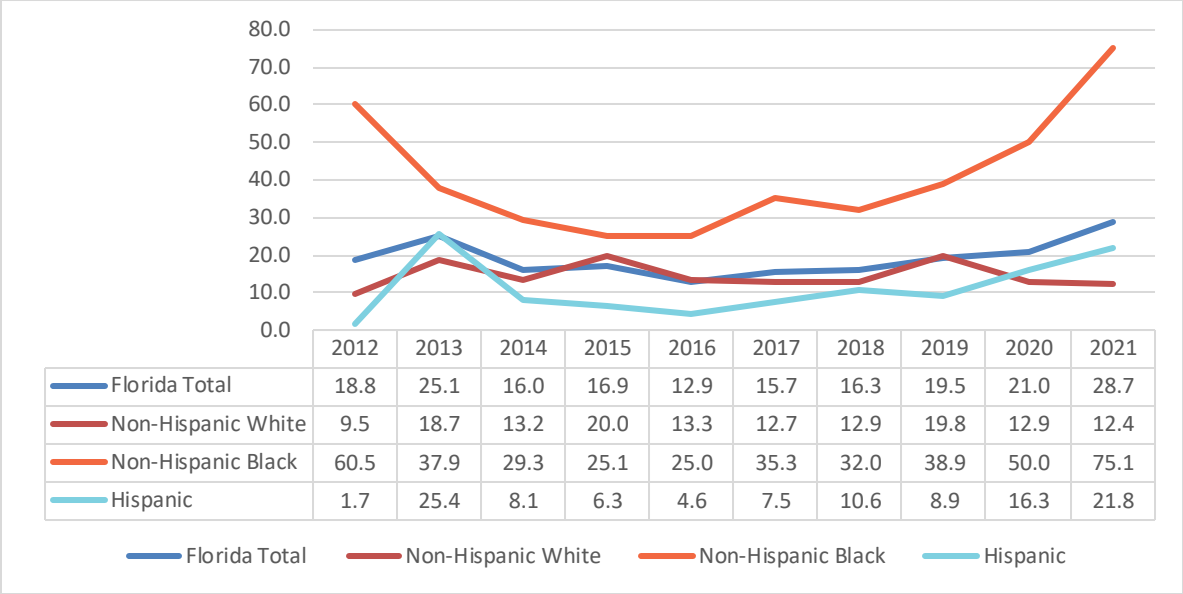
[7] "Affordable" rental units mean those renting for $1,000 or less per month.
[8] University of Florida, Shimberg Center for Housing Studies. *Florida Affordable Housing Trends* (2022). Available at http://www.shimberg.ufl.edu/publications/FL_presentation_121422.pdf (last visited January 22, 2024).
[9] *Id.*
[10] Greene, S., Richardson, T., Bryon, J., & Cho, R. *Rise in homelessness averted amidst worsening housing needs in 2021. What does this tell us about how to end homelessness in the U.S.?* (2023). HUD User. Available at https://www.huduser.gov/portal/pdredge/pdr-edge-frm-asst-sec-082223.html (last visited January 22, 2024).
[11] *Id.*
[12] Welch-Lazoritz, M.L., Whitbeck, L.B., & Armenta, B.E. *Characteristics of mothers caring for children during episodes of homelessness*. (2015). Community Ment Health J. 51(8):913-920. doi: 10.1007/s10597-014-9794-8
[13] Kozlowski, Z., Sanders, J.N., Panushka, K., Myers, K., Millar, M.M., & Gawron, L.M. *"It's a Vicious Cycle": A Mixed Methods Study of the Role of Family Planning in Housing Insecurity for Women* (2022). *Journal of Health Care for the Poor and Underserved 33*(1), 104-119. https://doi.org/10.1353/hpu.2022.0009
[14] FL Health Charts, *Birth Counts Query System*. Available at https://www.flhealthcharts.gov/FLQUERY_New/Birth/Count (last visited January 9, 2024).
[15] Hernandez, L., Thompson, A., & Burch, D. *Florida's Pregnancy-Associated Mortality Review 2015 Update* (2017). Florida Department of Health. Available at http://www.floridahealth.gov/statistics-and-data/PAMR/pamr-2015-update.pdf (last visited January 22, 2024).
[16] U.S. Dep't of Health and Human Services, *The Surgeon General's Call to Action to Improve Maternal Health* (2020). Available at https://www.hhs.gov/sites/default/files/call-to-action-maternal-health.pdf (last visited December 5, 2023).
[17] Donna L. Hoyert, Ph.D., Division of Vital Statistics, National Center for Health Statistics, *Maternal Mortality Rates in the United States, 2021,* (March 2023). Available at https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.pdf https://www.cdc.gov/reproductivehealth/maternal-mortality/index.html (last visited January 8, 2024).
[18] *Id.*
[19] *Id.*

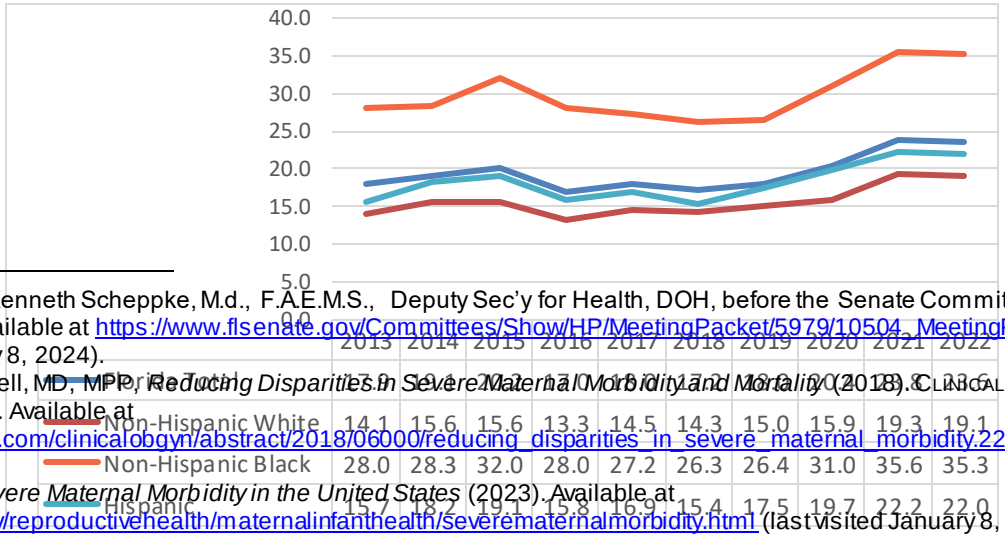
Although Florida's maternal mortality rate is lower than the national rate, it has been increasing in recent years. As of 2021, the maternal mortality rate in Florida is 28.7 deaths per 100,000 live births, an increase from a low of 12.9 deaths per 100,000 live births in 2016.[20] Similar to the national trend, racial and ethnic disparities exist in the maternal mortality rates in Florida as evidenced in the following chart:



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Florida Total	18.8	25.1	16.0	16.9	12.9	15.7	16.3	19.5	21.0	28.7
Non-Hispanic White	9.5	18.7	13.2	20.0	13.3	12.7	12.9	19.8	12.9	12.4
Non-Hispanic Black	60.5	37.9	29.3	25.1	25.0	35.3	32.0	38.9	50.0	75.1
Hispanic	1.7	25.4	8.1	6.3	4.6	7.5	10.6	8.9	16.3	21.8

For every maternal death, 100 women suffer a severe obstetric morbidity, a life-threatening diagnosis, or undergo a lifesaving procedure during their delivery hospitalization.[21] Severe maternal morbidity (SMM) includes unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman's health. SMM has been steadily increasing in recent years.[22]
The consequences of the increasing SMM prevalence, in addition to the health effects for the woman, are wide-ranging and include increased medical costs and longer hospitalization stays.[23]

From 2013 to 2022, there were 51,454 cases of SMM among delivery hospitalization in Florida.[24] Similar to maternal mortality rates, rates of SMM are higher in racial and ethnic minority women.[25] The following figure shows the trend over time for SMM rates in Florida per 1,000 delivery hospitalizations:[26]



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Non-Hispanic White	14.1	15.6	15.6	13.3	14.5	14.3	15.0	15.9	19.3	19.1
Non-Hispanic Black	28.0	28.3	32.0	28.0	27.2	26.3	26.4	31.0	35.6	35.3
Hispanic	15.7	18.2	19.1	15.8	16.9	15.4	17.5	19.7	22.2	22.0

[20] Presentation by Kenneth Scheppke, M.d., F.A.E.M.S., Deputy Sec'y for Health, DOH, before the Senate Committee on Health Policy (Nov. 14, 2023), available at https://www.flsenate.gov/Committees/Show/HP/MeetingPacket/5979/10504_MeetingPacket_5979_4.pdf (last visited January 8, 2024).
[21] Elizabeth A. Howell, MD, MPP, *Reducing Disparities in Severe Maternal Morbidity and Mortality* (2018). CLINICAL OBSTETRICS AND GYNECOLOGY, 61(2). Available at https://journals.lww.com/clinicalobgyn/abstract/2018/06000/reducing_disparities_in_severe_maternal_morbidity.22.aspx (last visited January 8, 2024).
[22] *Id.,* and CDC, *Severe Maternal Morbidity in the United States* (2023). Available at https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html (last visited January 8, 2024).
[23] CDC, *Severe Maternal Morbidity in the United States* (2023). Available at https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html (last visited January 8, 2024).
[24] Presentation by Kenneth Scheppke, M.D., F.A.E.M.S., Deputy Sec'y for Health, DOH, before the Senate Committee on Health Policy (Nov. 14, 2023). Available at https://www.flsenate.gov/Committees/Show/HP/MeetingPacket/5979/10504_MeetingPacket_5979_4.pdf (last visited January 8, 2024).
[25] *Supra*, note 21.
[26] *Id.*

The consequences of maternal death and severe maternal morbidity are felt throughout a community. High rates of maternal death are associated with infant and child mortality, loss of economic opportunities, and cycles of poverty extending from the family into the broader community.[27]

Infant Health Outcomes

Infant mortality is the death of an infant before the first birthday. The infant mortality rate is the number of infant deaths for every 1,000 live births. DOH reports annually on fetal and infant deaths through the Florida Vital Statistics Annual Report.[28] This report provides the number of fetal deaths per 1,000 live births, the number of deaths by race, and compares that data to national figures. Florida ranks 19th in the nation in infant mortality with a rate of 5.9 deaths per 1,000 live births (1,275 in 2021).[29]

In Florida, the leading causes of infant mortality, per 1,000 live births, are:[30]

- Birth defects;
- Preterm and low birth weight;
- Unintentional injuries;
- Maternal complications of pregnancy;
- Complications of placenta, cord, and membranes; and
- Sudden Infant Death Syndrome.

The relationship between infant health outcomes and adequate prenatal care is well established. Adequate prenatal care frequently throughout a pregnancy can help to detect risks before they manifest dangerously, and can help women to manage both pregnancy and non-pregnancy related health conditions.[31] This is especially important for marginalized populations for whom access to health care services before pregnancy may have been limited. Adequate prenatal care is closely associated with improved birth weight and reduced rate of preterm births.[32]

Housing Insecurity and Pregnancy Outcomes

Florida's expecting mothers are not exempt from the state's affordable housing crisis. While the long-term effects of housing instability are detrimental to all who experience it, the impact on pregnant women is especially acute. Homelessness during pregnancy poses significant health risks for mothers and infants.

Extreme housing insecurity, in the form of homelessness or threatened eviction, among pregnant women is tied to significant pre-birth risk factors. This population is significantly more likely to have comorbidities and higher-risk pregnancies, including higher rates of substance use disorder and major mental health disorders.[33] The need for adequate perinatal health care is heightened for women with high-risk pregnancies, but pregnant women experiencing homelessness report barriers to prenatal

[27] Miller, S., & Belizán, J. M. *The true cost of maternal death: individual tragedy impacts family, community and nations* (2015). Reproductive Health, 12(1), 56–56. https://doi.org/10.1186/s12978-015-0046-3
[28] Florida Department of Health, *Florida Vital Statistics Annual Report 2020*. Available at http://www.flpublichealth.com/VSbook/PDF/2020/Fetal.pdf (last visited January 22, 2024).
[29] Id. *See also* Centers for Disease Control and Prevention, *Infant Mortality Rates by State* (2019). Available at https://www.cdc.gov/nchs/pressroom/sosmap/infant_mortality_rates/infant_mortality.htm (last visited Jan. 12, 2022).
[30] Presentation by Shay Chapman, BSN, MBA, Deputy Division Director, Community Health Promotion, Sept. 21, 2021 meeting of the Professions and Public Health Subcommittee. Available at https://www.myfloridahouse.gov/Sections/Documents/loaddoc.aspx?PublicationType=Committees&CommitteeId=3093&Session=2022&DocumentType=Meeting+Packets&FileName=pph+9-21-21.pdf (last visited January 22, 2024).
[31] Shah, J. S., Revere, F. L., & Toy, E. C. *Improving Rates of Early Entry Prenatal Care in an Underserved Population* (2018). Maternal & Child Health Journal, 22(12), 1738–1742. https://doi-org.proxy.lib.fsu.edu/10.1007/s10995-018-2569-z
[32] Alexander, G.R. & Kotelchuck, M. *Assessing the Role and Effectiveness of Prenatal Care: History, Challenges, and Directions for Future Research* (2001). Public Health Reports (1974-), 116(4), 306.
[33] Huang, K., Waken, R.J., Luke, A., Carter, E., Lindley, K., & Maddox, K. *Risk of Delivery Complications Among Pregnant People Experiencing Housing Insecurity* (2023). American Journal of Obstetrics & Gynecology, 5:2, https://doi.org/10.1016/j.ajogmf.2022.100819

health care, and lower rates of adequate prenatal care utilization, further increasing their risk of adverse birth outcomes.[34]

Women experiencing extreme housing insecurity experience worse birth outcomes than their securely housed counterparts, with higher rates of preterm birth and severe maternal morbidity.[35] Infants born to mothers experiencing homelessness or threatened eviction are at a significantly higher risk of being born preterm or with a low birth weight, require stays in neonatal intensive care units, and extended hospital stays after delivery.[36] More complex births and extended hospital stays lead to higher delivery-associated costs for this financially insecure population.[37]

Effect of the Bill

HB 1609 establishes the Florida State Maternity Housing Grant Program within DOH. The bill states the intent of the Legislature to provide housing resources to resident women and families during the prenatal period, regardless of age or marital status, whose financial resources have been determined inadequate to meet residential costs.

The bill outlines the types of expenses for which grant funding may be used, including:

- Housing in an authorized living arrangement for a period of time determined by the mother's due date;
- Services recommended by DOH to encourage economic independence and positive health outcomes;
- Staffing and reimbursements for housing providers; and
- All other costs related to the administration of the program, not to exceed 5 percent of the total grant funds.

The bill specifies that the total amount of grants awarded by DOH may not exceed the funding appropriated for the grant program.

The bill grants DOH rulemaking authority to adopt rules necessary for the administration of the program. The bill does not restrict the rules that DOH may adopt to administer the program, but provides that DOH may adopt rules pursuant to the following:

- A framework for the payment or reimbursement for expenses related to the "authorized living arrangement;"
- Eligibility criteria for expecting mothers and families seeking maternity housing services;
- Requirements for maternity housing grant applications; and
- Guidelines for assessing the appropriateness of living situations and the determination of approval.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Creates s. 381.97, F.S., relating to the Florida State Maternity Housing Grant Program.
Section 2: Provides an effective date of July 1, 2024.

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[34] DiTosto, J., Holder, K., Soyemi, E., Beestrum, M., & Yee, L. *Housing Instability and Adverse Perinatal Outcomes: A Systematic Review* (2021). American Journal of Obstetrics & Gynecology, 3:1, https://doi.org/10.1016/j.ajogmf.2021.100477; see also, Bloom, K.C., Bednarzyk, M.S., Devitt, D.L., Renault, R.A., Teaman, V., & Van Loock, D.M. *Barriers to prenatal care for homeless pregnant women* (2004). J Obstet Gynecol Neonatal Nurs. 2004;33(4):428-435. doi: 10.1177/0884217504266775

[35] Leifheit, K.M., Schwartz, G.L., Pollack, C.E., Edin, K.J., Black, M.M., Jennings, J.M., & Althoff, K.N. *Severe Housing Insecurity during Pregnancy: Association with Adverse Birth and Infant Outcomes* (2020). International Journal of Environmental Research and Public Health. 2020; 17(22):8659. https://doi.org/10.3390/ijerph17228659

[36] *Id.*

[37] Yamamoto, A., Gelberg, L., Needleman, J., Kominski, G., Vangala, S., Miyawaki, A., & Tsugawa, Y. *Comparison of Childbirth Delivery Outcomes and Costs of Care Between Women Experiencing vs Not Experiencing Homelessness* (2021). JAMA network open, *4*(4), e217491. https://doi.org/10.1001/jamanetworkopen.2021.7491

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The provisions of the bill are subject to appropriation; the bill has an indeterminant, negative fiscal impact on DOH.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking authority for DOH to implement its provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to pregnancy support services; creating s. 381.97, F.S.; providing legislative intent; establishing the Florida State Maternity Housing Grant Program within the Department of Health; requiring the program to provide certain resources; requiring the department to use grant funds for specified expenses; providing a limitation on the amount of grants awarded under the program; authorizing the department to adopt rules necessary to administer the program; providing an effective date.

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

Section 1. Section 381.97, Florida Statutes, is created to read:

381.97 Florida State Maternity Housing Grant Program.—

(1) It is the intent of the Legislature to provide housing resources for resident women and families experiencing homelessness during the prenatal period, regardless of age or marital status, whose financial resources have been determined inadequate to meet residential costs.

(2) There is created within the department the Florida State Maternity Housing Grant Program to provide approved living arrangements for residents experiencing homelessness during the

prenatal period.

(3) The grant program shall provide resources for approved persons to reside in an alternative living arrangement for a period not to exceed 8 months, which includes a maximum of 6 weeks of postpartum care.

(4) The department shall use grant funds specifically appropriated for the grant program to cover expenses related to any of the following:

(a) Housing in an authorized living arrangement for a period of time determined by the mother's estimated delivery date.

(b) Services recommended by the department for women and families approved for the grant program to encourage economic independence and positive health outcomes for participants.

(c) Staffing and reimbursements for providers of authorized living arrangements.

(d) All other related costs for the administration of the program, not to exceed five percent of the total grant funds.

(5) The total amount of grants awarded may not exceed the funding appropriated for the grant program.

(6) The department may adopt rules necessary to administer the program. The rules may include, but need not be limited to:

(a) A framework for the payment or reimbursement of funds to the mother for authorized living arrangements.

(b) Eligibility criteria for pregnant mothers and

expecting families seeking maternity housing services, including a sliding fee scale for participants.

(c) Requirements for maternity housing grant program applications.

(d) Guidelines for assessing the appropriateness of authorized living arrangements and for a determination of approval for authorized living arrangements.

Section 2. This act shall take effect July 1, 2024.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for HB 865 Youth Athletic Activities
SPONSOR(S): Healthcare Regulation Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Healthcare Regulation Subcommittee		Guzzo	McElroy

SUMMARY ANALYSIS

Sudden cardiac arrest is the leading cause of death for student athletes. Florida law requires public schools that are members of the Florida High School Athletic Association (FHSAA) to have a school employee or volunteer trained in cardiopulmonary resuscitation (CPR) and the use of an automated external defibrillator (AED) present at athletic activities, including competitions, practices, workouts, and conditioning sessions. However, public schools who are not members of the FHSAA are not required to comply with these standards.

The bill requires all athletic coaches employed by public schools to hold and maintain certification in CPR, first aid, and the use of an AED. The certification must be consistent with national evidence-based emergency cardiovascular care guidelines.

The bill has an indeterminate, yet likely insignificant, negative fiscal impact on the Department of Education and no fiscal impact on local government (*see fiscal comments)*.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Cardiac Arrest

Heart disease is the leading cause of death in the United States.[1] Sudden cardiac arrest is the leading cause of death for student athletes.[2]

Sudden cardiac arrest is the sudden loss of all heart activity due to an irregular heart rhythm. It can come on suddenly or in the wake of other symptoms. More than 356,000 cardiac arrests occur outside a hospital in the United States each year,[3] 7,037 of those cardiac arrests are children.[4]
Sudden cardiac arrest is often fatal if the individual does not receive timely emergency treatment.[5] Emergency treatment for sudden cardiac arrest includes cardiopulmonary resuscitation (CPR) and shocks to the heart with an automated external defibrillator (AED).

CPR

Though the vast majority of cardiac arrests occur at home, approximately 15 percent of adult cardiac arrests and 12 percent of juvenile cardiac arrests occur in public.[6] Bystander cardiopulmonary resuscitation (CPR) can double or triple a person's chances of survival if started immediately.[7] However, only 46 percent of cardiac arrests receive CPR from bystanders.[8] Bystanders often choose not to perform CPR because they aren't trained or they are concerned about causing additional injury to a patient, especially if the patient is elderly, female, or adolescent.[9]

AEDs

An AED is a computerized defibrillator that automatically analyzes the heart rhythm in people who are experiencing cardiac arrest. If the AED detects cardiac arrest, it delivers an electrical shock to the heart to restore its normal rhythm.[10] Sudden cardiac arrest has an 85 percent survival rate when an AED is applied within three minutes of a collapse.[11]

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[1] Center for Disease Control and Prevention, *Heart Disease,* https://www.cdc.gov/heartdisease/facts.htm (last visited January 20, 2024).
[2] Mayo Clinic, *Sudden Death in Young People: Heart Problems Often Blamed,* https://www.mayoclinic.org/diseases-conditions/sudden-cardiac-arrest/in-depth/sudden-death/art-20047571 (last visited January 20, 2024).
[3] *Id.*
[4] American Academy of Pediatrics, *Advocating for Life Support Training of Children, Parents, Caregivers, School Personnel, and the Public,* https://pediatrics.aappublications.org/content/141/6/e20180705#ref-1 (last visited January 20, 2024).
[5] American Heart Association, *About Cardiac Arrest,* https://www.heart.org/en/health-topics/cardiac-arrest/about-cardiac-arrest (last visited January 20, 2024).
[6] American Heart Association, *Why Women Fear Performing CPR on Women–and What to Do About It,* https://www.heart.org/en/news/2020/11/23/why-people-fear-performing-cpr-on-women-and-what-to-do-about-it (last visited January 20, 2024).
[7] *Id.*
[8] CPR Select, *CPR Success Rate: How Effective is CPR?*, available at https://www.mycprcertificationonline.com/blog/cpr-success-rate (last visited January 20, 2024).
[9] Heart Cert, *Why Don't Bystanders Perform CPR?* available at https://heartcertcpr.com/news/why-dont-bystanders-perform-cpr/#:~:text=Bystanders%20Fear%20Causing%20Additional%20Injury&text=The%20second%20most%20common%20reason,of%20CPR%20training%20and%20ability.&text=An%20additional%20reason%20given%20was,receive%20CPR%20from%20a%20bystander (last visited January 20, 2024).
[10] U.S. Food & Drug Administration, *How AEDs in Public Places Can Restart Hearts*, available at https://www.fda.gov/consumers/consumer-updates/how-aeds-public-places-can-restart-hearts (last visited January 20, 2024).
[11] Karl Weenig, M.D., National Federation of State High School Associations, *Emergency Action Plans Should be Reviewed, Rehearsed Annually* (Jan. 8, 2024) available at https://www.nfhs.org/articles/emergency-action-plans-should-be-reviewed-rehearsed-annually/#:~:text=It%20has%20been%20well%2Ddocumented,three%20minutes%20of%20a%20collapse (last visited January 20, 2024).

As part of student wellness and physical education policies, Florida law encourages school districts to provide basic training in first aid, including CPR, for all students in grade 6 and grade 8.[12] School districts are required to provide basic training in first aid, including CPR, for all students in grade 9 and grade 11.[13] The CPR instruction must be based on a one-hour, nationally recognized program that uses current evidence-based emergency cardiovascular care guidelines.[14] Florida law also requires the instruction to allow students to practice psychomotor skills associated with performing CPR and how to use an AED when a school district has the necessary equipment to provide AED instruction.[15] School districts are encouraged to pursue private and public partnerships to provide the requisite training or funding.[16]

Given concerns regarding the health and safety of student-athletes, Florida law requires public schools that are members of the Florida High School Athletic Association (FHSAA)[17] to meet certain requirements relating to CPR and the use of an AED. Currently, public schools that are members of the FHSAA are required to have a school employee or volunteer trained in CPR and use of an AED present at athletic activities, including competitions, practices, workouts, and conditioning sessions.[18] FHSAA member public schools are also required to have an operational AED available in a clearly marked, publicized location for all athletic contests, practices, workouts, and conditioning sessions.[19] The location of the AED must be registered with a local emergency medical services medical director.[20] Each employee or volunteer required to complete the training must annually be notified in writing of the location of each defibrillator on school grounds.[21]

Public schools who are not members of the FHSAA are not required to comply with the above standards. There are currently over 800 members of the FHSAA.[22] According to the Florida Department of Education, in 2022-23, there were 570 public middle schools, 641 public high schools, and 626 public combination schools in Florida.

Effect of the Bill

The bill requires athletic coaches employed by all public schools, not just schools that are members of the FHSAA, to hold and maintain certification in CPR, first aid, and the use of an AED. The certification must be consistent with national evidence-based emergency cardiovascular care guidelines.

B. SECTION DIRECTORY:

Section 1: Amends s. 1012.55, relating to positions for which certificates required.
Section 2: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

[12] S. 1003.453(3), F.S.
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] The term "high school" includes grades 6-12.
[18] Section 1006.165(1)(b), F.S.
[19] Section 1006.165(1)(a), F.S.
[20] Section 1006.165(1)(c), F.S.
[21] *Id.*
[22] FHSAA, Membership, *What is Membership in the FHSAA?*, available at https://fhsaa.com/sports/2020/1/30/Membership.aspx (last visited January 20, 2024).

2. Expenditures:

The number of coaches not already trained in accordance with the training requirements of the bill is unknown. However, current law requires public schools that are members of the FHSAA to have a school employee or volunteer trained in CPR and use of an AED present at all athletic activities, so it is likely that most athletic coaches are already trained in CPR and use of an AED. Therefore, the bill is expected to have an indeterminate, yet likely insignificant, negative fiscal impact on the Department of Education resulting from the costs associated with training athletic coaches in CPR and use of an AED.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Education has sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to youth athletic activities; amending s. 1012.55, F.S.; revising the requirements for certain athletic coaches to include certification in cardiopulmonary resuscitation, first aid, and the use of an automatic external defibrillator; providing requirements for such certification; providing an effective date.

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

Section 1. Paragraph (a) of subsection (2) of section 1012.55, Florida Statutes, is amended to read:

1012.55 Positions for which certificates required.—

(2)(a) 1. Each person who is employed and renders service as an athletic coach in any public school in any district of this state shall:

a. Hold a valid temporary or professional certificate or an athletic coaching certificate. The athletic coaching certificate may be used for either part-time or full-time positions.

b. Hold and maintain a certification in cardiopulmonary resuscitation, first aid, and the use of an automatic external defibrillator. The certification must be consistent with national evidence-based emergency cardiovascular care

guidelines.

2. The provisions of this subsection do not apply to any athletic coach who voluntarily renders service and who is not employed by any public school district of this state.

Section 2. This act shall take effect July 1, 2024.