The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Diaz, Chair
Senator Brodeur, Vice Chair

MEETING DATE: Wednesday, March 10, 2021
TIME: 10:30 a.m.—12:30 p.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

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

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
	PUBLIC TESTIMONY WILL BE RECEIVED FROM ROOM A3 AT THE DONALD L. TUCKER CIVIC CENTER, 505 W. PENSACOLA STREET, TALLAHASSEE, FL. 32301		
1	**SB 876** Diaz (Identical H 631)	Optometry; Revising the member composition requirements for the Board of Optometry; revising circumstances under which a certified optometrist may administer or prescribe ocular pharmaceutical agents; requiring the board to adopt a negative formulary of ocular pharmaceutical agents certified optometrists are prohibited from administering or prescribing; authorizing certain certified optometrists to perform laser and non-laser ophthalmic procedures and therapies under certain circumstances; requiring the board to determine the required content, grading criteria, and passing score for the licensure examination for certified optometrists; authorizing certified optometrists to remove superficial foreign bodies, etc. HP 03/03/2021 Temporarily Postponed HP 03/10/2021 Favorable AHS AP	Favorable Yeas 6 Nays 3
2	**SB 262** Harrell (Similar H 29)	Dispensing Medicinal Drugs; Authorizing certain hospitals to dispense supplies of prescribed medicinal drugs in a specified amount to emergency department patients or inpatients upon discharge under certain circumstances; authorizing a greater specified supply of medicinal drugs to be prescribed and dispensed in areas in which a state of emergency has been declared and is in effect; authorizing a prescriber to provide a patient with a prescription for medicinal drugs beyond the initial prescription period under certain circumstances, etc. HP 03/10/2021 Favorable MS AP	Favorable Yeas 9 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
3	**SB 990** Bradley (Similar H 543)	Occupational Therapy; Revising the fieldwork experience requirement for certain persons to take the examination for licensure as an occupational therapist; authorizing licensed occupational therapists to use a specified title and initials; prohibiting certain persons from using a specified title and initials; providing criminal penalties, etc. HP 03/10/2021 Fav/CS AHS AP	Fav/CS Yeas 9 Nays 0
4	**SB 1140** Rodrigues (Identical H 833)	Unlawful Use of DNA; Prohibiting DNA analysis and disclosure of DNA analysis results without authorization; prohibiting the collection or retention of a DNA sample of another person without authorization for specified purposes; prohibiting specified DNA analysis and disclosure of DNA analysis results without authorization, etc. HP 03/10/2021 Favorable CM RC	Favorable Yeas 9 Nays 0
5	**SB 1084** Pizzo (Identical H 805)	Volunteer Ambulance Services; Authorizing certain medical staff of a volunteer ambulance service to use red lights on a privately owned vehicle under certain circumstances; authorizing vehicles of volunteer ambulance services to show or display red lights and operate emergency lights and sirens under certain circumstances; prohibiting certain medical staff of volunteer ambulance services from operating red warning signals when not responding to an emergency in the line of duty; exempting volunteer first responder agencies from certificate of public convenience and necessity requirements, etc. HP 03/10/2021 Fav/CS CA AP	Fav/CS Yeas 9 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
6	**SB 634** Gibson (Similar CS/H 309)	Dementia-related Staff Training; Citing this act as the "Florida Alzheimer's Disease and Dementia Training Act"; requiring certain entities, as a condition of licensure, to provide specified dementia-related training for new employees within a specified timeframe; requiring annual dementia-related training for certain employees; providing that such additional training counts toward a certified nursing assistant's total annual training; authorizing certain health care practitioners to count certain continuing education hours toward the dementia-related training requirements under certain circumstances, etc. HP 03/10/2021 Fav/CS CF AP	Fav/CS Yeas 9 Nays 0
7	**SB 1064** Brodeur (Similar H 1219)	Hospital, Hospital System, or Provider Organization Transactions; Requiring certain entities to submit written notice of a specified filing to the Office of the Attorney General relating to certain hospital, hospital system, or provider organization mergers, acquisitions, and other transactions within a specified timeframe; requiring that such entities submit written notice of a material change to the office within a specified timeframe; providing requirements for such notice; authorizing the office to request additional information or issue a civil investigative demand, etc. HP 03/10/2021 Favorable JU AP	Favorable Yeas 5 Nays 4
8	**SB 240** Book	Donor Human Milk Bank Services; Authorizing the Agency for Health Care Administration to pay for donor human milk bank services as an optional Medicaid service if certain conditions are met; adding donor human milk bank services to the list of Medicaid services authorized for reimbursement on a fee-for-service basis; adding donor human milk bank services to the list of minimum benefits required to be covered by Medicaid managed care plans, etc. HP 03/10/2021 Fav/CS AHS AP	Fav/CS Yeas 9 Nays 0
	Other Related Meeting Documents		

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 876
INTRODUCER:	Senator Diaz
SUBJECT:	Optometry
DATE:	March 9, 2021
REVISED:	

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

I. Summary:

SB 876:

- Expands the scope of practice for certified optometrists;
- Amends the definition of "certified optometrist" to provide that the term "certified optometric physician" is synonymous with the former term;
- Adds the following elements to the definition of "optometry" which do not exist under the current-law definition:
  - The "evaluation, treatment, and management" of conditions of the human eye and its appendages, and, under the bill, such conditions include "any chronic systemic conditions relating to the eye;" and
  - The prescribing and application of "vision therapy, low-vision rehabilitation services, and ophthalmic procedures and therapy for the diagnosis, evaluation, treatment, or management" of any insufficiency, anomaly, abnormality, or disease condition relating to the human eye or its appendages.
- Deletes the current-law prohibition against an optometrist performing surgeries on the eye;
- Provides that optometrists may be certified to perform "ophthalmic procedures" such as laser and non-laser ophthalmic procedures and therapy approved by the Board of Optometry (Board);
- Creates a new section of statute for ophthalmic procedures that an optometrist may become certified to perform;
- Repeals the current-law formulary process for topical ocular agents that an optometrist may prescribe, as developed by the Board;
- Repeals the current-law statutory formulary of oral ocular agents that an optometrist may prescribe;
- Replaces the current-law formularies with a negative formulary system, to be established by the Board, that will include ocular agents that an optometrist is prohibited from prescribing;

- Removes the current-law limitation on the administration methods a certified optometrist may use for ocular pharmaceuticals (topical and oral), thereby allowing certified optometrists to use additional medication delivery systems;
- Removes from law the current requirement for a certified optometrist or a holder of a optometric faculty certificate to provide proof to the Department of Health (DOH) that he or she has successfully completed a course and passed an exam on general and ocular pharmaceuticals and their side effects, before he or she may administer or prescribe oral ocular pharmaceuticals;
- Revises current law relating to controlled substances that certified optometrists are prohibited from administering or prescribing, except for oral analgesics for the relief of pain due to ocular conditions, by adding Schedule II controlled substances to that provision;
- Limits the time frame for applicants to retake failed part(s) of the licensure examination;
- Authorizes the creation of a new certification for certified optometrists to perform Board-approved laser and non-laser ophthalmic procedures and therapy if certain conditions are met;
- Directs the Board to:
  - Review and approve the initial content of the ophthalmic procedures and therapy course and examination, and subsequent examinations, to satisfy the criteria set out in the bill;
  - Establish the new negative formulary of ocular medications;
  - Determine the required content, grading criteria, and passing score for the certified optometrist licensure examination;
  - Adopt rules relating to:
    - The practices and procedures for the administration and prescription of eye medications;
    - The Laser and non-laser ophthalmic procedures and therapies an optometrist certified in ophthalmic procedures may perform;
    - The standards of practice for each Board-approved ophthalmic procedure or therapy an optometrist certified in ophthalmic procedures may perform;
    - The scope of practice of optometry;
    - The required content, grading criteria, and passing score for the licensure examination for certified optometrists; and
- Specifies a list of ophthalmic procedures which are excluded from the scope of practice of optometry.

The bill provides an effective date of July 1, 2021.

II. Present Situation:

The Department of Health

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

[1] Section 20.43, F.S.

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

Board of Optometry (Board)

The Board was established to ensure that every person engaged in the practice of optometry in this state meets minimum requirements for safe practice. The Board is composed of seven members appointed by the Governor and confirmed by the Senate.[4] Individuals who practice under the Board's regulatory authority are certified optometrists or "licensed practitioners."

Optometry

Optometry is the diagnosis of conditions of the human eye and its appendages.[5] The appendages of the eye are the eyelids, the eyebrows, the conjunctiva, and the lacrimal apparatus.[6]

Optometry is one of the health care professions the Legislature has charged the DOH with regulating to protect and promote the health of all residents and visitors in Florida for the preservation of the health, safety, and welfare of the public.[7]

Training of Optometrists and Ophthalmologists

Optometrists and ophthalmologists are both part of a patient's visual health care team. Optometrists attend optometry school for four years and are not required to undertake postgraduate training.[8] Ophthalmologists are either allopathic (M.D.) or osteopathic (D.O.) physicians[9] who are trained in medical schools to treat the whole person and who undertake four additional years of specialized training in eye care, diseases of the eye, and surgery. Optometrists are not medical doctors and receive an "O.D." degree. They attend optometry school for four years and are not required to undertake postgraduate training.[10]

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[2] Under s. 456.001(1), F.S., "board" is defined as any board, commission, or other statutorily created entity, to the extent such entity is authorized to exercise regulatory or rulemaking functions within the DOH or, in some cases, within the DOH MQA.
[3] Section 20.43, F.S.
[4] Sections 463.003 and 463.005, F.S. Five members of the Board must be licensed practitioners actively practicing in Florida. The remaining two members must be citizens of Florida who are not, and have never been, licensed practitioners and may not be connected with the practice of optometry or with any other vision-related profession or business. At least one member of the board must be 60 years of age or older.
[5] Section 463.002(7), F.S.
[6] Section 463.002(10), F.S.
[7] Section 20.43, F.S.
[8] American Academy of Ophthalmology, *Differences in Education Between Optometrists and Ophthalmologists*, *available at* https://www.aao.org/about/policies/differences-education-optometrists-ophthalmologists (last visited Feb. 18, 2021).
[9] Ophthalmologists are licensed under ch. 458, F.S., relating to the allopathic practice of medicine or ch. 459, F.S., relating to the osteopathic practice of medicine.
[10] American Academy of Ophthalmology, *Differences in Education Between Optometrists and Ophthalmologists available at https://www.aao.org/about/policies/differences-education-optometrists-ophthalmologists* (last visited Feb. 25, 2021).

Optometrists	Ophthalmologists
2,300 clinical hours	17,000+ clinical hours
At least 3 years of college or university	4 years college or university
4 years optometry school	4 years medical school
No hands-on training for lasers or scalpel surgery	1 year hospital internship
N/A	3 years of surgical ophthalmology residency (eye surgery and laser)
N/A	1-2 years of post-residency fellowship sub-specialized in ocular surgery

Optometric Education

While every optometry school is slightly different, this analysis uses the Nova Southeastern College of Optometry as an example. A doctor of optometry (O.D.) degree at Nova Southeastern requires four years of study. Students must have a minimum of a 2.0 grade point average and have a passing score on the Optometry Admissions Test (OAT).[11]

During the first year, optometry students concentrate on the basic biological sciences including anatomy and physiology, microbiology, and neuroanatomy. In addition, they receive lecture, laboratory, and clinical instruction in theoretical optics and the conducting of an optometric examination.

In the second year, students study ocular physiology and psychophysics; and begin their first courses in ocular disease and anomalies of binocular vision. In the summer between the second and third years, students begin to examine patients in the university's Eye Care Institute. They care for adults, children, and geriatric patients with all types of ocular and visual needs in the primary eye care clinic.

Third-year students continue to study ocular disease, contact lenses, and clinical medicine. A two-semester practice management course begins in the third year with introduction of basic business and management concepts. In the fourth year, students receive training in secondary-tertiary eye care, specialized optometric care, and continued clinical education. Training emphasizes practical experience through externships, specialty clinical rotations, and clinical practice. In the fourth year a practice management course presents business decisions and concepts that may be necessary for a successful practice.[12] Nova Southeastern also offers a small number of optional primary care residencies in ocular disease, cornea and contact lenses, pediatrics and binocular vision and low vision. It does not offer any surgical residencies.[13]

[11] Nova Southeastern University, College of Optometry, Doctor of Optometry, *Admission Requirements, available at* https://optometry.nova.edu/od/admissions/index.html (last visited Feb. 17, 2021).
[12]Nova Southeastern University, College of Optometry, *Overview, available at* https://optometry.nova.edu/od/index.html (last visited Feb. 17, 2021).
[13] Nova Southeastern University, College of Optometry, Residency, *Residency in Primary Care, available at* https://optometry.nova.edu/residency/index.html (last visited Feb. 17, 2021).

Ophthalmological Education

Ophthalmologists differ from optometrists in their levels of training and in what they can diagnose and treat.[14] In addition to four years of medical school and one year of internship, every ophthalmologist spends a minimum of three years of residency (hospital-based training) in ophthalmology.

During residency, an ophthalmologist receives special training in all aspects of eye care, including prevention, diagnosis and medical and surgical treatment of eye conditions and diseases.[15] Many, but not all, ophthalmologist are board certified. A board-certified ophthalmologist has passed a rigorous two-part examination given by the American Board of Ophthalmology designed to assess his/her knowledge, experience and skills.[16]

To be licensed by and practice in Florida, ophthalmologists must also demonstrate financial responsibility to pay claims and costs arising out of the provision of ophthalmological care and treatment.[17] Optometrists are not required to care professional liability insurance. Often, an ophthalmologist spends an additional one to two years training in a subspecialty that involves a specific area of eye care.[18]

The Practice of Optometry

The practice of optometry includes:

- The use of any objective or subjective means or methods, including ocular pharmaceutical agents, to determine:
  - The refractive powers of the human eyes; or
  - Any visual, muscular, neurological, or anatomic anomalies of the eyes or their appendages; and
- The prescribing and use of any of the following for the correction, remedy, or relief of any insufficiencies or abnormal conditions of the eyes and their appendages:
  - Lenses;
  - Prisms;
  - Frames;
  - Mountings;
  - Contact lenses;
  - Orthoptic exercises;
  - Light frequencies; and

[14] American Academy of Ophthalmology, *What is an Ophthalmologist? available at* https://www.aao.org/eye-health/tips-prevention/what-is-ophthalmologist (last visited Feb. 18, 2021).
[15] American Academy of Ophthalmology, *Training and Certification for Ophthalmologists, available at* https://www.aao.org/eye-health/tips-prevention/ophthalmology-training-certification (last visited Feb. 18, 2021).
[16] *Id*.
[17] *See* ss. 458.320, 459.0085, and 456.048, F.S.
[18] American Academy of Ophthalmology, *Subspecialties in Ophthalmology, available at* https://www.aao.org/eye-health/tips-prevention/ophthalmology-training-certification (last visited Feb. 17, 2021).

- Ocular pharmaceutical agents.[19,20]

Current law in Florida prohibits all surgery for optometrists[21] and defines the term "surgery" to include a procedure using an instrument, such as a laser, scalpel, or needle, in which human tissue is cut, burned, scraped, or vaporized, by incision, injection, ultrasound, laser, infusion, cryotherapy, or radiation. The term also includes a procedure using an instrument which requires the closure of human tissue by suture, clamp, or other device.[22] The following procedures performed by a certified optometrist are considered within the definition of optometry:[23]

- The removal of a superficial foreign body embedded in the conjunctiva or cornea but not penetrating the globe;
- The removal of an eyelash by epilation;
- The probing of an uninflamed tear duct of an adult;
- The blocking of the puncta by plug or superficial scraping to remove damaged epithelial tissue or superficial foreign bodies; or
- The taking of a culture from the surface of the cornea or conjunctiva.[24]

Licensed Practitioners of Optometry

"Licensed practitioners" engaged in the practice of optometry, who are not certified optometrists, may use topically applied anesthetics solely for the purpose of glaucoma examinations, but are otherwise prohibited from administering or prescribing ocular pharmaceutical agents.[25] A licensed practitioner is required to post at his or her practice location a sign, which states: "*I am a Licensed Practitioner, not a Certified Optometrist, and I am not able to prescribe ocular pharmaceutical agents*."[26] Current law allows licensed practitioners wishing to become certified optometrists to do so by:

- Submitting an application for certification to the DOH;
- Completing 110 hours of Board-approved coursework and clinical training in general and ocular pharmacology conducted by an accredited institution which has facilities for both didactic and clinical instruction in pharmacology;
- Completing one year of a supervised experience in differential diagnosis of eye diseases or disorders during either optometric training or in a clinical setting as part of optometric experience in an academic or non-academic environment; and
- Successfully passing Part II (Patient Assessment and Management, including an embedded Treatment and Management of Ocular Disease examination) of the National Boards of Examiners in Optometry (NBEO) examination.[27]

[19] *Supra*, note 5.
[20] Section 463.002(5), F.S. An "Ocular pharmaceutical agent" is a pharmaceutical agent that is administered topically or orally for the diagnosis or treatment of ocular conditions of the human eye and its appendages, without the use of surgery or other invasive techniques.
[21] Section 463.014(4), F.S.
[22] Section 463.002(6), F.S.
[23] Section 463.002(7), F.S.
[24] Section 463.014(4), F.S.
[25] Section 463.0055(1)(a), F.S.
[26] Section 463.002(3), F.S.
[27] Fla. Admin. Code R. 64B13-10.001 (2020).

As of January 6, 2021, in Florida there were 56 clear and active, and seven clear and inactive, "licensed practitioners" engaging in the practice of optometry.[28]

Licensed and Certified Optometrists

All optometrists initially licensed after July 1, 1993,[29] are now required to be both licensed and certified and may administer and prescribe ocular pharmaceutical agents for the diagnosis and treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques.[30]

Before a certified optometrist can administer or prescribe oral ocular pharmaceutical agents, the certified optometrist must provide proof to the DOH of the successful completion of a course and subsequent Board-approved examination on general and ocular pharmaceutical agents and their side effects. The course must consist of 20 contact hours; and all may be web-based. Successful completion of the course and examination may be used by a certified optometrist to satisfy 20 hours of the continuing education but only for the biennial period in which the Board-approved course and examination were taken. If a certified optometrist does not complete such a Board-approved course and examination, the certified optometrist is only authorized to administer and prescribe topical ocular pharmaceutical agents.[31]

Under ch. 456, F.S., the general provisions applicable to all professions regulated by MQA within the DOH must provide for the development, preparation, administration, scoring, score reporting, and evaluation of all examinations in consultation with the appropriate regulatory board. For each examination developed by the DOH or a contracted vendor, the respective board must specify by rule:

- The general areas to be covered by each examination;
- The relative weight to be assigned in grading each area tested; and
- The score necessary to achieve a passing grade.[32]

A board and the DOH may not administer a state-developed written examination if a national examination has been certified by the DOH.[33] A board may administer a state-developed practical or clinical examination, if required by the applicable practice act if all costs are paid by

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[28] E-mail from Anthony B. Spivey Dr.BA, Executive Director, Board of Optometry, Division of Medical Quality Assurance, Bureau of Health Care Practitioner Regulation, Department of Health (Jan. .7, 2021) (on file with the Senate Health Policy Committee).

[29] Section 463.002(3), F.S. In 1986 the Legislature amended ch. 463, F.S., to require that anyone applying for an optometrist license after July 1, 1993, become a Certified Optometrist. The legislation required all applicants after that date to meet additional education and examination requirements. *See also* the Department of Health, Board of Optometry, *Licensing and Registration*, *available at* http://floridasoptometry.gov/licensing/, (last visited Feb. 9, 2021).

[30] Sections 463.002(4) and 463.0055, F.S.

[31] *See* s. 463.005(1)(b), F.S. The course and examination are developed and offered jointly by a statewide professional association of physicians accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award (AMA PRA) Category 1 credit and a statewide professional association of licensed practitioners which provides Board-approved continuing education on an annual basis. The Board must review and approve of the content of the initial course and examination; and will annually review and approve of the course and examination to ensure that the content continues to satisfy the statutory criteria.

[32] Section 456.017(1)(a) and (b), F.S.

[33] Section 456.017(1)(c)2., F.S.

the candidate. If a national practical or clinical examination is available and certified by the DOH, a board may administer the national examination.[34]

Currently, any person desiring to be a licensed certified optometrist in Florida must apply to the DOH to take the licensure and certification examinations.[35] To be a licensed certified optometrist, an applicant must submit proof that he or she:

- Has completed the application forms and remitted the fees for the application, the certification exam, and the licensure exam;
- Is at least 18 years of age;
- Has graduated from an accredited school or college of optometry approved by the Board;[36]
- Is of good moral character;
- Has completed at least 110 hours of transcript quality course work and clinical training in general and ocular pharmacology at an institution that:
  - Has both didactic and clinical instruction in pharmacology; and
  - Is accredited by an organization recognized by the Commission on Recognition of Postsecondary Accreditation or the U. S. Department of Education.
- Has completed at least one year of supervised experience in differential diagnosis of eye diseases or disorders as part of the optometric training or in a clinical setting as part of the optometric experience;
- Has successfully pass all parts of the Florida Licensure Examination, consisting of:
  - The NBEO examination Part II and Part III;
  - The Florida Practical Examination, which is taken simultaneously with Part III and includes the NBEO Part III skills of Biomicroscopy, Binocular Indirect Ophthalmoscopy and Dilated Biomicroscopy, and Non-Contact Fundus Lens Evaluation with a minimum score of 75 percent on each skill on the same attempt; and
  - Part IV (Florida Laws and Rules) with a score of 84 percent or higher.

If the applicant is, or has ever been, licensed in another state, he or she must also submit a licensure verification form from each state in which he or she has held a license.[37]

Applicants must receive passing scores on all four parts of the Florida Licensure Examination within the three years immediately preceding submission of an application or after submission of an application. Applicants who submit an application that is complete in all respects, but who have not passed all parts of the examinations, may be approved by the DOH, but a license to practice will not be issued until the DOH has received proof of passage of all parts of the Florida Licensure Examination.[38]

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[34] Section 456.017, F.S.
[35] Section 463.006(1), F.S.
[36] Pursuant to Fla. Admin. Code R. 64B13-4.004 (2020), all Board-approved schools or colleges must be accredited by the Accreditation Council for Optometric Education. In addition, applicants must provide documentation of passage of National Boards of Examiners in Optometry (NBEO) Part I in order to demonstrate graduation from a Board-approved school or college. See Department of Health, Board of Optometry, Certified Optometrist, *Requirements, available at* *https://floridasoptometry.gov/licensing/certified-optometrist/* (last visited Feb. 9, 2021).
[37] *Id*.
[38] Department of Health, Board of Optometry, Certified Optometrist, *Requirements, available at* https://floridasoptometry.gov/licensing/certified-optometrist/ (last visited Feb. 9, 2021).

An applicant who fails to achieve a passing score on Part I, Part II, Part III, or Part IV of the licensure examination may retake any part by registering directly with the NBEO. There is no limitation on the number of times an applicant may retake any examination part.[39] There are no surgery sections on any part of the Florida Licensure or the Florida Practical Examinations.

According to the DOH 2019-2020 Annual Long Range Plan there are 2,922 in-state, active certified optometrists.[40]

The Topical and Oral Ocular Formularies – Limits on Controlled Substances

Florida law contains separate provisions for the authority of a certified optometrist to administer or prescribe topical ocular agents versus oral ocular agents. And, current law provides no authorization for optometrists to administer ocular agents by any means other than topical or oral.

Topical Ocular Agents

For topical ocular agents, the Board has authority to create a formulary containing topical agents a certified optometrist may administer or prescribe. The topical ocular formulary must consist of topical ocular agents that are appropriate to treat or diagnose ocular diseases and disorders and that a certified optometrist is qualified to use in the practice of optometry. The Board may add to, delete from, or modify the topical formulary by rule. The topical formulary rules becomes effective 60 days from the date they are filed with the Secretary of State. Upon the adoption, and each addition, deletion, or modification of the topical formulary, the Board must mail a copy of the amended formulary to each certified optometrist and to each pharmacy in the state.[41]

Oral Ocular Agents

Only certified optometrists who provide proof to the DOH of having successfully completed the Board-approved pharmaceutical course and examination are authorized to administer and prescribe oral ocular pharmaceutical agents or their therapeutic equivalents.[42] Certified optometrists may write prescriptions, using a prescriber number issued by the Board, for the medications listed on the formulary of topical ocular pharmaceutical agents established by Board rule[43] and the statutory formulary of oral ocular pharmaceutical agents.[44]

A certified optometrist may not administer or prescribe controlled substances:

- Listed in Schedule III, IV, or V of s. 893.03, F.S., except for an oral analgesic on the statutory oral ocular formulary for relief of pain due to conditions of the eye and its appendages.[45]

[39] Fla. Admin. Code R. 64B13-4.002 (2020).
[40] Florida Department of Health, Medical Quality Assurance, *Annual Report and Long-Range Plan Fiscal Year 2019-2020, available at* http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/2019-2020-annual-report.pdf (last visited Feb. 17, 2021).
[41] Section 463.0055(2)(d), F.S.
[42] Section 463.0055(1)(b), F.S.
[43] Section 463.0055(2), F.S. and Fla. Admin. Code R. 64B13-18.002 (2020).
[44] Section 463.0055(3), F.S. and Fla. Admin. Code R. 64B13-10-002 (2020).
[45] Section 463.0055(4)(a), F.S.

- For the treatment of chronic nonmalignant pain.[46]

Instead of directing the Board to develop a formulary of oral ocular agents by rule, the Legislature has written such a formulary into the Florida Statutes. The statutory oral ocular formulary includes:

- Two analgesics, which may not be prescribed for more than 72 hours without a consultation with an ophthalmologist, including;
  - Tramadol hydrochloride (which is a Schedule IV controlled substance);[47]
  - Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg. (a Schedule III controlled substance);[48]
- Antibiotics;
- Antivirals; and
- Anti-glaucoma agents which may not be prescribed for more than 72 hours.

There is no specific statutory authority under current law for an optometrist to administer or prescribe a Schedule II controlled substance.

Optometrists – Required Medical Referrals

Florida law requires optometrists to refer patients to an ophthalmologist for further treatment when he or she diagnoses the patient with:

- Angle closure, infantile, or congenital forms of glaucoma;[49]
- Infectious corneal disease condition that has not responded to standard treatment;[50] or
- A sudden onset of spots or "floaters" in a patient's eyes with loss of all or part of the visual field.[51]

Optometrists are also required to maintain the names of at least three allopathic or osteopathic physicians, clinics, or hospitals to which they may refer patients who experience adverse drug reactions.[52]

Authority Granted by States for Optometrists to Prescribe Controlled Substances

Currently, four states – Maryland, Massachusetts, New York, and Hawaii – and the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and the Marianna Islands, do not permit optometrists to prescribe any controlled substances. The other 46 states permit varying levels of Schedule II through V[53] prescribing of controlled substances by optometrists, as the chart below indicates.

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[46] Sections 463.0055(4)(b), F.S., and 456.44(1)(f).
[47] *See* note 53.
[48] *Id.*
[49] Section 463.0135(2), F.S.
[50] Section 463.0135(3), F.S.
[51] Section 463.0135(4), F.S.
[52] Section 463.0135(8), F.S.
[53] U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division, *Mid-Level Practitioners Authorization by State*, *available at* https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf (last visited Feb. 22, 2021).

Optometrist Authorization to Use Controlled Substances by State[54]

	Schedule II										Schedule III						Schedule IV	Schedule V
	All	Hydrocodone products only			Codeine			Tramadol			Narcotic			Non-narcotic				
A=Administer, P=Prescribe, D=Dispense		A	P	D	A	P	D	A	P	D	A	P	D	A	P	D		
Connecticut, Idaho, Kansas, Iowa, Missouri, Montana, Nebraska, North Carolina, Tennessee	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	A, P, D	A, P, D
Louisiana, Nevada, Texas	x	x	x		x	x		x	x		x	x		x	x		A, P	A, P
South Dakota	x		x			x			x			x			x		P	P
New Mexico, South Carolina, Wisconsin		x	x	x							x	x	x	x	x	x	A, P, D	A, P, D
Ohio		x	x								x	x		x	x		A, P	A, P
Virginia***		x	x								x	x		x	x		A, P	no
California			x			x			x			x			x		P	no
Alaska, Arkansas, Colorado, Illinois, Michigan, Delaware, Kentucky, New Jersey, Oklahoma, Rhode Island			x									x			x		P	P
Georgia			x									x			x		P	no
Oregon			x								Analgesics per formulary - no prescribing							
Pennsylvania			x								Use of drug in practice - not to exceed 6 weeks							
Utah			x								x	x		x	x		A, P	A, P
Vermont												x		x			P	P
Washington*** West Virginia			x								x	x	x	x	x	x	A, P, D	A, P, D
Arizona			x								x	x	x	x	x	x	no	no
Maine, North Dakota, Wyoming											x	x	x	x	x	x	A, P, D	A, P, D
Alabama											x	x		x	x		A, P	A, P
Florida*,**												x	x				A, P	no
New Hampshire												x	x		x	x	P, D	no
Minnesota																	A, P, D	A, P, D
Indiana**																	A, P, D	no
Mississippi																	P	P

* Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.
** Tramadol Hydrochloride
*** Hydrocodone in combination with acetaminophen

Authority Granted by States for Optometrists to Perform Laser and Non-laser Surgery

Currently, five states – Oklahoma, Kentucky, Alaska, Louisiana and Arkansas – permit optometrists to perform advanced procedures (i.e., laser treatments, injections, and removal of lesions and growths). These five states also authorize optometrists to perform some level of laser

[54] *Id.*

and non-leaser ophthalmic surgery.[55] The remaining forty-five states do not currently permit optometrists to perform advanced laser and non-laser surgical procedures.

Oklahoma was the first state to permit optometrists to perform surgery in 1988. Oklahoma defines the practice of optometry to include the diagnosis of conditions of the eye, and the correcting and relief of ocular abnormalities, by means of laser and non-laser surgical procedures; and requires optometrists to be certified by the board to perform those procedures authorized by the board.[56] The Oklahoma statutes and board rules are silent on how a practitioner becomes certified by the board prior to performing laser or non-laser surgery procedures; though the statutes do prohibit optometrists from performing laser retinal, laser in-situ keratomileusis (LASIK), and cosmetic lid surgery. The board has by rule, however, published a list of 14 prohibited non-laser surgical procedures.[57]

In 2011, Kentucky defined the practice of optometry to include using vision therapy or orthoptics, low vision rehabilitation, and laser surgery procedures, excluding retina, LASIK, and PRK, and 16 other prohibited procedures.[58] Any licensed optometrist in Kentucky desiring to also perform "expanded therapeutic procedures" is required to takes a course and meet additional educational and competence criteria set by the board to obtaining a laser credential. However, Kentucky statutes and rules are silent on what constitutes an, "expanded therapeutic procedures." Kentucky's credentialing process for a candidate indicates that he or she must, among other things, demonstrate to his or her board-approved preceptor[59] that he or she has performed an anterior segment laser procedure on a living human eye, thus indicating that an anterior segment laser procedure is probably an "expanded therapeutic procedure."[60]

In 2014 Louisiana authorized optometrists to perform both laser and non-laser surgery. A Louisiana optometrist is required to complete a 32-hour course[61] focused on laser surgery topics,

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[55] *See* Alaska Stat. ss. 8.72.010 - 310 (2019); Ark. Stat. ss. 17-90-101 - 17-90-510 (2020); KY Rev. Stat. s. 320.210(2020); Louis. Rev. Stat., ch. 12, s. 37:1041(2020); and 59 OK Stat s. 581 (2021).

[56] 59 OK s. 581, D. (2021).

[57] Oklahoma Admin. Code R., Tit. 505:10-5-17(2020).

[58] Kentucky. Rev. Stat. 320.210 (2019). 1) Non-laser surgery to remove an eye; 2) Non-laser surgery using full thickness incision or excision of the cornea or sclera other than emergency situation to reduction the pressure in the eye; 3) Penetrating keratoplasty (corneal transplant), or lamellar keratoplasty; 4) Non-laser surgery with incision into iris and ciliary body, including iris diathermy or cryotherapy; 5) Non-laser surgery with incision into vitreous; 6) Non-laser surgery with incision into retina; 7) Non-laser surgical extraction of the crystalline lens; 8) Non-laser intraocular implants; 9) non-laser incision or excision of extraocular muscles; 10) Non-laser surgery of the eyelid malignancies or for cosmetic or blepharochalasis, ptosis, and tarsorrhaphy; 11) Non-laser surgery of the bony orbit, including orbital implants; 12) non-leaser incision or excision into the lacrimal system or related procedures; 13) Non-laser surgery using full thickness conjunctivoplasty with graft or flap; 14) Non-laser surgical procedure that does not provide for the correction and relief of ocular abnormalities; 15) Laser or non-laser injection into the posterior chamber of the eye to treat any macular or retinal disease; and 16) The administration of general anesthesia.

[59] Kentucky Admin. Code R. 5:110 s. 4 (2019) The Board-approved preceptor must be: 1) A licensed optometrist or ophthalmologist whose license is in good standing; 2) A full-time or adjunct faculty member of an accredited optometry or medical school; and 3) Credentialed in the expanded therapeutic procedure or expanded therapeutic laser procedure that the preceptor is teaching.

[60] *Id*.

[61] *See* an example of a board approved expanded therapeutic procedures course offered by Northeastern State University, Oklahoma College of Optometry, offering Association of Regulatory Boards, Inc. (ARBO), Council on Optometric Practitioner Education (COPE), approved *NSUOCO Advanced Procedures*, courses July 8th & 9th -16 hrs CE Surgical Procedures and July 10th & 11th, 2021 -16 hrs. CE Laser Therapy the Anterior Segment, schedule *available at*

to perform surgery, or, beginning with the graduating class of 2015, any optometrist who graduated from an optometry school whose program included all of the training and testing requirements established by the Louisiana Board of Optometry was be deemed to have met the requirements for certification to perform authorized ophthalmic surgery procedures, including certain laser procedures.[62] Louisiana defines "ophthalmic surgery" to include any procedure upon the human eye in which in vivo human tissue is injected, cut, burned, frozen, sutured, vaporized, coagulated, or photo-disrupted by the use of surgical instruments such as, but not limited to, a scalpel, cryoprobe, laser, electric cautery, or ionizing radiation,[63]and includes primary eye care surgical procedures such as YAG laser capsulotomy, laser peripheral iridotomy, and laser trabeculoplasty. [64]

In 2017, Alaskan optometrists were authorized to perform ophthalmic surgery if it was within the scope of their education and training from an accredited school of optometry and they were authorized by certain regulations.[65] Alaska defines "ophthalmic surgery" as an invasive procedure in which human tissue is cut, ablated, or otherwise penetrated by incision, laser, or other means to treat diseases of the eye, alter or correct refractive error, or alter or enhance cosmetic appearance.[66] "Ophthalmic surgery" does not include the remove of superficial foreign bodies from the eye and its appendages.[67] An Alaskan optometrist may not perform ophthalmic surgery unless the procedure is an "expanded therapeutic procedure," and he or she is authorized by the Alaskan regulatory board to perform the procedure. An "expanded therapeutic procedure" is an ophthalmic surgery approved by the regulatory board and may include:[68]

- Anterior segment laser procedures;
- Anterior segment surgical procedures;
- YAG laser capsulotomy;
- Laser peripheral iridotomy (LPI); and
- Laser trabeculoplasty.

An Alaskan optometrist requesting authorization to perform an expanded therapeutic procedure must have satisfactorily completed a 32 hour course[69] in the expanded therapeutic procedure

https://optometry.nsuok.edu/continuingeducation/ScheduleofEvents/AdvancedProcedures/default.aspx (last visited Feb. 25, 2021). 20 Courses plus a review & Final Exam: Intro to Optometric Surgery and Ophthalmic Surgical Instruments; Review of Surgical Anatomy of the Face; Oculofacial Surgical Asepsis; Review of Eyelid Anatomy & Eyelid Lesions; Office-based Local Anesthesia; Radio Frequency Surgery in Optometric Practice; Introduction to Oculofacial Biopsy; Chalazion Management; Video Grand Rounds & Surgical Concepts; Intro to Suturing; Suture Techniques Lab; Lab Rotations| Injection Techniques, Radiosurgical Techniques, Oculofacial Biopsy; Laser Physics, Hazards & Safety; Laser Tissue Interactions; Clinical Workshops: Intro to Therapeutic Lasers; Gonioscopy: How to Interpret What You Are Seeing; Laser Therapy for the Open Angle Glaucomas: LT & SLT; Laser Therapy in Narrow Angles/Angle Closure: LPI and ALPI; YAG Laser Posterior Capsu¬lotomy; Managing Potential Laser Complications; Medicolegal Aspects of Ante¬rior Segment Laser Procedures: Panel Discussion; Lab Rotations: YAG Capsulotomy, Laser Peripheral Iridotomy, Gonioscopy & Laser Lenses, Laser Trabeculoplasty: ALT & SLT; Review & Final Exam. Cost is $1000 per course or $1,750.00 for both courses.

[61] Alaska Admin. Code R. 48.040(d) (2019).
[62] Louis. Admin Code R., Tit. 46, Pt, L1. ch. 5, s. 503 H (2020).
[63] Louis. Rev. Stat. ch. 12, s. 37-1041(4)(a), (2020).
[64] Louis. Admin Code R., Tit. 46, Pt, L1. ch. 5, s. 107 B (2020).
[65] Alaska Stat. s. 08.72.278(b)(2019).
[66] Alaska Stat. s. 08.072.278(c) (2019).
[67] Alaska Stat. s. 08.72.273 (2019).
[68] Alaska Admin. Code R. 48.040(l) (2019).
[69] *Supra*, note 64.

provided by an optometry school accredited by the Council for Higher Education Accreditation and approved by the Alaskan regulatory board.[70] The regulatory board also specifically prohibits 17 ophthalmic surgeries an optometrist may not perform under any circumstances.[71]

In 2019 Arkansas redefined the "practice of optometry" to include the following surgical and laser procedures:[72]

- Injections, excluding intravenous or intraocular injections;
- Incision and curettage of a chalazion;[73]
- Removal and biopsy of skin lesions with low risk of malignancy, excluding lesion involving the lid margin or nasal to the puncta;
- Laser capsulotomy; and
- Laser trabeculoplasty.

The Arkansas regulatory board establishes the credentialing requirements for optometrists to obtain certification[74] for surgical and laser procedures[75] and requires every optometrist who is certified to perform authorized laser procedures to report to the regulatory board regarding the outcome of the each procedure.[76]All licensed optometrists are prohibited from performing cataract surgery and performing radial keratotomy.[77]

Optometrist and Ophthalmologist - Access, Safety, and Costs

Access

The University of Washington conducted a peer-reviewed study of respondents aged 65 and older from a 2010 U.S. Census survey to quantify the proximity of eye care in the contiguous United States by calculating driving routes and driving time. Their analysis estimated that 90 percent of the United States Medicare population lives within 15 minutes' driving time of an optometrist and half an hour of an ophthalmologist. In the case of a patient seen by an optometrist, needing an elevated level of care, 90 percent of optometrists practices were within 20 minutes of an ophthalmologist. For each U.S. state, the addresses of all practicing ophthalmologists and optometrists were obtained from the 2012 Medicare Provider Utilization and Payment Data from the Centers for Medicare & Medicaid Services (CMS). While there were regional variations, the study concluded that overall, more than 90 percent of Medicare beneficiaries lived within a 30-minute drive of an ophthalmologist and within 15 minutes of an

[70] Alaska Admin. Code R. 48.040(d) (2019).
[71] Alaska Admin. Code R. 48.040(h) (2019).
[72] Ark. Stat. s. 17-90-101(2020).
[73] American Academy of Ophthalmology, What Are Chalazia and Styes?, *What is a chalazion?*, *available at* https://www.aao.org/eye-health/diseases/what-are-chalazia-styes (last visited (Feb. 26, 2021). A chalazion is a swollen bump on the eyelid.
[74] Ark. Stat. s. 17-90-301 (2020).
[75] Ark. Stat. s. 17-90-204(9) (2020).
[76] Ark. Stat. s. 17-90-206 (2020).
[77] *Supra,* note 65.

optometrist.[78] Current CMS data from the U.S. Census show that 96.3 percent of the Florida population lives within one-half hour drive to an ophthalmology point of service.[79]

Safety and Cost

One peer-reviewed research study published in the *Journal of the American Medical Association* suggested that there was an increased risk of medically necessary follow-up surgeries when the same procedures were performed by an optometrist as compared to when the procedures were performed by an ophthalmologist. Medicare beneficiaries who underwent laser trabeculoplasty (LTP) by optometrists had a 189 percent increased risk of requiring additional LTPs in the same eye compared with those who underwent LTP by ophthalmologists. The study concluded that twice as many laser surgeries were done on patients (on the same eye) if performed by optometrists as compared to ophthalmologists, resulting in twice the risk of additional surgeries, twice as many visits, and twice the cost.[80] The American Optometric Association alleged that this study was inaccurate based on the claim that repeated LTP sessions were, "an acceptable model" of care.[81]

The Florida Optometric Association indicates that optometrist performance of laser and non-laser ophthalmic procedures in states where such procedures are permitted is safe. The Association points to the fact that liability insurance rates for optometrists in those states have not increased and that, even in the states with the most advanced scope of practice for optometrists, the professional liability insurance rates are significantly lower than for comparable insurance in Florida.[82]

In response to similar assertions, Ophthalmology Mutual Insurance Company (OMIC), a large insurance company that insures thousands of ophthalmologist and optometrists nationwide, issued a written statement on February 10, 2021, in which the company addressed the relative stability of optometric malpractice rates and the known complications that can arise from the performance certain ocular surgical procedures. In the statement, OMIC indicated it had implemented new underwriting guidelines to ensure that coverage would be available to health care providers for those procedures for which they had the necessary education, training, and expertise; and that because OMIC did not have the experience to properly underwrite, rate, and administer claims arising from surgical procedures performed by optometrists, and lacked available data on this liability risk, OMIC had made the decision to not offer coverage to

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[78] National Institute of Health, National Library of Medicine, National Center for Biotechnology information, Lee CS, Morris A, Van Gelder RN, Lee AY. *Evaluating Access to Eye Care in the Contiguous United States by Calculated Driving Time in the United States Medicare Population.* Ophthalmology. 2016 Dec; 123(12):2456-2461. doi: 10.1016/j.ophtha.2016.08.015. Epub 2016 Sep 12. PMID: 27633646; PMCID: PMC5608548. *available at* https://pubmed.ncbi.nlm.nih.gov/27633646/ (last visited Feb. 26, 2021).

[79] Florida Society of Ophthalmology, Centers for Medicare & Medicaid Services, 2010 U.S. Census, Ophthalmology Point of Service, *Drive Time to an Ophthalmology Point of Service, Map* (on file with the Senate Health Policy Committee).

[80] National Institute of Health, National Library of Medicine, *Comparison of Outcomes of Laser Trabeculoplasty Performed by Optometrists vs Ophthalmologists in Oklahoma*. Stein JD, Zhao PY, Andrews C, Skuta GL. reprint from JAMA Ophthalmol. 2016 Oct 1;134(10):1095-1101, *available at* https://pubmed.ncbi.nlm.nih.gov/27467233/ (last visited Feb. 25, 2021).

[81] American Optometric Association, *Criticized Laser Study Resurfaces in Scope Battles*, April 28, 2017, *available at* https://www.aoa.org/news/clinical-eye-care/trabeculoplasty-commentary (last visited Feb. 26, 2021).

[82] Florida Optometric Association, *Recommended Updates to Florida Optometry Practice Act 2021* (on file with the Senate Health Policy Committee).

optometrists who administered injections or perform procedures using scalpels or lasers, other than diagnostic lasers, such as OCT.[83]

The U.S. Veteran's Health Administration (VHA), as part of its facilities medical staff, utilizes optometrists, optometrist fellows and residents, and ophthalmologists and ophthalmology residents. The VHA only permits therapeutic laser eye procedures in VHA facilities to be performed by ophthalmologists or ophthalmology residents.

Physicians who perform laser surgery at VHA medical facilities must also be current in laser safety training provided within the VHA Talent Management System for initial granting of and maintenance of laser privileges.[84]

On January 15, 2020, the State of Vermont, Secretary of State, Office of Professional Regulation (OPR) released a *Study of Optometric Advanced Procedures* that the 2019 Vermont legislature directed the OPR to perform to evaluate the safety and public health needs of enlarging the scope of practice of optometrists to include advanced surgical procedures.[85] The study addresses the impact of enlarging the scope of practice of optometrists on public safety, the need and impact on access to healthcare, and the costs. Specifically, the study looked at the following four anterior segment laser procedures, in addition to other:[86]

- Laser Capsulorhexis;
- YAG Capsulotomy;
- Laser Trabeculoplasty (LTP); and
- Laser Iridotomy.

The Vermont OPR study reviewed the laser capsulorhexis and YAG capsulotomy procedures for cataracts, noting that laser capsulorhexis is a procedure using a laser to make an incision around the capsule of the eye to permit the removal of the lens for cataract surgery. Whether performed by an optometrist or an ophthalmologist, this procedure must be done in an operating room because surgery to remove the cataract and replacement of the lens follows. The Vermont ORP noted there were reported challenges controlling the size and contour of the incision with the laser; and complications noted in the study included:[87]

- Imprecise and/or incomplete incision;
- Repeated surgery;
- Poor visual acuity following surgery;
- Repeat tear of the incision;
- Blindness;

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[83] Ophthalmology Mutual Insurance Company (OMIC), *Statement on Optometric Malpractice Rates*, Feb. 10, 2021(on file with the Senate Health Policy Committee).
[84] United States Department of Veterans Affairs, Veterans Health Administration, Washington, DC 20420, Oct. 2, 2019, amended. Aug. 18, 2020, VHA DIRECTIVE 1121(2), V*HA EYE AND VISION CARE*, Appendix G, *available at* https://www.va.gov/OPTOMETRY/docs/VHA_Directive_1121-2_VHA_Eye_and_vision_Care_10-02-2019_Amended_08-19-2020.pdf (Last Visited Feb. 26, 2021).
[85] Vermont Act 30, s. 13 (2019).
[86] State of Vermont, Secretary of State, Office of Professional Regulation, *Study of Optometric Advanced Procedures*, Jan. 15, 2020, *available at* https://sos.vermont.gov/media/dhlgd0ve/optometry-advanceed-proceedures-report-january-2020.pdf (last visited Feb. 26, 2021).
[87] *Id.*

- Loss of the eye.

Based on its findings in the study, Vermont's OPR concluded that there was little evidence to demonstrate lack of access, cost savings, or that an optometrist received the education and training necessary to provide the proposed advanced procedures safely.[88]

III. Effect of Proposed Changes:

SB 876:

- Expands the scope of practice for certified optometrists;
- Amends the definition of "certified optometrist" to provide that the term "certified optometric physician" is synonymous with the former term;
- Adds the following elements to the definition of "optometry" which do not exist under the current-law definition:
  - The "evaluation, treatment, and management" of conditions of the human eye and its appendages, and, under the bill, such conditions include "any chronic systemic conditions relating to the eye;" and
  - The prescribing and application of "vision therapy, low-vision rehabilitation services, and ophthalmic procedures and therapy for the diagnosis, evaluation, treatment, or management" of any insufficiency, anomaly, abnormality, or disease condition relating to the human eye or its appendages.
- Removes from law the current requirement for a certified optometrist or a holder of a optometric faculty certificate to provide proof to the Department of Health (DOH) that he or she has successfully completed a course and passed an exam on general and ocular pharmaceuticals and their side effects, before he or she may administer or prescribe oral ocular pharmaceuticals;
- Limits the time frame for applicants to retake any failed part(s) of the licensure examination to within three years after the submission of the application;
- Authorizes the creation of a new certification for certified optometrists, the optometrist certified in ophthalmic procedures and therapy, to perform Board-approved laser and non-laser ophthalmic procedures and therapy if certain conditions are met;
- Revises the composition of the Board to require that all optometrist members must be certified optometrists or optometrists certified in ophthalmic procedures;
- Revises current law relating to controlled substances that certified optometrists are prohibited from administering or prescribing, except for oral analgesics for the relief of pain due to ocular conditions, by adding Schedule II controlled substances to that provision, which will authorize certified optometrists to prescribe or administer Schedule II controlled substances under the exception;[89]

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[88] *Id*.

[89] United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, *Controlled Substance Schedules, available at* https://www.deadiversion.usdoj.gov/schedules/#:~:text=Examples%20of%20Schedule%20II%20narcotics,Sublimaze%C2%AE%2C%20Duragesic%C2%AE) (last visited Feb. 27, 2021). Examples of Schedule II analgesics include the following narcotics: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®), (Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone.

- Repeals the current-law formulary process for topical ocular agents that an optometrist may prescribe, as developed by the Board;
- Repeals the current-law statutory formulary of oral ocular agents that an optometrist may prescribe;
- Replaces the current-law formularies with a negative formulary system, to be established by the Board, that will include ocular agents that an optometrist is prohibited from prescribing;
- Removes the current-law limitation on the administration methods a certified optometrist may use for ocular pharmaceuticals, thereby allowing certified optometrists to use additional medication delivery systems – including subcutaneous (Sub-Q), intramuscular (IM), and intravenous (IV) – for ocular pharmaceutical agents not listed in the negative formulary;
- Directs the Board to:
    - Establish the negative formulary of ocular medications that certified optometrists are prohibited from administering or prescribing;
    - Adopt rules relating to:
        - The practices and procedures for the administration and prescription of eye medications;
        - The laser and non-laser ophthalmic procedures and therapies an optometrist certified in ophthalmic procedures may perform;
        - The standards of practice for each Board-approved ophthalmic procedure or therapy an optometrist certified in ophthalmic procedures may perform;
        - The scope of practice of optometry;
        - The required content, grading criteria, and passing score for the licensure examination for certified optometrists; and
- Specifies that the following ophthalmic procedures are excluded from the scope of practice of optometry:
    - Any procedure that requires preoperative medication;
    - Any procedure that requires drug induced alteration of consciousness;
    - Laser vision correction;
    - Penetrating keratoplasty;
    - Corneal or lamellar keratoplasty;
    - Laser of the vitreous chamber or retina to treat vitreomacular or retinal disease;
    - Eyelid surgery for:
    - Suspected eyelid malignancies;
    - Incisional cosmetic or mechanical repair of blepharochalasis, ptosis, or tarsorrhaphy.
    - Boney orbit surgery, including, but not limited to:
    - Orbital implants; or
    - Removal of the human eye.
    - Surgery of the lacrimal system other than lacrimal probing;
    - Full thickness surgeries of the cornea or sclera other than paracentesis in an emergency;
    - Iris and ciliary body surgery requiring a scalpel including, iris diathermy or cryotherapy;
    - Surgery of the vitreous or retina;
    - Surgery of the crystalline lens or an intraocular prosthetic implant;
    - Surgery on extraocular muscles;
    - A full thickness conjunctivoplasty with graft or flap; and
    - Pterygium surgery.

Any other ophthalmology laser and non-laser surgical procedure could be authorized by the Board to be performed by optometrists certified in ophthalmic procedures.[90]

- Provides that all applicable provisions of ch. 456, F.S., relating to the activities of the DOH's regulatory boards will apply to the Board, except for the provisions of that chapter which conflict with the provisions of ch. 463, F.S., relating to the practice of optometry; and
- Makes conforming and cross-referencing changes.

The bill provides an effective date of July 1, 2021.

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

IV. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Due to the bill's expansion of services that optometrists may perform, the bill might result in increased costs borne by private health insurers and HMOs that cover optometric services. The fiscal impact is indeterminate at this time.

C. Government Sector Impact:

Due to the bill's expansion of services that optometrists may perform, the bill might result in increased costs for optometric services under state group health insurance and

[90] Florida Society of Ophthalmology, *Examples of Surgeries SB 876/HB 631 Would Authorize Optometrists to Perform* (on file with the Senate Health Policy Committee).

Medicaid, to the extent such services are covered and provided under those respective benefit packages. The fiscal impact is indeterminate at this time.

V. Technical Deficiencies:

None.

VI. Related Issues:

- The bill directs the Board to review and approve the content of the initial course and examination for certification as an optometrist certified in ophthalmic procedures, and the course and examination must adequately and reliably satisfy the criteria set forth in s. 463.0056, F.S., as created by the bill, relating to ophthalmic procedures certified optometrists may perform. The bill also directs the Board to annually review and approve the examination if the Board determines that the content continues to adequately and reliably satisfy such criteria. However, the bill provides no such criteria in that new section of statute, aside from criteria specifying organizations that may develop and offer the course and exam. For example, the bill does not give guidance as to the number of hours required, the procedures to be included, whether the course and exam can be completed online, or whether the course is lecture-only or requires clinical experience.

- The bill requires an optometrist desiring to be certified to perform ophthalmic procedures, to first provide proof to the DOH of his or her successful completion of a course and subsequent examination, approved by the Board, on laser and non-laser ophthalmic procedures and therapy. The bill defines an "optometrist certified in ophthalmic procedures" as a certified optometrist who is authorized under s. 463.0056, F.S., as created by the bill, to perform Board-approved laser and non-laser ophthalmic procedures and therapy in accordance with that section.

  The bill does not provide any guidance as to what happens after a certified optometrist submits his or her proof to the DOH. To wit:
  - The bill contains no provision as to who issues the certification, i.e. the DOH or the Board.
  - The bill contains no provision for the certification to expire or be renewed.
  - The bill contains no continuing education requirements to maintain the certification.

- The bill expands the scope of the practice of optometry to include the ability of optometrist certified in ophthalmic procedures to perform laser and non-laser procedures that are currently only performed by ophthalmology physicians, who are required to carry medical malpractice insurance or provide proof of financial responsibility. Physicians must also report adverse incidents to the DOH. The bill contains no such requirements for optometrists who become certified to perform ophthalmic procedures.

- The bill does not define "minimal tranquilization" that the optometrist certified to perform ophthalmic procedures is permitted to utilize. That term is not a standard term of induced levels of consciousness.

VII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 463.002, 463.003, 463.005, 463.0055, 463.0057, 463.006, 463.0135, 463.014, 463.009, and 641.31.

This bill creates section 463.0056 of the Florida Statutes.

VIII. Additional Information:

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

None.

B. Amendments:

None.

By Senator Diaz

36-00524-21 2021876__

A bill to be entitled

An act relating to optometry; reordering and amending s. 463.002, F.S.; revising and defining terms; amending s. 463.003, F.S.; revising the member composition requirements for the Board of Optometry; revising applicability; amending s. 463.005, F.S.; revising specified rules the board must adopt; amending s. 463.0055, F.S.; revising circumstances under which a certified optometrist may administer or prescribe ocular pharmaceutical agents; deleting requirements a certified optometrist must satisfy to administer or prescribe ocular pharmaceutical agents; requiring the board to adopt a negative formulary of ocular pharmaceutical agents certified optometrists are prohibited from administering or prescribing; deleting provisions relating to the topical and oral ocular pharmaceutical agent formularies established by the board; requiring the board to mail a copy of the negative formulary to all certified optometrists and licensed pharmacies under certain circumstances; revising the controlled substances that certified optometrists are prohibited from administering or prescribing; creating s. 463.0056, F.S.; authorizing certain certified optometrists to perform laser and non-laser ophthalmic procedures and therapies under certain circumstances; providing certification requirements certified optometrists must satisfy to perform such procedures and therapies; requiring the board to approve the courses and examinations to be

36-00524-21 2021876__

used for certification if certain conditions are met; requiring the board to review and approve the examination annually if certain conditions are met; authorizing certified optometrists to use the board-approved course and examination to satisfy their continuing education requirements under certain circumstances; prohibiting a certified optometrist who does not complete such course and examination from performing certain ophthalmic procedures; specifying ophthalmic procedures that are excluded from the scope of practice of optometry, with an exception; amending s. 463.0057, F.S.; conforming a provision to changes made by the act; amending s. 463.006, F.S.; conforming provisions to changes made by the act; requiring the board to determine the required content, grading criteria, and passing score for the licensure examination for certified optometrists; making technical changes; amending s. 463.0135, F.S.; authorizing certified optometrists to remove superficial foreign bodies; defining the term "superficial foreign bodies"; specifying circumstances under which optometrists may perform procedures within the practice of optometry which may otherwise be considered surgery; requiring licensed practitioners who are not certified optometrists to display in their practices a sign containing specified information; amending s. 463.014, F.S.; deleting a prohibition on surgery performed by certified optometrists to conform to changes made by the act; amending ss. 463.009 and

641.31, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Section 463.002, Florida Statutes, is reordered and amended to read:

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

(2) ~~(1)~~ "Board" means the Board of Optometry.

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

(8) ~~(3)(a)~~ "Licensed practitioner" means a person who is a primary health care provider licensed to engage in the practice of optometry under the authority of this chapter. With respect to persons initially licensed under this chapter after July 1, 1993, the term includes only certified optometrists.

~~(b) A licensed practitioner who is not a certified optometrist shall be required to display at her or his place of practice a sign which states, "I am a Licensed Practitioner, not a Certified Optometrist, and I am not able to prescribe ocular pharmaceutical agents."~~

~~(c) All practitioners initially licensed after July 1, 1993, must be certified optometrists.~~

(3) ~~(4)~~ "Certified optometrist" or "certified optometric physician" means a licensed practitioner authorized by the board to administer and prescribe ocular pharmaceutical agents.

(9) ~~(5)~~ "Ocular pharmaceutical agent" means a pharmaceutical agent that is administered or prescribed ~~topically or orally~~ for the diagnosis or treatment of ocular conditions of the human eye and its appendages ~~without the use of surgery or other invasive techniques~~.

(13) ~~(6)~~ "Surgery" means a procedure using an instrument, including a laser, scalpel, or needle, in which human tissue is cut, burned, scraped except as provided in s. 463.0135(12) ~~s. 463.014(4)~~, or vaporized, by incision, injection, ultrasound, laser, infusion, cryotherapy, or radiation. The term includes a procedure using an instrument which requires the closure of human tissue by suture, clamp, or other such device.

(11) ~~(7)~~ "Optometry" means the diagnosis, evaluation, treatment, and management of conditions of the human eye and its appendages, including any visual, muscular, neurological, or anatomical anomalies and chronic systemic conditions relating to the eye; the determination of the refractive powers of the human eye; and the prescribing and employment of any ~~objective or subjective~~ means or methods, including ~~the administration of~~ ocular pharmaceutical agents, contact lenses, spectacle lenses, magnification lenses, vision therapy, low vision rehabilitation devices, and ophthalmic procedures and therapy, for the diagnosis, evaluation, correction, remedy, treatment, management, or relief of any insufficiency, anomaly, abnormality, or disease condition relating to the human eye or its appendages ~~for the purpose of determining the refractive powers of the human eyes, or any visual, muscular, neurological, or anatomic anomalies of the human eyes and their appendages; and the prescribing and employment of lenses, prisms, frames, mountings, contact lenses, orthoptic exercises, light frequencies, and any other means or methods, including ocular pharmaceutical agents, for the correction, remedy, or relief of any insufficiencies or abnormal conditions of the human eyes and~~

~~their appendages~~.

(6)~~(8)~~ "Direct supervision" means supervision to an extent that the licensee remains on the premises while all procedures are being done and gives final approval to any procedures performed by an employee.

(7)~~(9)~~ "General supervision" means the responsible supervision of supportive personnel by a licensee who need not be present when such procedures are performed, but who assumes legal liability therefor. Except in cases of emergency, "general supervision" shall require the easy availability or physical presence of the licensee for consultation with and direction of the supportive personnel.

(1)~~(10)~~ "Appendages" means the eyelids, the eyebrows, the conjunctiva, and the lacrimal apparatus.

(14)~~(11)~~ "Transcript-quality" means a course that ~~which~~ is in conjunction with or sponsored by a school or college of optometry or equivalent educational entity, which course is approved by the board and requires a test and passing grade.

(4)~~(12)~~ "Clock hours" means the actual time engaged in approved coursework and clinical training.

(10) "Optometrist certified in ophthalmic procedures" means a certified optometrist who is authorized under s. 463.0056 to perform board-approved laser and non-laser ophthalmic procedures and therapy in accordance with that section.

(12) "Refraction" means the use of lenses and ocular pharmaceutical agents during the course of a comprehensive medical eye examination to determine a patient's visual, neurological, and physical requirements to attain optimal visual and perceptual performance.

Section 2. Subsections (2) and (4) of section 463.003, Florida Statutes, are amended to read:

463.003 Board of Optometry.—

(2) Five members of the board must be certified optometrists or optometrists certified in ophthalmic procedures ~~licensed practitioners~~ actively practicing in this state. The remaining two members must be citizens of this ~~the~~ state who are not, and have never been, licensed practitioners and who are in no way connected with the practice of optometry or with any vision-oriented profession or business. At least one member of the board must be 60 years of age or older.

(4) All applicable provisions of chapter 456 relating to activities of regulatory boards which do not conflict with this chapter shall apply.

Section 3. Subsection (1) of section 463.005, Florida Statutes, is amended to read:

463.005 Authority of the board.—

(1) The Board of Optometry shall ~~has authority to~~ adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it. Such rules must ~~shall~~ include, but need not be limited to, rules relating to all of the following:

(a) Standards of practice, including, but not limited to, those provided ~~for~~ in s. 463.0135.

(b) Minimum equipment that ~~which~~ a licensed practitioner must ~~shall~~ at all times possess to engage in the practice of optometry.

(c) Minimum procedures that ~~which shall~~ constitute a visual examination.

(d) Procedures for the safekeeping and transfer of prescription files or case records ~~upon the discontinuance of practice~~.

(e) Supervision of supportive personnel.

(f) Courses and procedures for continuing education.

(g) Practices and procedures for the administration and prescription of ocular pharmaceutical agents.

(h) Laser and non-laser ophthalmic procedures and therapies an optometrist certified in ophthalmic procedures may perform, including, but not limited to, the standards of practice for such ophthalmic procedures and therapies.

(i) The scope of practice of optometry consistent with this chapter.

(j) Required content, grading criteria, and passing scores for the licensure examinations set forth in s. 463.006.

Section 4. Section 463.0055, Florida Statutes, is amended to read:

463.0055 Administration and prescription of ocular pharmaceutical agents.—

(1)~~(a)~~ Certified optometrists may administer and prescribe ocular pharmaceutical agents as provided in this section for the diagnosis and treatment of ocular conditions of the human eye and its appendages ~~without the use of surgery or other invasive techniques~~. However, a licensed practitioner who is not certified may use topically applied anesthetics solely for the purpose of glaucoma examinations, but is otherwise prohibited from administering or prescribing ocular pharmaceutical agents.

~~(b) Before a certified optometrist may administer or prescribe oral ocular pharmaceutical agents, the certified optometrist must provide proof to the department of successful completion of a course and subsequent examination, approved by the board, on general and ocular pharmaceutical agents and the side effects of those agents. The course shall consist of 20 contact hours, all of which may be web-based. The first course and examination shall be presented by October 1, 2013, and shall be administered at least annually thereafter. The course and examination shall be developed and offered jointly by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award (AMA PRA) Category 1 credit and a statewide professional association of licensed practitioners which provides board-approved continuing education on an annual basis. The board shall review and approve the content of the initial course and examination if the board determines that the course and examination adequately and reliably satisfy the criteria set forth in this section. The board shall thereafter annually review and approve the course and examination if the board determines that the content continues to adequately and reliably satisfy the criteria set forth in this section. Successful completion of the board-approved course and examination may be used by a certified optometrist to satisfy 20 hours of the continuing education requirements in s. 463.007(3), only for the biennial period in which the board-approved course and examination are taken. If a certified optometrist does not complete a board-approved course and examination under this section, the certified optometrist is only authorized to administer and prescribe topical ocular pharmaceutical agents.~~

(2)~~(a)~~ The board shall establish a negative formulary of ~~topical~~ ocular pharmaceutical agents that a certified optometrist may not administer or prescribe ~~be prescribed and administered by a certified optometrist~~. ~~The formulary shall consist of those topical ocular pharmaceutical agents that are appropriate to treat or diagnose ocular diseases and disorders and that the certified optometrist is qualified to use in the practice of optometry. The board shall establish, add to, delete from, or modify the topical formulary by rule. Notwithstanding any provision of chapter 120 to the contrary, the topical formulary rule becomes effective 60 days from the date it is filed with the Secretary of State.~~

~~(b) The formulary may be added to, deleted from, or modified according to the procedure described in paragraph (a). Any person who requests an addition, deletion, or modification of an authorized topical ocular pharmaceutical agent shall have the burden of proof to show cause why such addition, deletion, or modification should be made.~~

~~(c) The State Surgeon General shall have standing to challenge any rule or proposed rule of the board pursuant to s. 120.56. In addition to challenges for any invalid exercise of delegated legislative authority, the administrative law judge, upon such a challenge by the State Surgeon General, may declare all or part of a rule or proposed rule invalid if it:~~

~~1. Does not protect the public from any significant and discernible harm or damages;~~

~~2. Unreasonably restricts competition or the availability of professional services in the state or in a significant part of the state; or~~

~~3. Unnecessarily increases the cost of professional services without a corresponding or equivalent public benefit.~~

~~However, there shall not be created a presumption of the existence of any of the conditions cited in this subsection in the event that the rule or proposed rule is challenged.~~

~~(d)~~ Upon adoption of the negative formulary ~~required by this section~~, and upon each addition, deletion, or modification to the formulary, the board shall mail a copy of the amended formulary to each certified optometrist and to each pharmacy licensed by the state.

~~(3) In addition to the formulary of topical ocular pharmaceutical agents established by rule of the board, there is created a statutory formulary of oral ocular pharmaceutical agents, which includes the following agents:~~

~~(a) The following analgesics or their generic or therapeutic equivalents, which may not be administered or prescribed for more than 72 hours without consultation with a physician licensed under chapter 458 or chapter 459 who is skilled in diseases of the eye:~~

~~1. Tramadol hydrochloride.~~

~~2. Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.~~

~~(b) The following antibiotics or their generic or therapeutic equivalents:~~

~~1. Amoxicillin with or without clavulanic acid.~~

~~2. Azithromycin.~~

~~3. Erythromycin.~~

~~4. Dicloxacillin.~~

~~5. Doxycycline/Tetracycline.~~

~~6. Keflex.~~

~~7. Minocycline.~~

~~(c) The following antivirals or their generic or therapeutic equivalents:~~

~~1. Acyclovir.~~

~~2. Famciclovir.~~

~~3. Valacyclovir.~~

~~(d) The following oral anti-glaucoma agents or their generic or therapeutic equivalents, which may not be administered or prescribed for more than 72 hours:~~

~~1. Acetazolamide.~~

~~2. Methazolamide.~~

~~Any oral ocular pharmaceutical agent that is listed in the statutory formulary set forth in this subsection and that is subsequently determined by the United States Food and Drug Administration to be unsafe for administration or prescription shall be considered to have been deleted from the formulary of oral ocular pharmaceutical agents. The oral ocular pharmaceutical agents on the statutory formulary set forth in this subsection may not otherwise be deleted by the board, the department, or the State Surgeon General.~~

(3)~~(4)~~ A certified optometrist shall be issued a prescriber number by the board. Any prescription written by a certified optometrist for an ocular pharmaceutical agent pursuant to this section shall have the prescriber number printed thereon. A certified optometrist may not administer or prescribe any of the following:

(a) A controlled substance listed in Schedule II, Schedule

III, Schedule IV, or Schedule V of s. 893.03, except for an oral analgesic ~~placed on the formulary pursuant to this section~~ for the relief of pain due to ocular conditions of the eye and its appendages.

(b) A controlled substance for the treatment of chronic nonmalignant pain as defined in s. 456.44(1)(f).

Section 5. Section 463.0056, Florida Statutes, is created to read:

463.0056 Ophthalmic Procedures.—

(1)(a) An optometrist certified in ophthalmic procedures may perform laser and non-laser ophthalmic procedures and therapies as authorized by the board but may not perform an ophthalmic procedure or therapy that requires preoperative medications or drug-induced alteration of consciousness. However, an optometrist certified in ophthalmic procedures may use medication for minimal tranquilization of the patient and local or topical anesthesia if the chances of complications requiring hospitalization of the patient as a result are remote.

(b) To be certified to perform ophthalmic procedures, a certified optometrist must first provide proof to the department of successful completion of a course and subsequent examination, approved by the board, on laser and non-laser ophthalmic procedures and therapy. The course and examination shall be developed and offered jointly by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit and a statewide professional association of licensed practitioners which provides board-approved continuing education on an annual

basis. The board shall review and approve the content of the initial course and examination if the board determines that the course and examination adequately and reliably satisfy the criteria set forth in this section. The board shall thereafter annually review and approve the examination if the board determines that the content continues to adequately and reliably satisfy the criteria set forth in this section. Successful completion of the board-approved course and examination may be used by a certified optometrist to satisfy the continuing education requirements in s. 463.007(3) only for the biennial period in which the board-approved course and examination are taken. If a certified optometrist does not complete a board-approved course and examination under this section, the certified optometrist may not perform ophthalmic procedures described in paragraph (a).

(2) The following ophthalmic procedures are excluded from the scope of practice of optometry, except for the preoperative and postoperative care of these procedures:

(a) Laser vision correction, penetrating keratoplasty, and corneal or lamellar keratoplasty.

(b) Laser of the vitreous chamber or retina of the eye to treat any vitreomacular or retinal disease.

(c) Surgery of the eyelid for suspected eyelid malignancies or for incisional cosmetic or mechanical repair of blepharochalasis, ptosis, or tarsorrhaphy.

(d) Surgery of the boney orbit, including, but not limited to, orbital implants or removal of the human eye.

(e) Incisional or excisional surgery of the lacrimal system other than lacrimal probing or related procedures.

(f) Surgery requiring full thickness incision or excision of the cornea or sclera other than paracentesis in an emergency situation requiring immediate reduction of elevated pressure inside the eye.

(g) Surgery requiring incision or excision by scalpel of the iris and ciliary body, including, but not limited to, iris diathermy or cryotherapy.

(h) Surgery requiring incision or excision of the vitreous or retina.

(i) Surgery requiring incision or excision of the crystalline lens or an intraocular prosthetic implant.

(j) Surgery involving incision or excision of the extraocular muscles.

(k) Surgery requiring full thickness conjunctivoplasty with graft or flap.

(l) Pterygium surgery.

(m) Any other procedure or therapy the board deems appropriate.

Section 6. Subsection (3) of section 463.0057, Florida Statutes, is amended to read:

463.0057 Optometric faculty certificate.—

(3) The holder of a faculty certificate may engage in the practice of optometry as permitted by this section but may not administer or prescribe topical ocular pharmaceutical agents unless the certificateholder has satisfied the requirements of s. 463.006(1)(e) and (f). ~~If a certificateholder wishes to administer or prescribe oral ocular pharmaceutical agents, the certificateholder must also satisfy the requirements of s. 463.0055(1)(b).~~

Section 7. Section 463.006, Florida Statutes, is amended to read:

463.006 Licensure and certification by examination.—

(1) Any person desiring to be a certified optometrist ~~licensed practitioner~~ pursuant to this chapter must apply to the department and must submit proof to the department that she or he:

(a) Has completed the application forms as required by the board, remitted an application fee for certification not to exceed $250, remitted an examination fee for certification not to exceed $250, and remitted an examination fee for licensure not to exceed $325, all as set by the board.

(b) Is at least 18 years of age.

(c) Has graduated from an accredited school or college of optometry approved by rule of the board.

(d) Is of good moral character.

(e) Has successfully completed at least 110 hours of transcript-quality coursework and clinical training in general and ocular pharmacology as determined by the board, at an institution that:

1. Has facilities for both didactic and clinical instructions in pharmacology; and

2. Is accredited by a regional or professional accrediting organization that is recognized and approved by the Commission on Recognition of Postsecondary Accreditation or the United States Department of Education.

(f) Has completed at least 1 year of supervised experience in differential diagnosis of eye disease or disorders as part of the optometric training or in a clinical setting as part of the

optometric experience.

(2) The board shall approve a licensure examination consisting of the appropriate subjects and including applicable state laws and rules and general and ocular pharmacology with emphasis on the use and side effects of ocular pharmaceutical agents. The board may by rule substitute a national examination as part or all of the examination and, notwithstanding chapter 456, may by rule offer a practical examination in addition to a written examination. The board shall determine the required content, grading criteria, and passing score for the licensure examination.

(3) Each applicant who submits proof satisfactory to the board that he or she has met the requirements of subsection (1), who successfully passes the licensure examination within 3 years before the date of application or within 3 years after the submission of an application, and who otherwise meets the requirements of this chapter is entitled to be licensed as a certified optometrist ~~practitioner and to be certified to administer and prescribe ocular pharmaceutical agents in the diagnosis and treatment of ocular conditions~~.

Section 8. Subsections (12) and (13) are added to section 463.0135, Florida Statutes, to read:

463.0135 Standards of practice.—

(12) Certified optometrists may remove superficial foreign bodies. For the purpose of this subsection, the term "superficial foreign bodies" means any foreign matter that is embedded in the conjunctiva or cornea but that has not penetrated the globe. Notwithstanding the definition of surgery in s. 463.002, a certified optometrist may provide any

optometric care within the practice of optometry as defined in s. 463.002, including, but not limited to, removing an eyelash by epilation, probing an uninflamed tear duct in a patient 18 years of age or older, blocking the puncta by plug, or superficial scraping for the purpose of removing damaged epithelial tissue or superficial foreign bodies or taking a culture of the surface of the cornea or conjunctiva.

(13) A licensed practitioner who is not a certified optometrist is required to display at her or his place of practice a sign that states, "I am a Licensed Practitioner, not a Certified Optometrist, and I am not able to prescribe ocular pharmaceutical agents or perform ophthalmic procedures."

Section 9. Subsection (4) of section 463.014, Florida Statutes, is amended to read:

463.014 Certain acts prohibited.—

~~(4) Surgery of any kind is expressly prohibited. Certified optometrists may remove superficial foreign bodies. For the purposes of this subsection, the term "superficial foreign bodies" means any foreign matter that is embedded in the conjunctiva or cornea but that has not penetrated the globe. Notwithstanding the definition of surgery as provided in s. 463.002(6), a certified optometrist is not prohibited from providing any optometric care within the practice of optometry as defined in s. 463.002(7), such as removing an eyelash by epilation, probing an uninflamed tear duct in a patient 18 years of age or older, blocking the puncta by plug, or superficial scraping for the purpose of removing damaged epithelial tissue or superficial foreign bodies or taking a culture of the surface of the cornea or conjunctiva.~~

Section 10. Section 463.009, Florida Statutes, is amended to read:

463.009 Supportive personnel.—No person other than a licensed practitioner may engage in the practice of optometry as defined in s. 463.002 ~~s. 463.002(7)~~. Except as provided in this section, under no circumstances shall nonlicensed supportive personnel be delegated diagnosis or treatment duties; however, such personnel may perform data gathering, preliminary testing, prescribed visual therapy, and related duties under the direct supervision of the licensed practitioner. Nonlicensed personnel, who need not be employees of the licensed practitioner, may perform ministerial duties, tasks, and functions assigned to them by and performed under the general supervision of a licensed practitioner, including obtaining information from consumers for the purpose of making appointments for the licensed practitioner. The licensed practitioner shall be responsible for all delegated acts performed by persons under her or his direct and general supervision.

Section 11. Subsection (19) of section 641.31, Florida Statutes, is amended to read:

641.31 Health maintenance contracts.—

(19) Notwithstanding any other provision of law, health maintenance policies or contracts which provide coverage, benefits, or services as described in s. 463.002 ~~s. 463.002(7),~~ shall offer to the subscriber the services of an optometrist licensed pursuant to chapter 463.

Section 12. This act shall take effect July 1, 2021.

Rossitto-Vanwinkle, Tari

From:	Spivey, Anthony B <Anthony.Spivey@flhealth.gov>
Sent:	Thursday, January 7, 2021 1:22 PM
To:	Rossitto-Vanwinkle, Tari
Subject:	Optometrists licensed under s. 463.002(3)(b), F.S.
Attachments:	OPT only clear inactive.docx; Opt only clear active.docx

Good afternoon Ms. Rossitto-Vanwinkle,

I am attaching your request for a list of the licensed optometrists who are not *certified* per your January 6, 2021 request to Ms. Hartman. Please contact me if you have any questions.

Sincerely,

Dr. Spivey

Anthony B. Spivey, DrBA
Executive Director
Boards of Chiropractic Medicine, Clinical Laboratory Personnel,
Nursing Home Administrators, Optometry
EMT/Paramedics, Radiology Technologists, and Medical Physicists
4052 Bald Cypress Way, Bin #C-07
Tallahassee, FL 32399
850 901-6830

Florida Medical Quality Assurance
License Master Report

License Type: 1801 Optometrist
Selection Criteria: Status=20; Secondary Status=40; Rank=OP; Rank=OP; Address Type=MA;

File #	License #	Name	Rank	Status	Expiry Date	Modifiers	Zip	Region	County
721	1079	HARVEY A DUBIN	OPTOMETRIST	CLEAR, INACTIVE	02/28/2021	NDEA,PLP3	10606	None	Out of State
752	1110	ALTON L PROVOST	OPTOMETRIST	CLEAR, INACTIVE	02/28/2021	PLP3	30052	None	Out of State
779	1140	WILLIAM F BILLMAN	OPTOMETRIST	CLEAR, INACTIVE	02/28/2021	NDEA,PLP3	46240	None	Out of State
1074	1443	STUART D SCHATZ	OPTOMETRIST	CLEAR, INACTIVE	02/28/2023	PLP3	20740	None	Out of State
1820	2195	TIMOTHY C MCKERNAN	OPTOMETRIST	CLEAR, INACTIVE	02/28/2021	PLP3	16046	None	Out of State
1904	2279	TAMMY LYNNE HOLSCLAW-JONES	OPTOMETRIST	CLEAR, INACTIVE	02/28/2021	PLP3	37601	None	UNKNOWN
1970	2345	FRANK MICHAEL DERIENZO	OPTOMETRIST	CLEAR, INACTIVE	02/28/2021	PLP3	07726	None	Out of State

Florida Medical Quality Assurance
License Master Report

License Type: 1801 Optometrist
Selection Criteria: Status=20; Secondary Status=20; Rank=OP; Rank=OP; Address Type=MA;

File #	License #	Name	Rank	Status	Expiry Date	Modifiers	Zip	Region	County
253	570	DAVID D HAUGHTON	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	33407-6555	West Palm Beach	PALM BEACH
300	628	DALE FAUST	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3,NDEA	33871-1147		HIGHLANDS
469	818	WILLIAM FLEISHER	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	33308	Ft. Lauderdale	BROWARD
501	853	D B COCHRAN	OPTOMETRIST	CLEAR, ACTIVE	02/28/2023	PLP3,PLP2	33759	St. Petersburg	PINELLAS
519	872	ROBERT L AGNEW	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	34957	West Palm Beach	MARTIN
549	902	ALLEN I SOBEL	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	34429	Gainesville	CITRUS
615	969	TIMOTHY P ALLEN	OPTOMETRIST	CLEAR, ACTIVE	02/28/2023	PLP3	78251-4302	None	Out of State
657	1014	GARY ROBERT ALLEGRETTI	OPTOMETRIST	CLEAR, ACTIVE	02/28/2023	PLP3	33410	West Palm Beach	PALM BEACH
672	1030	KEITH A FINGER	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	32626	Gainesville	LEVY
676	1034	GILBERT G JANNELLI	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	33756	St. Petersburg	PINELLAS
687	1045	GARY E RADISH	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	37043	None	Out of State
737	1095	MAURY J HOLLANDER	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	32701	Orlando	SEMINOLE
750	1108	CLAYTON L OLESEN JR	OPTOMETRIST	CLEAR, ACTIVE	02/28/2023	PLP3	32931	Orlando	BREVARD
766	1126	FRANK WASSERMAN O.D.	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	63130	None	Out of State
772	1132	SAMUEL D WINN	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	32904	Orlando	BREVARD
803	1166	REUBEN MARGULIS	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	33324	Ft. Lauderdale	BROWARD
829	1193	RICHARD C STEVENS	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3,NDEA	32137	Jacksonville	FLAGLER

Florida Medical Quality Assurance
License Master Report

File #	License #	Name	Rank	Status	Expiry Date	Modifiers	Zip	Region	County
839	1203	HARRY NEIL SNYDER OD	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	33412	West Palm Beach	PALM BEACH
849	1214	JAMES E FABRICANT OD	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	85750	None	Out of State
861	1226	RICHARD K HAUSER	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	10583-1923	None	Out of State
869	1234	CLIFFORD A LEMKIN	OPTOMETRIST	CLEAR, ACTIVE	02/28/2023	NDEA,PLP3	11733-1946	None	UNKNOWN
878	1243	BENJAMIN PARRISH	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	37659	None	Out of State
904	1270	GERALD J GALLENTINE MR	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	33684	Tampa	HILLSBOROUGH
918	1286	JOEL S JUSTIN	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	15241	None	Out of State
952	1320	DONALD R WALKER OD	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	07869	None	Out of State
972	1340	MICHAEL M SLOANE	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	11561-2713	None	Out of State
986	1354	DAVID IRVING HORN	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	10475	None	Out of State
1008	1376	WARREN ZIMMERMAN	OPTOMETRIST	CLEAR, ACTIVE	02/28/2023	PLP3,PLP2	11576	None	Out of State
1034	1403	ALAN J DEYONG	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	10901	None	Out of State
1040	1409	GAYLE H FUQUA	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	32175-0032	Jacksonville	VOLUSIA
1063	1432	RICARDO A MORENO OD	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	33015	Miami	MIAMI-DADE
1084		1453 AMY HOLLANDER BEACH WOLNERMAN	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	33433	West Palm Beach	PALM
1086	1455	SCOTT WEIL	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	11050	None	Out of State
1101	1470	EUGENE BENNETT FRANK	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	08057	None	Out of State
1106	1475	ANDREW GALLANT HAHN OD	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	28106	None	Out of State

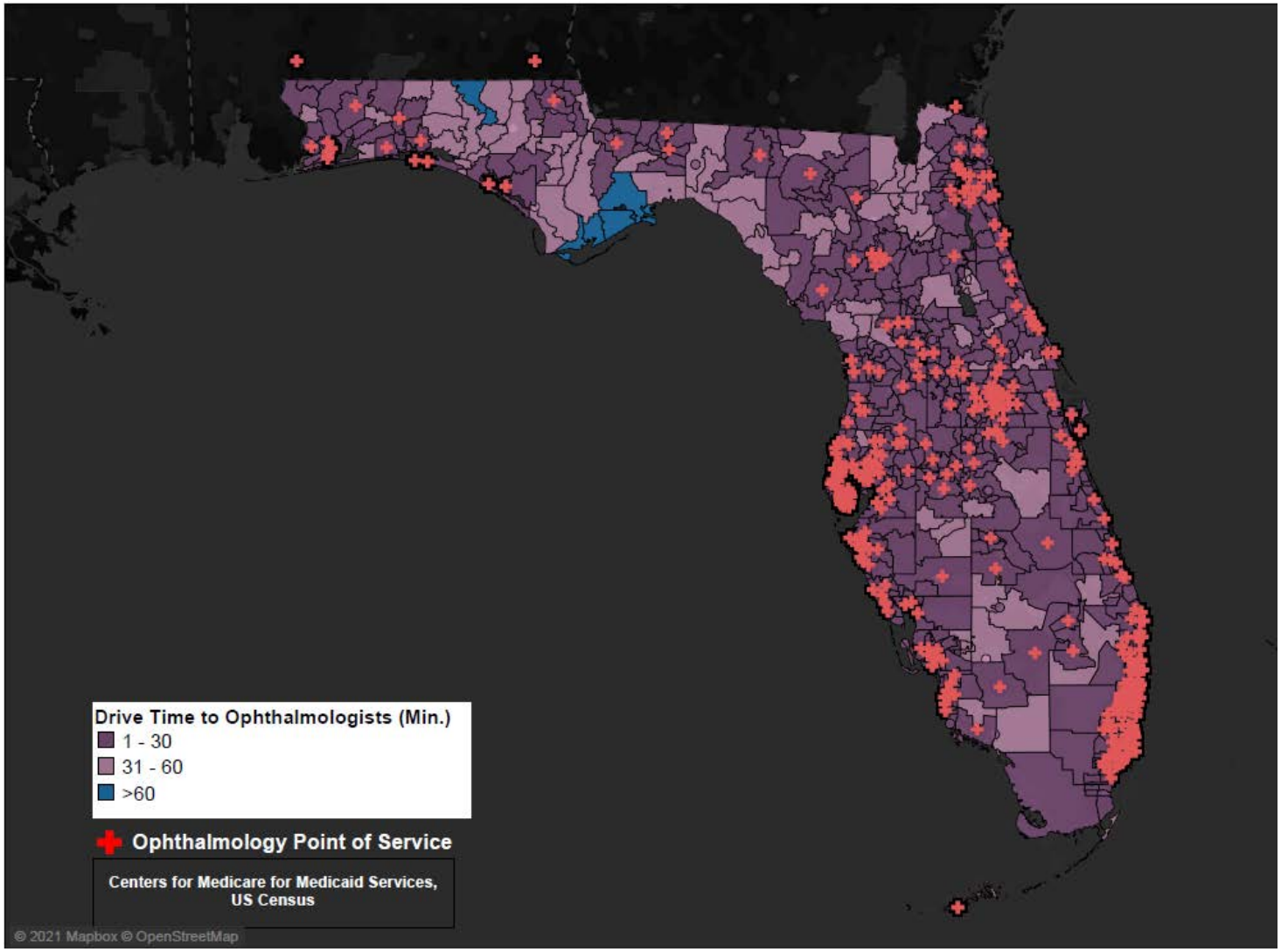
Florida Medical Quality Assurance
License Master Report

File #	License #	Name	Rank	Status	Expiry Date	Modifiers	Zip	Region	County
1178	1548	DOUGLAS LEE MEIER	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	32714-5833	Orlando	SEMINOLE
1194	1564	STEVEN MICHAEL WILSON	OPTOMETRIST	CLEAR, ACTIVE	02/28/2023	PLP3	32250	Jacksonville	DUVAL
1244	1614	BRUCE M STEIN	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	32951	Orlando	BREVARD
1248	1618	STEVEN ROBERT ALI	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	10022	None	Out of State
1268	1639	HOWELL M FINDLEY O.D.	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	40356	None	Out of State
1289	1662	STUART WARREN KRASNOFF	OPTOMETRIST	CLEAR, ACTIVE	02/28/2023	PLP3	11804-1018	None	Out of State
1434	1808	MARK J LICHT	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	11235-2451	None	Out of State
1509	1884	ALAN R TITELBAUM	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	02145-3129	None	Out of State
1525	1900	MICHAEL S BERK	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	43230	None	Out of State
1540	1915	DEBORAH F MCDONALD	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	31602	None	Out of State
1569	1944	BARNET LOUIS LELAND	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	48323	None	Out of State
1619	1994	DIANE L GALPER	OPTOMETRIST	CLEAR, ACTIVE	02/28/2023	PLP3	48377	None	Out of State
1704	2079	JILL KIMBERLY MEYER	OPTOMETRIST	CLEAR, ACTIVE	02/28/2023	PLP3	35124	None	Out of State
1778	2153	WILLIAM SHOCKLEY	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	30265-3420	None	Out of State
1837	2212	KURT ERIC TREU	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	30517	None	Out of State
1898	2273	JOSEPH LEE EDMISTON	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	37075-4374	None	Out of State
1981	2356	SIDNEY ALAN GOTTLIEB	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	30022	None	Out of State

Florida Medical Quality Assurance
License Master Report

2040	2416	LORI ANN ROTHMAN	OPTOMETRIST	CLEAR, ACTIVE	02/28/2023	PLP3,NDEA	10022	None	UNKNOWN
2148	2525	CATHY LYNN EDWARDS	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	NDEA,PLP3	72758	None	Out of State
2177	2555	VITO PROSCIA	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	11788	None	Out of State
2269	2647	FRANK GRAYSON FLOWERS	OPTOMETRIST	CLEAR, ACTIVE	02/28/2021	PLP3	39819	None	Out of State

96% of Florida's Population is Within a 30-Minute Drive to an Ophthalmologist*



*SOURCES:

- *Centers for Medicare and Medicaid (CMS): National Physician Compare File*
- *U.S. Census Bureau*

Recommended Updates to Florida Optometry Practice Act
2021

THE PROBLEM

At its core, updating Florida Optometry practice laws is a matter of removing unnecessary barriers to reduce patients' costs, provide patients more choices, and increase patients' access to quality, affordable health care.

Currently, Florida has some of the most narrow and restrictive optometric scope of practice laws in the United States. Many other states updated their laws years (and in some cases decades) ago with no overall adverse effects.

Notably, no state legislature has ever repealed modernized optometric scope of practice. No state licensure board where advanced ophthalmic procedures are practiced has ever been notified by the National Practitioner Data bank of a judgement against one of their licensees. And liability insurance rates for Doctors of Optometry in states with modernized scope of practice have not increased even though they are based and driven using state specific data.

Optometrists are the doctoral level primary care provider for the eye and its appendages. They have specialized advanced education and training and are held to the same standard of care as any medical doctor. And yet, in Florida, they are not allowed to practice to the level of their education and training or remain contemporary through certification processes available to other allied health providers. In fact, in many instances, Physician Assistants - who do not have the same level of background, specialized education and training as ODs - are permitted to perform more advanced eye procedures and possess broader prescriptive authority than an optometrist in Florida.

Physician Assistants act as extenders of an Ophthalmologist's practice to serve patients – but only when the patient is accepted by the Ophthalmologist. In Florida, PAs can and are successfully performing many ocular procedures that an updated optometric scope of practice law revision would allow Doctors of Optometry to perform. PAs can do so without physical supervision by the Supervising Physician / Ophthalmologist – so long as the PA can reach the physician by phone (Fla. Stat. 458.347). Additionally, Supervising Physicians can delegate unsupervised prescriptive authority of Schedule II-V drugs, limited only by a 7-day prescription maximum for Schedule II.

To be clear, noting these facts is merely intended to educate the reader as to the need for updating the optometric practice act. It is not intended to imply or advocate any need for limiting PAs currently provided authority. On the contrary, Florida Optometrists simply request that the laws be updated to allow them to utilize a fuller range of the available skillsets and "tools" to provide the most effective care possible for their patients.

Resistance to reform comes from a narrow subset of the specialty practitioners (Ophthalmologists) who could potentially lose market share for a limited suite of services if patients were provided more choices and increased access to affordable care. However, many Ophthalmologists support reform.

There are far less Ophthalmologists than Optometrists nationally and in Florida. And, although they have offices, Ophthalmology practitioners themselves are not in every community or county in Florida as are many Optometrists. Furthermore, as advanced surgeons, much of an Ophthalmologist's time is devoted to providing highly needed advanced surgeries performed in the ASC or hospital setting. This results in less access and longer wait times for patients needing primary eye care and leading to more negative healthcare outcomes due to delays in care for patients over time.

The federal government has recognized the access problem created by these outdated laws, and the fact that it drives up healthcare costs for patients and government healthcare programs. Notably, the federal government has sought corrections where it can, namely in veteran care delivered through the VA.

THE SOLUTION

Updating Florida's optometric scope of practice laws to allow Doctors of Optometry to practice to a fuller scope of their education and training will increase access to primary care for patients, provide patients more choices and control over their healthcare, and result in lower costs for patients and the healthcare system over time.

This has been done in many other states for a long time, with great success and without adverse effects. The reforms proposed here would not even go as far as other states which also have not experienced negative consequences.

WHAT ARE WE ASKING YOU TO DO?

1. **We are asking you to stand for *patients, not providers.***
    - It is about patient access and patient choice.
        - Florida has among the most restrictive optometric scope of practice laws in the country, limiting patients' options and access to care as provided by Doctors of Optometry.
        - Between 2000-2020 there has been an increase of 15,711 Doctors of Optometry nationwide, yet there has only been an increase of 2,000 ophthalmologists.
        - Doctors of Optometry are the only eye care providers in over 10,000 U.S. communities.
2. **We are asking you to stand for *data, not deception.***
    - States across the country have updated optometric scope of practice, without adverse effects.
        - No state licensure board where ophthalmic procedures are practiced has ever been notified by the National Practitioner Data Bank of a judgement against one of their licensees regarding ophthalmic procedures.
        - Liability insurance rates for Doctors of Optometry in states with up-to-date scope have not increased even though they are based on state specific data.
        - No state legislature has ever repealed optometric scope of practice.
3. **We are asking you to safely *expand our toolchest, not our treatment area.***
    - Optometric care is still limited to the eye and its appendages.
        - This will not broaden the scope of what conditions Doctors of Optometry currently manage and/or treat but will allow them to utilize the latest proven, safe, and approved technologies and medications to bring patients the best possible care.
        - Oversight of competency of Doctors of Optometry shall be exercised by the state-run licensure board, consistent with the authority of other doctoral level licensure boards.
        - To perform additional procedures, state certified Doctors of Optometry must meet specific educational requirements. No current licensee will be "grandfathered" into certification to perform additional procedures.

WHAT IS A DOCTOR OF OPTOMETRY?

They are doctoral level independent health care practitioners educated on the human body with specific emphasis on the eye, vision, and ophthalmic manifestations of systemic conditions.

They complete an undergraduate degree as well as four years of professional education at a school of optometry and earn a Doctor of Optometry degree. Many choose to get additional clinical training or complete a specialty residency after optometry school.

They prescribe medication, provide visual rehabilitation, prescribe corrective lenses, and perform specified minor surgical procedures.

They are held to the same standard of care as medical doctors. They have been designated as physicians in the State of Florida since 1993 (Fla. Stat. 456.056) and Federally since 1986.

WHAT DOES A DOCTOR OF OPTOMETRY DO?

Provide the following services:

- Primary care and, like all primary care doctors, total eye care coordination
- Annual or routine eye exams, including eye health education
- Diagnosis of eye conditions
- Prescriptions for eyeglasses, contact lenses, and other visual aids
- Medical treatments and minor surgical procedures for eye conditions
- Post-surgical eye care

They can prescribe controlled medications for eye conditions. Depending on the state's laws, some optometrists can also perform more advanced ocular surgeries. (www.healthline.com, 2019)

THREE AREAS OF SCOPE OF PRACTICE FOR DOCTORS OF OPTOMETRY

- **Practice authority** can be defined as an optometrist's ability to perform procedures that fall within their scope of practice, as determined by the state board of optometry. Procedures that may fall under an optometrist's scope of practice include foreign body removal, minor surgical procedures, and other state authorized procedures.
- **Prescriptive authority** refers to whether an optometrist can prescribe certain medications and limited and specified classifications of controlled substances.
- **Procedures Authority** refers to minor surgical procedures an optometrist can provide in treatment of the orbital structures for tear production and drainage, also known as the lacrimal system.

HOW DO FLORIDA'S OPTOMETRIC SCOPE OF PRACTICE LAWS COMPARE TO OTHERS?

- Florida has among the most restrictive and narrow optometric scope of practice laws in the United States.
    - Approximately 35 states allow broader prescription authority (Schedule II) than Florida.
    - Approximately 20 states allow wider latitude to provide minor surgical procedures.
        - Oklahoma has been doing it the longest, since 1988. In a letter from a board member of the Oklahoma Board of Examiners in Optometry, Oklahoma's experience with expanded scope is summarized as follows: "*an estimated 25,000 anterior laser surgery procedures have been performed by Oklahoma Optometrists. To this date there has been no complaints reported to the Board of Examiners by any entity, including members of the public, the legislature, any other regulatory body, the Oklahoma State Medical Association and the Oklahoma Academy of Ophthalmology*."

DO CURRENT FLORIDA OPTOMETRIC SCOPE OF PRACTICE LAWS ALIGN WITH PATIENT FOCUSED REFORM OF THE HEALTHCARE SYSTEM?

No.

- In late 2018, the **Department of Health and Human Services published a report** that outlaid reforms the government should take to deliver optimal care to Americans, including realizing new health care choices for the public and identifying barriers on federal and state levels to market competition. Notably, that report specifically stated that Doctors of Optometry can provide the same services as other physicians and stressed "states should consider changes to their scope of practice statues to allow all health care providers to practice to the top of their license, utilizing their full skill set."

- In an update to the Veterans Health Administration's (VHA) Eye and Vision Care policy on August 18, 2020, the administration rescinded a previous directive that effectively limited veteran access to therapeutic laser eye procedures at VA medical facilities, and, in turn, issued a new directive that emphasizes the use of interdisciplinary care. This recent VA action is one in a series of access-focused efforts, including an April 2020 policy underscoring that veterans are best served when all VA Doctors of Optometry and other essential care providers deliver care with full practice authority. (American Optometric Association, 2020)

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Overview of Recommended Changes to Florida Optometry Practice Act

1. **Contemporizing Control over the Scope of Practice:** The scope of practice of the field of Optometry will now be defined by the Board of Optometry over the prescription of pharmaceutical agents and the practice of any surgical procedures via final approval by the Surgeon General.
    - State Surgeon General shall have standing under Section 456.012, Florida Statutes, to challenge any rule or proposed rule of the board.
    - Consistent with authority of other doctoral level medical boards.
2. **Modernization of Scope of Practice for Prescriptive Authority:** The use of all FDA approved drugs and medications will be streamlined. Rather than relying on a quickly outdated enumerated list in the current law, the Board shall establish by rule a negative formulary of pharmaceutical agents or medications that may not be prescribed or administered due to known or reported problems, such as contamination or recall.
    - Certified (by the board) optometrists may administer and prescribe medically appropriate ocular pharmaceutical agents for the diagnosis and treatment of ocular conditions of the human eye and its appendages.
        - A licensed practitioner who is not certified may use topically applied anesthetics solely for the purpose of glaucoma examinations (currently allowed) but is otherwise prohibited from administering or prescribing ocular pharmaceutical agents.
        - A licensed practitioner who is not certified shall be required to display at her or his place of practice a sign which states, "I am a Licensed Practitioner, not a Certified Optometrist, and I am not able to prescribe ocular pharmaceutical agents or perform ophthalmic procedures."
    - Schedule II controlled substances could be prescribed or administered for the relief of short-term side effects due to ocular conditions of the eye and its appendages.
        - At least 35 states currently allow Doctors of Optometry to prescribe Schedule II substances. Some restrict Schedule II prescribing authority only to hydrocodone products; others allow prescription of all appropriate Schedule II substances.
    - The use of a negative formulary will create treatment and market efficiency by reducing duplicative approval processes at the state level. Once the federal government has approved a medication or modality for use within the scope of optometric care, a Doctor of Optometry could begin using it immediately unless challenged by the Surgeon General or placed on the negative formulary.
        - This will improve efficiency and reduce costs as it is very common for already-approved "new" medications and drugs to come to market as more affordable generics or combination drugs – but under new names that would automatically make them unusable until slow bureaucratic processes put them on a formulary for approved use.
3. **Modernization of Scope of Practice for Minor "Surgical" Procedures:** Removes the complete ban on all surgical procedures for Doctors of Optometry and allows certain minor "surgical" procedures to be performed within the scope of education, training, and certification – consistent with what other states have allowed.
    - Surgeries that require general anesthesia or penetration of the vitreous chamber or retina of the eye will be *not* be permissible.
    - Optometrists cannot perform *any* surgical procedures unless they complete a detailed certification course that will be developed and offered jointly by a statewide professional association of physicians accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit and a professional association of licensed practitioners which provides board-approved continuing education on an annual basis.
    - Expanded scope of optometric practices involving surgical procedures is already permitted in several states - Oklahoma, Louisiana, Kentucky, Alaska, Arkansas and expanded individual procedures are permitted in approximately 20 states throughout the nation.
        - In the states that have approved this expansion in scope, there has been zero increase in complications as compared to ophthalmologists performing identical procedures.
    - Physicians assistants are already performing many of these procedures **and more** in Florida without requisite (or additional) training. The objective of the current prohibition is not to serve or protect the patient, but to prohibit the expansion of scope of optometrists unreasonably and unethically to preserve market share, and as a result, deny greater access to primary eye health care for patients.

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Statement on Optometric Malpractice Rates
February 10, 2021

OMIC currently insures more than 5,500 ophthalmologists and more than 1,000 optometrists nationwide. During our 30+ years in operation, we have handled over 11,000 medical professional liability incidents and claims arising from the actions of the entire eye care team, from ophthalmologists to optometrists to technicians.

I will address the two issues that are frequently inquired about:

1. The stability of malpractice rates for optometrists; and
2. The complications that can arise from the performance of certain surgical procedures.

Insurance Premiums

Regarding the stability of optometric malpractice rates, the answer is very straightforward and is actuarial in nature.

- Most optometrists in the United States do not manage patients with complex ophthalmic conditions or perform laser and incisional surgery.
- Therefore, the number of "opportunities" for potential malpractice is relatively small, and such cases typically take three to four years to come to final adjudication.
- Without large numbers of cases having yet moved through the courts, there is little statistical information on which to base rate increases.
- This is particularly true compared to ophthalmologists who spend much of their time managing (including surgically) complex and sight-threatening cases and therefore have significantly more "opportunities" to incur malpractice allegations.

Surgical Complications

Regarding outcomes, every surgical procedure has associated potential complications. OMIC has drafted consent forms for most ophthalmic surgical procedures that explain the risks – or potential complications – for those procedures.

- For example, the consent form for laser iridotomy, which involves making a hole in the iris with the laser to treat narrow angle glaucoma, lists risks for this procedure that include:
    - Inflammation or bleeding in the eye,
    - Cataract formation, and
    - Damage to the cornea or retina from the laser light.
- All ocular surgical procedures have their own associated risks, including permanent loss of vision, even for surgeries seemingly as safe as draining a chalazion (an inflamed oil gland) of the eyelid.
- These complications cannot always be prevented, but the likelihood can be decreased by having a trained and skilled surgeon perform the procedure.

OMIC is committed to risk management, loss prevention, and patient safety. To this end, we have implemented underwriting guidelines to ensure that coverage is extended to health care providers only for those procedures for which they have the necessary education, training, and expertise. For this reason, as well as the company's assessment that it does not have the experience to properly underwrite, rate, and administer claims arising from surgical procedures performed by optometrists, and the lack of data available on this liability risk, OMIC does not offer coverage to optometrists who administer injections or perform procedures using scalpels or lasers (other than diagnostic lasers, such as OCT).

Timothy J. Padovese
President & CEO
Ophthalmic Mutual Insurance Company

Examples of Surgeries SB 876/HB 631 Would Authorize Optometrist to Perform

Current Procedural Terminology (**CPT**) is a medical code set that is used to report medical, surgical, and diagnostic procedures and services to entities such as physicians, allied health practitioners (e.g. optometrists), and health insurance companies. It is a universal code. Some CPT codes are extremely specific (*11441: Excise benign lesion, skin only 0.6-1.0 cm*) and some are very broad (*66999: anterior segment unlisted code: for eye surgery that has not yet been assigned a code, now or in the future*).

Because SB 876/HB 631 contains "exclusionary" language, surgery that is not specifically excluded in the optometric bill, would now be permissible for optometrists to perform. Also, *any* future surgical procedure that has not yet been invented would also be permissible under the legislation.

- This following list of authorized procedures ***is not intended to be a comprehensive list*** of surgeries because ***no such list could be made.***

- Only specific items are excluded by SB 876/HB 631, but each CPT code may describe **multiple procedures.**
    - Examples of multiple procedures with a single CPT code include 65450 and 65756

- CPT codes that include the phrase "unlisted procedure" include **ALL procedures not specifically defined by an existing CPT code.** Additionally, there are many ophthalmologic, dermatologic and anesthesia procedures/ CPT codes which are not included here.

- A **grave concern** regarding removal of "benign" skin lesions is that it completely leaves out the fact that **it's impossible to know for certain a lesion is benign until the pathology repot is complete back.** A lesion could *appear* benign but still be malignant. This is where proper surgical training and experience are vitally important—experience that is not part of the optometric training model. Improper removal of a malignant lesion could result in the cancer spreading to other parts of the body.

SB 876/HB 631: Authorized Surgeries for Optometrists:

CPT Code	Procedure	Description
10060	Drain skin abscess, simple/single	Surgery to make an incision to drain an infected cyst
11100	Biopsy of skin, subcutaneous tissue; single lesion with closure	Surgery to biopsy a portion of a lesion involving tissue deep to the skin, then suture wound
11101	Biopsy of skin, subcutaneous tissue; each additional lesion	Surgery to biopsy a portion of a lesion involving tissue deep to the skin (additional lesions)
11200	Removal of skin tags, any area, 15 or more	Surgery to cut off skin tags

12016	Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes, 12.6 to 20.0 cm	Surgery for one-layer closure of wound 12.6 to 20.0 cm. ANY closure of a wound to the face or eyelids is likely to be complex, not "simple"
12017	Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes, 20.1 to 30.0 cm	Surgery for one-layer closure of wound 20.1 to 30.0 cm. ANY closure of a wound to the face or eyelids is likely to be complex, not "simple"
12018	Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes over 30.0 cm	Surgery for one-layer closure of wound over 30.0 cm. ANY closure of a wound to the face or eyelids is likely to be complex, not "simple"
12051	Layer closure of wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.5 cm or less	Surgery for two or more layer closure of wound <2.5cm. **Requires suturing of deep tissue and skin.**
12052	Layer closure of wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 to 5.0 cm	Surgery for two or more layer closure of wound 2.6 cm to 5.0cm. See 12051
12053	Layer closure of wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 5.1 to 7.5 cm	Surgery for two or more layer closure of wound 5.1 cm to 7.5 cm. See 12051
12054	Layer closure of wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 7.6 to 12.5 cm	Surgery for two or more layer closure of wound 7.6 cm to 12.5 cm. See 12051
12055	Layer closure of wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 12.6 to 20.0 cm	Surgery for two or more layer closure of wound 12.6 cm to 20.0 cm. See 12051
12056	Layer closure of wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 20.1 to 30.0 cm	Surgery for two or more layer closure of wound 20.1 cm to 30.0 cm. See 12051
12057	Layer closure of wounds of face, ears, eyelids, nose, lips and/or mucous membranes; over 30.0 cm	Surgery for two or more layer closure of wound over 30.0 cm. See 12051
13150	Complex repair: eyelids, nose, ears, lips; 1.0 cm or less	Surgery for complex repair of wound <1.0 cm
13151	Complex repair: eyelids, nose, ears, lips; 1.1 cm to 2.5 cm	Surgery for complex repair of wound 1.1 cm to 2.5 cm
13152	Complex repair: eyelids, nose, ears, lips; 2.6 cm to 7.5 cm	Surgery for complex repair of wound 2.6 cm to 7.5 cm
13153	Complex repair: eyelids, nose, ears, lips - each additional 5cm or less	Surgery for complex repair of wound (each additional 5cm or less)
14060	Tissue transfer or rearrangement eyelids, nose, ears, lips 10 cm^2	Surgery to move eyelid, nose, ears, and lips tissue to reconstruct the eyelid
14061	Tissue transfer or rearrangement eyelids, nose, ears, lips 10-30 cm^2	Surgery to move eyelid, nose, ears, and lips tissue to reconstruct the eyelid

31239	Nasal endoscopy, surgical; with dacryocystorhinostomy	Using a probe and camera to examine inside the nose and perform SURGERY involving the sinuses and tear duct
37609	Temporal Artery Biopsy	Surgery to biopsy a blood vessel in the temple to look for inflammation. Risks include uncontrolled hemorrhage, stroke,
64612	Chemodenervation of muscles innervated by facial nerve	Botox injection to treat muscle spasms near the eyes and mouth. **Incorrect diagnosis can mask a brain tumor or aneurysm.**
64615	Chemodenervation of muscles innervated by facial nerve, trigeminal, cervical and accessory nerves	Botox injection to treat muscle spasms near the eyes, mouth, neck, and head. **Incorrect diagnosis can mask a brain tumor or aneurysm.**
64732	Transection or avulsion of; supraorbital nerve	Surgery to cut the nerve that gives sensation to the forehead
65091	Evisceration of Ocular contents; without implant	Surgery to scoop out the inner contents of the eye
65093	Evisceration of Ocular contents; with implant	Surgery to scoop out the inner contents of the eye and place implant
65125	Modification of Orbit, implant w/ Peg Placement/replacement	Surgery to alter an ocular implant (usually used to couple it to a peg for better movement)
65130	Secondary ocular implant after evisceration (in scleral shell)	Surgery to place an implant after the inner part of the eye was scooped out
65135	Secondary ocular implant after enucleation, muscle not attached to implant	Surgery to place an implant after the eye was removed
65150	Reinsertion of ocular implant; w/ or w/o conjunctival graft	Surgery to reinsert an ocular implant
65155	Reinsertion of ocular implant; w/ or w/o conjunctival graft, with the use of foreign material for reinforcement	Surgery to reinsert an ocular implant along with foreign material to bolster it
65175	Removal of ocular implant	Surgery to remove an ocular implant
65210	Removal of foreign body, conjunctival embedded, subconjunctival, or scleral non-perforating	Surgery to remove a foreign body embedded in the outer surface of the eye (can be embedded deep in the outer coating of the eye, but excludes penetrating into the inside of the eye)
65235	Removal of foreign body from the anterior chamber	Surgery to go inside the eye and remove a foreign body
65270	Repair of laceration, conjunctiva, with or without nonperforating laceration sclera, direct closure	Surgery to repair a wound to the conjunctiva, (non-penetrating or penetrating)
65275	Repair of laceration of cornea, nonperforating, with or without removal of foreign body	Surgery to repair laceration of cornea (nonperforating)

65860	Severing adhesions of anterior segment with laser	Surgery using laser to cut scar tissue within the front segment of the eye
65865	Severing adhesions of anterior segment, incisional technique	Surgery to release scarring in the anterior segment
65900	Removal of epithelial downgrowth	Surgery to remove abnormal cells from an area of the cornea
65920	Removal of implanted material; anterior segment	Surgical removal of implant from inside the front part of the eye
65930	Removal of blood clot; anterior segment	Surgical removal of a blood clot from behind the cornea
66030	Injection of medication into anterior segment	Penetrating the eye with a needle to deliver medication
66130	Excision of lesion, sclera	Surgery to remove lesion from the wall of the eye (white part) which is beneath the conjunctiva
66184	Revision of aqueous shunt to extraocular reservoir; without graft	Surgical alteration of the shunt that goes to a subconjunctival reservoir following glaucoma surgery
66185	Revision of aqueous shunt to extraocular reservoir; with graft	Surgical alteration of the shunt that goes to a subconjunctival reservoir following glaucoma surgery
66250	Revision or repair of operative wound of anterior segment, any type, early or late, major or minor procedure	Surgery to repair previous surgical wound in anterior segment (can be penetrating or nonpenetrating). Revision of a glaucoma wound (bleb) may result in **dangerously low or high eye pressure, resulting in blindness.**
66682	Repair of iris or ciliary body using internal sutures	Surgical repair of iris or ciliary body, using difficult internal suturing technique, most commonly following surgery or trauma
66700	Ciliary body destruction; diathermy	Surgery utilizing a surgical device which transmits electrically-induced heat to outer surface of the eye in order to destroy ciliary body tissue (inside the eye). **Risks include pain, bleeding, blindness, loss of eye.**
66710	cyclophotocoagulation	Laser surgery to burn the ciliary body. **Risks include pain, bleeding, blindness, loss of eye.**
66711	cyclophotocoagulation, endoscopic	Using an internal scope and laser to burn the ciliary body tissue
66720	Ciliary body destruction; cryotherapy	Surgery via surgical device using freezing to destroy ciliary body tissue (inside the eye). **Risks include pain, bleeding, blindness, loss of eye.**

J2778	Injection of Lucentis	Injection of medication into vitreous, near the retina, to treat retinal disease, such as "wet" macular degeneration. Risks noted above
J3300	Injection of Triessence	Injection of medication into vitreous, near the retina, to treat inflammatory disease. Risks noted above.
J3590	Injection of Avastin	Injection of chemotherapy into vitreous, near the retina, to treat retinal disease, such as "wet" macular degeneration. Risks noted above
J3713	Injection of Iluvien	Injection of medication into vitreous, near the retina, to treat inflammatory disease. Risks noted above.
J7316	Injection of Jetrea	Injection of medication into vitreous, near the retina, to cause separation of the vitreous from the retina. Increases risk of retinal detachment. Other risks noted above.
67031	Severing of vitreous strands, opacities by laser (vitreolysis)	Laser surgery to disrupt floaters or adhesions in the back of the eye near the retina. Risks include **retinal detachment**.
67101	Repair of retinal detachment; cryotherapy	Using a freezing probe to causing retinal scarring in hopes of repairing a retinal detachment
67115	Release of encircling material (posterior segment)	Surgery to adjust encircling silicone band around the outer surface of the eye (non-penetrating)
67120	Removal of implanted material posterior segment; extraocular	Surgery to remove implants placed on the back outer surface of the eye (non-penetrating)
67141	Prophylaxis of retinal detachment, without drainage, cryotherapy, diathermy	Using a freezing probe or electrical heat to causing retinal scarring in hopes of preventing a retinal detachment
67208	Destruction of localized lesion of the retina (tumor or swelling); cryotherapy	Using a freezing probe to reduce swelling or tumor in the retina. Misdiagnosis and/or inadequate treatment of reye cancer may be LIFE THREATENING
67218	by radioactive implant	Surgical placement of a radioactive seed on the eye to treat **cancer of the eye**.
67227	Destruction of progressive retinopathy; cryotherapy, diathermy	Using a freezing probe or heated probe to cause retinal scarring in the treatment of retinopathy (such as from diabetes)
67229	Destruction of progressive retinopathy of prematurity IN A PRETERM INFANT	Using a laser or freezing probe to scar a premature infant's retina. MAY CAUSE BLINDNESS
67250	Scleral reinforcement (separate procedure); without graft	Surgery to reinforce coating of eye (sclera); without graft tissue (non-penetrating)
67255	Scleral reinforcement (separate procedure); with graft	Surgery to reinforce coating of eye (sclera); with graft tissue (non-penetrating)

67825	Epilation, cryotherapy	Destroy eyelash roots by freezing them
67830	Correction of trichiasis; incision of lid margin	Surgery to eyelid to correct for abnormal eyelash growth
67840	Excision of lesion of eyelid (except chalazion) involving the margin without closure or with simple direct closure	Surgery to remove a lesion on the eyelid margin with possible one-layer closure
67850	Destruction of lesion of the lid margin (up to 1 cm)	Surgery to destroy a lesion on the margin without cutting (freezing, laser, etc.)
67911	Lid retraction, correction	Surgery to lower the upper lid or raise the lower lid by multiple techniques
67912	Placement of Gold or Platinum Weight	Surgery to sew a metal weight into the upper eyelid to help it close
67914	Ectropion repair - Suture	Surgery to rotate the eyelid inward with sutures only. Risks include penetrating the eye inadvertently with suture needle.
67915	Ectropion repair - Thermocauterization	Surgery to rotate the eyelid inward with cautery only
67916	Ectropion repair - Excision tarsal wedge	Surgery to tighten the eyelid by cutting it horizontally in the outer corner and shortening it so that it turns inward
67917	Ectropion repair - Extensive (e.g. Lateral Tarsal Strip)	Surgery to tighten the eyelid by cutting the lid vertically and shortening it so that it turns inward
67921	Entropion repair - Suture	Surgery to rotate the eyelid outward with sutures only. Risks include penetrating the eye inadvertently with suture needle.
67922	Entropion repair - Thermocauterization	Surgery to rotate the eyelid outward with cautery only
67923	Entropion repair - Excision tarsal wedge	Surgery to tighten the eyelid by cutting the lid vertically and shortening it so that it turns outward
67924	Entropion repair - Extensive (e.g. Lateral Tarsal Strip)	Surgery to tighten the eyelid by cutting the lid vertically and shortening it so that it turns outward
67930	Suture of recent wound, eyelid, involving lid margin, tarsus, and/or palpebral conjunctiva direct closure; partial thickness	Surgery to repair eyelid laceration that is partial thickness of the eyelid
67935	Suture of recent wound, eyelid, involving lid margin, tarsus, and/or palpebral conjunctiva direct closure; full thickness	Surgery to repair eyelid laceration that involves the full thickness of the eyelid
67938	Removal of embedded foreign body, eyelid	Surgery to remove foreign body from eyelid
67950	Canthoplasty (reconstruction of canthus)	Reconstruction of the inner or outer corner of the eyelids
67999	Unlisted procedure, eyelids	ANY SURGERY, **now or in the future**, that is not described specifically by the preceding CPT codes (67700-67975), includes inradermal filler materials

95875	Cholinesterase inhibitor challenge test	Intravenous injection of a chemical that increases muscle function briefly in patients with Myasthenia Gravis. THIS TEST MAY CAUSE RESPITORY FAILURE/ DEATH
0191T	Insertion of anterior segment drainage device; trabecular meshwork	Surgical placement of a drainage device into the trabecular meshwork, where the cornea meets the sclera internally
0253T	Insertion of anterior segment drainage device; suprchoroidal space	Surgical placement of a drainage device into the space posterior to the iris
0290T	Laser incisions in the cornea	Femto laser incisions through corneal tissue. Femto laser can also be used to incise the lens capsule and fragment the lens (cataract) of the eye
0402T	Collagen crosslinking of cornea	Using chemicals and UV light to stiffen the cornea
0449T	insertion of drainage device, internal approach, into the subconjunctival space	Surgical placement of a drain connecting the anterior chamber and the surface of the eye beneath the conjunctiva
Anesthesia	**Use of anesthesia, other than general, to assist in the performance of any surgery or procedure**	**Use of ANY type of anesthesia, except for general (putting the patient to "sleep" requiring mechanical ventilation "respirator" and a "breathing tube"), to assist in performing surgery. This includes administration of intravenous sedatives and narcotics, including fentanyl and propofol, which are two of the most common drugs administered during routine eye surgery. These drugs have been implicated in the DEATHS of popular musical artist.**

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THE FLORIDA SENATE

APPEARANCE RECORD

3/10/2021
Meeting Date

SB876
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Optometric Scope of Practice

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Speaking: ☐ For ☒ Against ☐ Information

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

Representing Florida Society of Ophthalmology

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

10 March 2
Meeting Date

876
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Optometry

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing Luxottica

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

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THE FLORIDA SENATE

APPEARANCE RECORD

3/10/21
Meeting Date

876
Bill Number (if applicable)

Topic Senate Bill 876 - patient safety concern

Amendment Barcode (if applicable)

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Speaking: ☐ For ☑ Against ☐ Information

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

Representing myself, Florida Society of Ophthalmology

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

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THE FLORIDA SENATE

APPEARANCE RECORD

3/10/21
Meeting Date

876
Bill Number (if applicable)

Topic Optometry

Amendment Barcode (if applicable)

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Osteopathic Medical Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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S-001 (10/14/14)

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Reset Form

THE FLORIDA SENATE

APPEARANCE RECORD

03/10/2021
Meeting Date

876
Bill Number (if applicable)

Topic Patient Safety - Bill 876

Amendment Barcode (if applicable)

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Speaking: ☐ For ☑ Against ☐ Information

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

Representing Florida Society of Ophthalmology

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/10/21
Meeting Date

876
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic _____

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Speaking: ☐ For ☑ Against ☐ Information

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

Representing Florida Society of Plastic Surgeons

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

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THE FLORIDA SENATE

APPEARANCE RECORD

3/10/2021
Meeting Date

SB 876
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Patient Safety

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Speaking: ☐ For ☑ Against ☐ Information

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

Representing Florida Society of Ophthalmology

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/10/21
Meeting Date

SB 876
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic OPTOMETRY Bill 867

Name DOUGLAS R MURPHY MD

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Speaking: ☐ For ☑ Against ☐ Information

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

Representing Florida Medical Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 262
INTRODUCER:	Senator Harrell
SUBJECT:	Dispensing Medicinal Drugs
DATE:	March 9, 2021
REVISED:	

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

I. Summary:

SB 262 amends s. 465.019, F.S., to authorize medicinal drugs to be dispensed by a hospital that operates a Class II or Class III institutional pharmacy to a patient of the hospital's emergency department or a hospital inpatient upon discharge if a prescriber treating the patient in the hospital determines that:

- The medicinal drug is warranted; and
- Community pharmacy services are not readily accessible to the patient, geographically or otherwise.

If such prescribing and dispensing occurs, the bill requires that a supply of the drug must be dispensed that will last for the greater of up to 48 hours or through the end of the next business day, except that during a declared state of emergency, a 72-hour supply may be dispensed by a hospital located in an area affected by the emergency.

The bill has an insignificant fiscal impact on the Department of Health (DOH) that can be absorbed within existing resources.

The bill has an effective date of July 1, 2021.

II. Present Situation:

Medicinal Prescribing and Dispensing Practitioners

There are several professions in Florida that have prescriptive authority at various levels, including:

- Allopathic physicians;
- Osteopathic physicians;
- Podiatrists;

- Dentists;
- Advanced practice registered nurses;[1]
- Physician assistants;[2] and
- Pharmacists.[3]

A person may not dispense medicinal drugs unless licensed as a pharmacist, except that a practitioner authorized by law to prescribe drugs may dispense medicinal drugs to his or her patients in the regular course of her or his practice.[4] A practitioner who dispenses medicinal drugs for human consumption for a fee or remuneration of any kind, whether directly or indirectly, must:

- Register with her or his professional licensing board as a dispensing practitioner and pay a board-established fee at the time of such registration and upon each renewal of his or her license;
- Comply with, and be subject to, all laws and rules applicable to pharmacists and pharmacies, including, but not limited to, chs. 456, 499, and 893, F.S., and all applicable federal laws and federal regulations; and
- Give each patient a written prescription and, orally or in writing, advise the patient that the prescription may be filled in the practitioner's office or at any pharmacy, before dispensing any drug.[5]

Pharmacy

The practice of pharmacy and the licensure of pharmacies are regulated under ch. 465, F.S. The "practice of the profession of pharmacy" includes:

- Compounding, dispensing, and consulting the consumer concerning the contents, therapeutic values, and uses of any medicinal (prescription)[6] drug; and
- Other pharmaceutical services.[7, 8]

[1] Section 464.012(3)(a), F.S.
[2] *See* ss. 458.347(4)(e)4., and 459.022(4)(e)4., F.S.
[3] *See* s. 465.186, F.S., and Fla. Admin. Code R. 64B8-36.001 (2019).
[4] Section 465.0276, F.S.
[5] Section 465.0276(2), F.S.
[6] Under s. 465.003(8), F.S., "medicinal drugs" means substances commonly known as "prescription" or "legend" drugs required by law to be dispensed by prescription only.
[7] Section 465.003(13), F.S.
[8] In the context of pharmacy practice, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chs. 458, 459, 461, or 466, F.S., or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. The "practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, expressly permits a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients, and includes the administration of vaccines to adults. *See* s. 465.003(13), F.S.

The Board of Pharmacy

The Board of Pharmacy (BOP) is created within the DOH and is authorized to make rules to regulate the practice of professional pharmacy in pharmacies meeting minimum requirements for safe practice.[9] All pharmacies must obtain a permit before operating, unless exempt by law. This is true whether opening a new establishment or simply changing locations or owners.[10]

The Practice of Pharmacy

There are seven types of pharmacies eligible for various operating permits issued by the DOH:
- Community pharmacy;[11]
- Institutional pharmacy;[12]
- Nuclear pharmacy;[13]
- Special pharmacy;[14]
- Internet pharmacy;[15]
- Non-resident sterile compounding pharmacy;[16] and
- Special sterile compounding pharmacy.[17]

Institutional Pharmacies

An "institutional pharmacy" includes any pharmacy located in a health care institution, which includes a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.[18] Institutional pharmacy permits are required for any pharmacy located in any health care institution.[19]

All institutional pharmacies must designate a consultant pharmacist[20] who is responsible for maintaining all drug records required by law, and for establishing drug handling procedures for the safe handling and storage of drugs. The consultant pharmacist may also be responsible for

[9] *See ss.* 465.002, and 465.0155, F.S.
[10] Fla. Admin. Code R. 64B16-28.100(1) (2019).
[11] 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. *See* ss. 465.003(11)(a)1. and 465.018, F.S.
[12] *See* ss. 465.003(11)(a)2., and 465.019, F.S.
[13] The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold, but does not include hospitals licensed under ch. 395, F.S., or the nuclear medicine facilities of such hospitals. *See* ss. 465.003(11)(a)3. and 465.0193, F.S.
[14] The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined by law. *See* ss. 465.003(11)(a)4. and 465.0196, F.S.
[15] The term "internet pharmacy" includes locations not otherwise licensed or issued a permit under ch. 465, F.S., whether or not in Florida, 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. *See* ss. 465.003(11)(a)5. and 465.0197, F.S.
[16] The term "nonresident sterile compounding pharmacy" includes a pharmacy that ships, mails, delivers, or dispenses, in any manner, a compounded sterile product into Florida, and a nonresident pharmacy registered under s. 465.0156, F.S., or an outsourcing facility, must hold a nonresident sterile compounding permit. *See* s. 465.0158, F.S.
[17] *See* Fla. Admin. Code R. 64B16-28.100 and 64B16-28.802 (2019). An outsourcing facility is considered a pharmacy and must hold a special sterile compounding permit if it engages in sterile compounding.
[18] Section 465.003(11)(a)2., F.S.
[19] Fla. Admin. Code R. 64B16-28.100(3) (2019).
[20] *See* ss. 465.003(11), and 465.0125, F.S.

ordering and evaluating any laboratory or clinical tests when such tests are necessary for the proper performance of his or her responsibilities.[21] Such laboratory or clinical tests may be ordered only with regard to patients residing in a nursing home, and then only when authorized by the facility's medical director. The consultant pharmacist must complete additional training and demonstrate additional qualifications in the practice of institutional pharmacy, as required by the BOP, and be licensed as a registered pharmacist.[22, 23]

Currently there are four types of institutional pharmacy permits issued by the BOP to institutional pharmacies: Institutional Class I, Class II, Modified Class II, and Class III.[24]

Institutional Class I Pharmacy

A Class I institutional pharmacy is an institutional pharmacy in which all medicinal drugs are administered from individual prescription containers to an individual patient and in which medicinal drugs are not dispensed on the premises, except licensed nursing homes[25] may purchase medical oxygen for administration to residents.[26]

Institutional Class II Pharmacy

A Class II institutional pharmacy is a pharmacy that employs the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of the institution, for use on the premises of the institution.[27] A Class II institutional pharmacy is required to be open sufficient hours to meet the needs of the hospital facility.[28] The consultant pharmacist of record is responsible for establishing a written policy and procedure manual.[29] An institutional Class II pharmacy may elect to participate in the Cancer Drug Donation Program within the Department of Business and Professional Regulation.[30]

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[21] *Id*.
[22] Section 465.0125, F.S.
[23] As required by Fla. Admin. Code R. 64B16-28.501(1), (2), and (3) (2019), the consultant pharmacist must also "conduct Drug Regimen Reviews required by Federal or State law, inspect the facility and prepare a written report to be filed at the permitted facility at least monthly, . . . monitor the facility system for providing medication administration records and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review, and may utilize additional consultant pharmacists to assist in this review and in the monthly facility inspection." A licensed consultant pharmacist may "remotely access a facility or pharmacy's electronic database from outside the facility or pharmacy to conduct any services additional or supplemental to regular drug regimen reviews, subject to the pharmacy or facility establishing policies and procedures to ensure the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations." The BOP must be notified in writing within ten days of any change in the consultant pharmacist of record, pursuant to Fla. Admin. Code R. 64B16-28.100(3)(b) (2019).
[24] Section 465.019, F.S.
[25] *See* part II, ch. 400, F.S., relating to nursing homes.
[26] Section 465.019(2)(a), F.S.
[27] *See* s. 565.019(2)(b), F.S. Exceptions apply when there is a state of emergency and for single doses of a drug ordered by physicians under limited circumstances.
[28] Fla. Admin. Code R. 64B16-28.603 (2019).
[29] Section 465.019(5), F.S.
[30] *See* s. 499.029, F.S., relating to the Cancer Drug Donation Program Act.

Modified Institutional Class II Pharmacy Permits

Modified Institutional Class II pharmacies are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.[31] Modified Class II Institutional pharmacies are designated as Type A, Type B, and Type C according to the specialized type of the medicinal drug delivery system utilized at the facility, either a patient-specific or bulk drug system, and the quantity of the medicinal drug formulary at the facility.[32]

All Modified Class II institutional pharmacies must be under the control and supervision of a certified consultant pharmacist. The consultant pharmacist of record is responsible for developing and maintaining a current policy and procedure manual. The permittee must make available the policy and procedure manual to the appropriate state or federal agencies upon inspection.[33]

Institutional Class III Pharmacies

Class III institutional pharmacies are those pharmacies, including central distribution facilities, affiliated with a hospital that provide the same services that are authorized by a Class II institutional pharmacy permit. Class III institutional pharmacies may also:

- Dispense, distribute, compound, and fill prescriptions for medicinal drugs;
- Prepare prepackaged drug products;
- Conduct other pharmaceutical services for the affiliated hospital and for entities under common control that are each permitted under ch. 465, F.S., to possess medicinal drugs; and
- Provide the services in Class I institutional pharmacies, Class II institutional pharmacies, and Modified Class II institutional pharmacies that hold an active health care clinic establishment permit.[34,35]

A Class III institutional pharmacy must also maintain policies and procedures addressing the following:

- The consultant pharmacist responsible for pharmaceutical services;

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[31] Section 465.019(2)(c), F.S.

[32] Fla. Admin. Code R. 64B16-28.702(2) (2019). Modified Class II Institutional Pharmacies provide the following pharmacy services: (1) Type "A" Modified Class II Institutional Pharmacies provide pharmacy services in a facility which has a formulary of not more than 15 medicinal drugs, excluding those medicinal drugs contained in an emergency box, and in which the medicinal drugs are stored in bulk and in which the consultant pharmacist provides on-site consultations not less than once every month, unless otherwise directed by the BOP after review of the policy and procedure manual; (2) Type "B" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and in bulk form and which has an expanded drug formulary, and in which the consultant pharmacist provides on-site consultations not less than once per month, unless otherwise directed by the BOP after review of the policy and procedure manual; and (3) Type "C" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and which has an expanded drug formulary, and in which the consultant pharmacist provides onsite consultations not less than once per month, unless otherwise directed by the BOP after review of the policy and procedure manual.

[33] *See* Florida Board of Pharmacy, *Institutional Pharmacy Permit available at* http://floridaspharmacy.gov/licensing/institutional-pharmacy-permit/ (last visited Oct. 3, 2019).

[34] Section 465.019(2)(d)1., F.S.

[35] *See* s. 499.01(2)(r), F.S.

- Safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products;
- Recordkeeping to monitor the movement, distribution, and transportation of medicinal drugs and prepackaged drug products;
- Recordkeeping of pharmacy staff responsible for each step in the preparation, dispensing, prepackaging, transportation, and distribution of medicinal drugs and prepackaged drug products; and
- Medicinal drugs and prepackaged drug products that may not be safely distributed among Class III institutional pharmacies.[36]

Institutional Pharmacies – Dispensing Medicinal Drugs

Class II and Class III institutional pharmacies are permitted to dispense medicinal drugs to outpatients only when that institution has been issued a community pharmacy permit from the DOH.[37] An individual licensed to prescribe medicinal drugs may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II or Class III institutional pharmacy, provided the physician treating the patient in such hospital's emergency department determines the following:

- The medicinal drug is warranted; and
- Community pharmacy services are not readily accessible, geographically or otherwise, to the patient.[38]

Such dispensing from the emergency department must be in accordance with the procedures of the hospital. For any patient for whom a medicinal drug is determined to be warranted by the treating emergency department physician for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the patient with a prescription for the drug for use after the initial 24-hour period.[39] The BOP is authorized to adopt rules necessary to carry out these provisions.

III. Effect of Proposed Changes:

The bill permits medicinal drugs to be dispensed by a hospital that operates a Class II or Class III institutional pharmacy to a patient of the hospital's emergency department or a hospital inpatient upon discharge if a prescriber treating the patient in the hospital determines that:

- The medicinal drug is warranted; and
- Community pharmacy services are not readily accessible to the patient, geographically or otherwise.

If such prescribing and dispensing occurs, the bill requires that a supply of the drug must be dispensed that will last for the greater of up to 48 hours or through the end of the next business day; however, a supply lasting up to 72 hours may be dispensed during a declared state of emergency by a hospital located in an area affected by the emergency.

[36] Section 465.019(2)(d)2., F.S.
[37] *See* s. 465.019, F.S., which prohibits a Class I institutional pharmacy from dispensing medicinal drugs.
[38] Section 465.019(4), F.S.
[39] *Id.*

A prescriber who prescribes medicinal drugs under the above circumstances may provide the patient with a prescription for such drug for use beyond the initial prescription period if the prescriber determines that such use is warranted.

The BOP is authorized to adopt rules to implement the bill.

The bill provides an effective date of July 1, 2021.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The DOH may incur nonrecurring costs associated with rulemaking that can be absorbed within existing resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 465.019 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Harrell

25-00486-21 2021262__

A bill to be entitled

An act relating to dispensing medicinal drugs; amending s. 465.019, F.S.; authorizing certain hospitals to dispense supplies of prescribed medicinal drugs in a specified amount to emergency department patients or inpatients upon discharge under certain circumstances; authorizing a greater specified supply of medicinal drugs to be prescribed and dispensed in areas in which a state of emergency has been declared and is in effect; authorizing a prescriber to provide a patient with a prescription for medicinal drugs beyond the initial prescription period under certain circumstances; providing an effective date.

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

Section 1. Subsection (4) of section 465.019, Florida Statutes, is amended to read:

465.019 Institutional pharmacies; permits.—

(4)(a) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, ~~an individual licensed to prescribe~~ medicinal drugs ~~in this state~~ may be dispensed by ~~dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of~~ a hospital that operates a Class II or Class III institutional pharmacy to a patient of the hospital's emergency department or a hospital inpatient upon discharge if a prescriber, as defined in s. 465.025(1), ~~provided that the physician~~ treating the

Florida Senate - 2021 **SB 262**

25-00486-21 2021262__

patient in such hospital ~~hospital's emergency department~~ determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the patient. Such prescribing and dispensing ~~from the emergency department must be in accordance with the procedures of the hospital~~ must be for a supply of the drug that will last for the greater of the following:

1. Up to 48 hours; or

2. Through the end of the next business day.

(b) Notwithstanding subparagraph (a)1., if a state of emergency has been declared and is in effect for an area of this state pursuant to s. 252.36, a supply of a medicinal drug which will last up to 72 hours may be prescribed and dispensed under paragraph (a) in that area ~~For any such patient for whom a medicinal drug is warranted for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the patient with a prescription for such drug for use after the initial 24-hour period~~.

(c) A prescriber as defined in s. 465.025(1) who prescribes medicinal drugs under this subsection may provide the patient with a prescription for such drug for use beyond the initial prescription period if the prescriber determines that such use is warranted.

(d) The board may adopt rules ~~necessary~~ to implement ~~carry out the provisions of~~ this subsection.

Section 2. This act shall take effect July 1, 2021.

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

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

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

JOINT COMMITTEE:
Joint Committee on Public Counsel Oversight

SENATOR GAYLE HARRELL
25th District

December 22, 2020

Senator Manny Diaz
404 South Monroe Street
Tallahassee, FL 32399

Chair Diaz,

I respectfully request that **SB 262 – Dispensing Medicinal Drugs** be placed on the next available agenda for the Health Policy Committee Meeting.

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

Thank you,

Gayle

Senator Gayle Harrell
Senate District 25

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

ENTERED
12-22-20

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

Senate's Website: *www.flsenate.gov*

BILL GALVANO
President of the Senate

DAVID SIMMONS
President Pro Tempore

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THE FLORIDA SENATE

APPEARANCE RECORD

3/10/21
Meeting Date

262
Bill Number (if applicable)

Topic Dispensing Medicinal Drugs

Amendment Barcode (if applicable)

Name Steve Winn

Job Title Executive Director

Address 2544 Blairstone Pines Dr
Street

Phone 878-7364

Tallahassee FL 32301
City *State* *Zip*

Email winnsr@earthlink.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Osteopathic Medical Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/10/21
Meeting Date

262
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Dispensing Medicinal Drugs

Name Phillip Swaerman

Job Title Policy Director

Address _____ Phone _____
Street

_____ Email _____
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Americans for Prosperity

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

Duplicate

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THE FLORIDA SENATE

APPEARANCE RECORD

03/10/2021
Meeting Date

262
Bill Number (if applicable)

Topic _____
Amendment Barcode (if applicable)

Name Clay Meenan

Job Title Government Relations Coordinator

Address _____ Phone 682-276-5245
Street

_____ Email claym@fha.org
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Hospital Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 990
INTRODUCER:	Health Policy Committee and Senator Bradley
SUBJECT:	Occupational Therapy
DATE:	March 10, 2021 REVISED:

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 990:

- Expands the scope of practice of the occupational therapist and the occupational therapy assistant;
- Provides that any person who is issued a license as an occupational therapist by the state of Florida may use the words "occupational therapist doctorate" to denote his or her registration;
- Amends the definition of "occupational therapy" to include the therapeutic use of occupations with individuals, groups, or populations, along with their families or organizations, to support participation, performance, and function in roles and situations in the home, school, workplace, community, and other settings for clients who have, or are at risk of developing, an illness, injury, disease, disorder, condition, impairment, disability, activity limitation, or participation restriction;
- Creates definitions of the following terms:
  - Activities of daily living;
  - Behavioral health services;
  - Health Management;
  - Instrumental activities of daily living;
  - Mental health services;
  - Occupations; and
  - Occupational Performance;
- Adds the following to the practice of occupational therapy:

- Assessment, treatment, and education of, and consultation with, individuals, groups, and populations whose abilities to participate safely in various occupations are impaired or at risk for impairment due to issues related to, but not limited to, developmental deficiencies, the aging process, learning disabilities, physical environment and sociocultural context, physical injury or disease, cognitive impairments, and psychological and social disabilities;
- Methods or approaches to determine abilities and limitations related to performance of occupations, including, but not limited to, the identification of physical, sensory, cognitive, emotional, or social deficiencies; and
- Specific techniques used for treatment which involve, but are not limited to, training in activities of daily living; environmental modification; the designing, fabrication, and application of orthotics or orthotic devices; selecting, applying, and training in the use of assistive technology and adaptive devices; sensory, motor, and cognitive activities; therapeutic exercises; manual therapy; physical agent modalities; behavioral health services; and mental health services; and

- Deletes a list of "occupational therapy services" from current law.

The bill provides an effective date of July 1, 2021.

II. Present Situation:

The Department of Health

The Legislature created the Department of Health (DOH) to protect and promote the health of all residents and visitors in the state.[1] The DOH is charged with the regulation of health practitioners for the preservation of the health, safety, and welfare of the public. The Division of Medical Quality Assurance (MQA) is responsible for the boards[2] and professions within the DOH.[3]

Occupational Therapy

Current law defines occupational therapy as the use of purposeful activities or interventions to achieve functional outcomes. For individuals with a limiting physical injury or illness, a cognitive impairment, a psychosocial dysfunction, a mental illness, a developmental or learning disability, or an adverse environmental condition, achieving a functional outcome means to maximize their independence and maintain their health.[4]

Occupational therapy is performed by licensed occupational therapists (OTs), licensed occupational therapy assistants (OTAs) who work under the responsible supervision and control[5]

[1] Section 20.43, F.S.
[2] Under s. 456.001(1), F.S., "board" is defined as any board, commission, or other statutorily created entity, to the extent such entity is authorized to exercise regulatory or rulemaking functions within the DOH or, in some cases, within the DOH, MQA.
[3] Section 20.43, F.S.
[4] Section 468.203(4), F.S.
[5] Section 468.203(8), F.S. Responsible supervision and control by the licensed OT includes providing both the initial direction in developing a plan of treatment and periodic inspection of the actual implementation of the plan. The plan of treatment must not be changed by the supervised individual without prior consultation and approval of the supervising OT. The supervising OT is not always required to be physically present or on the premises when the occupational therapy

of a licensed OT, and occupational therapy aides who are not licensed but assist in the practice of occupational therapy under the direct supervision of a licensed OT or occupational therapy assistant.[6] However, physicians, physician assistants, nurses, physical therapists, osteopathic physicians or surgeons, clinical psychologists, speech-language pathologists, and audiologists are permitted to us occupational therapy skills and techniques as part of their professions, when they practice their profession under their own practice acts.[7]

Occupational therapy services include, but are not limited to:

- The assessment, treatment, and education of, or consultation with, the individual, family, or other persons;
- Interventions directed toward developing daily living skills, work readiness or work performance, play skills or leisure capacities, or enhancing educational performance skills;
- Providing for the development of:
  - Sensory-motor, perceptual, or neuromuscular functioning;
  - Range of motion; or
  - Emotional, motivational, cognitive, or psychosocial components of performance.
- Using devices subject to federal regulation[8] and identified by the Board of Occupational Therapy (Board) as expressly prohibited except by an occupational therapist or occupational therapy assistant who has received Board-specified training.[9]

These services require skilled assessment[10] to determine the need for use as interventions including:

- The design, development, adaptation, application, or training needed to use the assistive devices;
- The design, fabrication, or application of rehabilitative technology such as selected orthotic devices;
- Training in the use of assistive technology;
- Orthotic or prosthetic devices;
- The application of physical modalities as an adjunct to or in preparation for activity;
- The use of ergonomic principles;
- The adaptation of environments and processes to enhance functional performance; or
- The promotion of health and wellness.

assistant is performing services; but, supervision requires the availability of the supervising occupational therapist for consultation with and direction of the supervised individual.

[6] Section 468.203, F.S.

[7] Section 468.225, F.S.

[8] 21 C.F.R. s. 801.109, references devices, which, because of their potential for harmful effect, or the method of their use, or the collateral measures necessary to the device, they are not safe to use except under the supervision of a practitioner.

[9] Fla. Admin. Code R. 64B11-4.001(2020).

[10] Section 468.203(4)a.2., F.S., defines "Assessment" to mean the use of skilled observation or the administration and interpretation of standardized or non-standardized tests and measurements to identify areas for occupational therapy services.

Occupational Therapists and Occupational Therapy Assistants

Education

There are four levels of educational programs available to individuals desiring to enter the profession of occupational therapy in an institution accredited by the Accreditation Council for Occupational Therapy Education (ACOTE), which is the certifying arm of the American Occupational Therapy Association (AOTA), as follows:

- The Doctoral-Degree-Level Occupational Therapist (Ph.D.);[11]
- Master's-Degree-Level Occupational Therapist (OTR);
- Baccalaureate-Degree-Level Occupational Therapy Assistant (certified occupational therapy assistant or COTA); and
- Associate-Degree-Level Occupational Therapy Assistant (also a COTA).[12]

The ACOTE requirements for accreditation for occupational therapy curriculum vary by degree levels, but all levels must include theory, basic tenets of occupational therapy, and supervised educational fieldwork for accreditation. Examples of some required theory and basic tenets for occupational therapy accreditation include:

- Theory
  - Preparation to Practice as a Generalist;
  - Preparation and Application of In-depth Knowledge;
  - Human Body, Development, and Behavior;
  - Sociocultural, Socioeconomic, Diversity Factors, and Lifestyle Choices; and
  - Social Determinants of Health.
- Basic Tenets
  - Therapeutic Use of Self;
  - Clinical Reasoning;
  - Behavioral Health and Social Factors;
  - Remediation and Compensation;[13]
  - Orthoses and Prosthetic Devices;[14]
  - Functional Mobility;[15]

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[11] National Board of Certification in Occupational Therapy (NBCOT), 2018 Accreditation Council for Occupational Therapy Education (ACOTE®) *Standards and Interpretive Guide (effective July 31, 2020) August 2020 Interpretive Guide Version,*, at pp. 20 and 49, *available at* https://acoteonline.org/wp-content/uploads/2020/10/2018-ACOTE-Standards.pdf (last visited Mar. 2, 2021). The Ph.D. in occupational therapy requires a minimum of six years of full time academic education and a Doctorial Capstone which is an in-depth exposure to a concentrated area, which is an integral part of the program's curriculum design. This in-depth exposure may be in one or more of the following areas: clinical practice skills, research skills, scholarship, administration, leadership, program and policy development, advocacy, education, and theory development. The doctoral capstone consists of two parts: the capstone experience and the capstone project.

[12] *Id.*at p. 1.

[13] *Supra* note 11, p. 31. *Remediation and Compensation* includes the design and implement intervention strategies to remediate and/or compensate for functional cognitive deficits, visual deficits, and psychosocial and behavioral health deficits that affect occupational performance.

[14] *Supra* note 11, p. 30. *Orthoses and Prosthetic Devices* requires the assessment of the need for orthotics, and design, fabricate, apply, fit, and train in orthoses and devices used to enhance occupational performance and participation.

[15] *Id. Functional Mobility*- provides recommendations and training in techniques to enhance functional mobility, including physical transfers, wheelchair management, and mobility devices.

- Community Mobility;[16]
- Technology in Practice;[17]
- Dysphagia[18] and Feeding Disorders;
- Superficial Thermal, Deep Thermal, and Electrotherapeutic Agents and Mechanical Devices; and
- Effective Communication.

Fieldwork education required for ACOTE accreditation must include traditional and non-traditional subject matter, as well as emerging settings to strengthen the ties between didactic and fieldwork education, and at two levels:

- Level I Fieldwork: required for Ph.D., OTR, and COTA candidates and could be met through one or more of the following instructional methods:
  - Simulated environments;
  - Standardized patients;
  - Faculty practice;
  - Faculty-led site visits; and
  - Supervision by a fieldworker instructor.
- Level II Fieldwork:
  - Ph.D. & Masters Candidates - require a minimum of 24 weeks of full-time Level II fieldwork. Level II fieldwork can be completed in one setting if reflective of more than one practice area, or in a maximum of four different settings.
  - BS & AA Candidates - require a minimum of 16 weeks full-time Level II fieldwork. Level II fieldwork may be completed in one setting if reflective of more than one practice area, or in a maximum of three different settings.[19]

The ACOTE also requires for accreditation that schools maintain an average passage rate on the National Board for Certification in Occupational Therapy (NBCOT) examination, over the three most recent calendar years, for graduates attempting the national certification exam within 12 months of graduation from the program, must be 80 percent or higher (regardless of the number of attempts).[20]

Licensure

To be licensed as an occupational therapist, or occupational therapy assistant, an individual must:

- Apply to the DOH and pay appropriate fees;[21]
- Be of good moral character;
- Have graduated from an ACOTE/AOTA accredited occupational therapy program, or occupational therapy assistant program;

[16] *Supra* note 11, p. 30. *Community Mobility* designs programs that enhance community mobility, and implement transportation transitions, including driver rehabilitation and community access.
[17] *Supra* note 11, p. 31. *Technology in Practice* requires the demonstration of knowledge of the use of technology in practice, which must include: Electronic documentation systems; virtual environments; and telehealth technology.
[18] Tabor's Cyclopedia Medical Dictionary, 17th Edition, pub.1993, F.A. Davis and Co., *Dysphonia* is the inability to swallow or difficulty swallowing.
[19] *Supra* note 11, p. 41.
[20] *Supra* note 11.
[21] Section 468.219, F.S.

- Have completed a minimum of six months of supervised fieldwork experience for occupational therapists, and a minimum of two months for occupational therapy assistants, at a recognized educational institution or a training program approved by the education institution where you met the academic requirements; and
- Have passed an examination approved by the NBCOT[22] for occupational therapists.[23,24]

An additional path to licensure as an occupational therapist is also available to applicants who have practiced as a state-licensed or American Occupational Therapy Association-certified occupational therapy assistant for four years and who, prior to January 24, 1988, have completed a minimum of six months of supervised occupational-therapist-level fieldwork experience. Such individuals may take the examination approved by the NBCOT to be licensed as an occupational therapist without meeting the educational requirements for occupational therapists to have graduated from a program accredited by the ACOTE/AOTA.[25]

Endorsement is yet another path to licensure for an occupational therapist, or occupational therapist assistant, in which the Board may waive the examination requirement and grant a license to any person who presents proof of:

- A current certification as an occupational therapist or occupational therapy assistant by a national certifying organization if the Board determines the requirements for such certification to be equivalent to the requirements for Florida licensure; or
- A current licensure as an occupational therapist or occupational therapy assistant in another state, the District of Columbia, or any territory or jurisdiction of the United States or foreign national jurisdiction which requires standards for licensure determined by the Board to be equivalent to the requirements for Florida licensure.[26]

A person may not use the title, "occupational therapist," "licensed occupational therapist," "occupational therapist registered," "occupational therapy assistant," "licensed occupational therapy assistant," "certified occupational therapy assistant;" or the letters "O.T.," "L.O.T.," "O.T.R.," "O.T.A.," "L.O.T.A.," or "C.O.T.A.;" or any other words, letters, abbreviations, or insignia indicating or implying that he or she is an occupational therapist or an occupational therapy assistant, unless the person holds a valid license. Any person who does so commits a second degree misdemeanor.[27]

The DOH, MQA, Annual Report and Long Range Plan for 2019-2020 indicates that there are 8,764 active licensed occupational therapists and 5,865 active licensed occupational therapy assistants currently in Florida.[28]

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[22] The examination is not offered by the Florida Board of Occupational Therapy Practice. Applicants must contact the NBCOT directly for the exam application and deadline information.
[23] Section 468.209(1), F.S.
[24] Section 468.209(1), F.S.
[25] Section 468.209(2), F.S.
[26] Section 468.213, F.S.
[27] Sections 468.215 and 468.223, F.S.
[28] Department of Health, Division of Medical Quality Assurance, *Annual Report and Long Range Plan for 2019-2020*, p. 16, *available at* http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/2019-2020-annual-report.pdf (last visited Mar. 3, 2021).

III. Effect of Proposed Changes:

CS/SB 990:

- Expands the scope of practice of the occupational therapist and the occupational therapy assistant;
- Provides that any person who is issued a license as an occupational therapist by the state of Florida may use the words "occupational therapist doctorate" to denote his or her registration;
- Amends the definition of "occupational therapy" to include the therapeutic use of occupations with individuals, groups, or populations, along with their families or organizations, to support participation, performance, and function in roles and situations in the home, school, workplace, community, and other settings for clients who have, or are at risk of developing, an illness, injury, disease, disorder, condition, impairment, disability, activity limitation, or participation restriction;
- Creates definitions of the following terms:
    - *Activities of daily living* which are functions and tasks for self-care performed on a daily or routine basis, including:
- Functional mobility;
- Bathing;
- Dressing;
- Eating;
- Swallowing;
- Personal hygiene;
- Grooming;
- Toileting; and
- Other similar tasks.
    - *Behavioral health services* which means the promotion of occupational performance through services to support positive mental health by providing direct individual and group interventions to improve the client's participation in daily occupations;
    - *Health Management* which means activities related to developing, managing, and maintaining health and wellness, including self-management, with the goal of improving or maintaining health to support participation in occupations;
    - *Instrumental activities of daily living* which means daily or routine activities a person must perform to live independently within the home and community;
    - *Mental health services* which means the promotion of occupational performance related to mental health, coping, resilience, and well-being by providing individual, group, and population level supports and services to improve the client's participation in daily occupations for those who are at risk of, experiencing, or in recovery from these conditions, along with their families and communities;
    - *Occupations* which means meaningful and purposeful everyday activities performed and engaged in by individuals, groups, populations, families, or communities which occur in contexts and over time, such as:
- Activities of daily living;
- Instrumental activities of daily living;
- Health management;
- Rest;

- Sleep;
- Education;
- Work;
- Play;
- Leisure; and
- Social participation.
  - *Occupations* includes more specific occupations and execution of multiple activities that are influenced by performance patterns, performance skills, and client factors.
  - *Occupational Performance* which means the ability to perceive, desire, recall, plan, and carry out roles, routines, tasks, and subtasks for the purposes of self-maintenance, self-preservation, productivity, leisure, and rest, for oneself or others, in response to internal or external demands of occupations and contexts.
- Adds the following to the practice of occupational therapy:
  - Assessment, treatment, and education of, and consultation with, individuals, groups, and populations whose abilities to participate safely in various occupations are impaired or at risk for impairment due to issues related to, but not limited to, developmental deficiencies, the aging process, learning disabilities, physical environment and sociocultural context, physical injury or disease, cognitive impairments, and psychological and social disabilities;
  - Methods or approaches to determine abilities and limitations related to performance of occupations, including, but not limited to, the identification of physical, sensory, cognitive, emotional, or social deficiencies; and
  - Specific techniques used for treatment which involve, but are not limited to, training in activities of daily living; environmental modification; the designing, fabrication, and application of orthotics or orthotic devices; selecting, applying, and training in the use of assistive technology and adaptive devices; sensory, motor, and cognitive activities; therapeutic exercises; manual therapy; physical agent modalities; behavioral health services; and mental health services;
- Deletes a list of "occupational therapy services" from current law;
- Amends the list of titles and letters that a person may not use to indicate his or her title unless he or she is a licensed occupational therapist, to include "occupational therapist doctorate" and the letters "O.T.D."
- Exempts from the application of the Occupational Therapy Practice Act any person fulfilling an occupational therapy doctoral capstone experience that involves clinical practice or projects; and
- Reenacts certain statutes relating to the Gardiner Scholarship and voluntary pre-kindergarten for the purpose of incorporating the bill's amendments to s. 468.203. F.S., into those programs.

The bill provides an effective date of July 1, 2021.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill might result in increased costs borne by private health insurers and HMOs that cover occupational therapy services.

C. Government Sector Impact:

The bill might result in increased costs for occupational therapy services under state group health insurance, Medicaid, the Gardiner scholarship program, and voluntary pre-kindergarten to the extent that occupational therapy is covered and provided under those respective benefit packages and programs. The fiscal impact is indeterminate at this time.

VI. Technical Deficiencies:

None.

VII. Related Issues:

CS/SB 990 expands the scope of practice of the occupational therapist and the occupational therapy assistant to include areas of practice that might be construed as overlapping with other licensed professions. This is not unusual, as many licensed healthcare practitioners scope of practice often overlap and many of the professions' practice acts have, by statute, created exemptions to the application of their respective practice acts for other licensees whose scope of practice overlaps theirs.[29] The physical therapy practice acts already exempts its application to

[29] *See* ss. 460.402, 461.402, 464,022, 465.027, 467.207, 486.161, 468.812, 468.1115, 480.035, 486.161, 490.014, and 491.014, F.S.

occupational therapy;[30] and occupational therapy exempts physical therapy as well as medicine, nursing, osteopathy, clinical psychology, speech-language pathology, and audiology from the practice of occupational therapy.[31]

School speech and language providers,[32] clinical social workers, marriage and family therapists, mental health counselors,[33] orthotics, prosthetics, and pedorthics[34] use similar practice skills, techniques, and dynamics as set out in the bill's expanded scope of practice for occupational therapists and occupational therapy assistants, and the latter practitioners could be found to be practicing occupational therapy without a license under the bill.

Similarly, the bill's expanded scope of practice for occupational therapists and occupational therapy assistants could expose those practitioners to allegations of practicing marriage and family therapy, mental health counseling, psychotherapy services,[35]clinical psychology,[36] orthotics, prosthetics, pedorthics,[37] speech-language pathology, and audiology,[38] without a license.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 468.203, 468.209, 468.215, 468.223, 468.225, 1002.385, and 1002.66.

IX. Additional Information:

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

CS by Health Policy on March 10, 2021:
The CS:

- Revises the underlying bill's definition of "occupational therapy" to include the therapeutic use of occupations with persons and organizations to support participation, performance, and function in situations in various settings for clients who have, or are at risk of developing, an illness, injury, disease, disorder, condition, impairment, disability, activity limitation, or participation restriction;
- Revises the underlying bill's definition of *the practice of occupational therapy* to include:
  - Assessment, treatment, education and consultation of clients who are impaired or at risk for impairment;
  - Methods or approaches to determine abilities and limitations related to performance of occupations; and

[30] Section 486.161, F.S.
[31] Section 468.225, F.S.
[32] *See* s. 1012.44, F.S.
[33] *See* ch. 491, F.S.
[34] *See* ch. 468, Part. XIV, F.S.
[35] Section 490.014, F.S.
[36] Section 491.014, F.S.
[37] Section 468.812, F.S.
[38] Section 468.1115, F.S.

- Specific occupational therapy techniques and training used in treatment.
- Eliminates the underlying bill's inclusion of "evaluation" from the scope of practice of occupational therapy and replaces that term with "assessment."

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/10/2021	.	
	.	
	.	
	.	

The Committee on Health Policy (Bradley) recommended the following:

Senate Amendment

Delete lines 29 - 173

and insert:

school, workplace, community, and other settings for clients who have or are at risk of developing an illness, injury, disease, disorder, condition, impairment, disability, activity limitation, or participation restriction ~~purposeful activity or interventions to achieve functional outcomes~~.

(a) For the purposes of this subsection:

373056

1. "Activities of daily living" means functions and tasks for self-care which are performed on a daily or routine basis, including functional mobility, bathing, dressing, eating and swallowing, personal hygiene and grooming, toileting, and other similar tasks ~~"Achieving functional outcomes" means to maximize the independence and the maintenance of health of any individual who is limited by a physical injury or illness, a cognitive impairment, a psychosocial dysfunction, a mental illness, a developmental or a learning disability, or an adverse environmental condition~~.

2. "Assessment" means the use of skilled observation or the administration and interpretation of standardized or nonstandardized tests and measurements to identify areas for occupational therapy services.

3. "Behavioral health services" means the promotion of occupational performance through services to support positive mental health by providing direct individual and group interventions to improve the client's participation in daily occupations.

4. "Health management" means activities related to developing, managing, and maintaining health and wellness, including self-management, with the goal of improving or maintaining health to support participation in occupations.

5. "Instrumental activities of daily living" means daily or routine activities a person must perform to live independently within the home and community.

6. "Mental health services" means the promotion of occupational performance related to mental health, coping, resilience, and well-being by providing individual, group, and

373056

population level supports and services to improve the client's participation in daily occupations for those who are at risk of, experiencing, or in recovery from these conditions, along with their families and communities.

7. "Occupations" means meaningful and purposeful everyday activities performed and engaged in by individuals, groups, populations, families, or communities which occur in contexts and over time, such as activities of daily living, instrumental activities of daily living, health management, rest and sleep, education, work, play, leisure, and social participation. The term includes more specific occupations and execution of multiple activities that are influenced by performance patterns, performance skills, and client factors.

8. "Occupational performance" means the ability to perceive, desire, recall, plan, and carry out roles, routines, tasks, and subtasks for the purposes of self-maintenance, self-preservation, productivity, leisure, and rest, for oneself or others, in response to internal or external demands of occupations and contexts.

(b) The practice of occupational therapy includes ~~services include~~, but is ~~are~~ not limited to:

1. Assessment, treatment, and education of, and consultation with, individuals, groups, and populations whose abilities to participate safely in occupations, including activities of daily living, instrumental activities of daily living, rest and sleep, education, work, play, leisure, and social participation, are impaired or at risk for impairment due to issues related to, but not limited to, developmental deficiencies, the aging process, learning disabilities, physical

373056

environment and sociocultural context, physical injury or disease, cognitive impairments, and psychological and social disabilities ~~The assessment, treatment, and education of or consultation with the individual, family, or other persons~~.

2. Methods or approaches to determine abilities and limitations related to performance of occupations, including, but not limited to, the identification of physical, sensory, cognitive, emotional, or social deficiencies ~~Interventions directed toward developing daily living skills, work readiness or work performance, play skills or leisure capacities, or enhancing educational performance skills~~.

3. Specific occupational therapy techniques used for treatment which involve, but are not limited to, training in activities of daily living; environmental modification; the designing, fabrication, and application of orthotics or orthotic devices; selecting, applying, and training in the use of assistive technology and adaptive devices; sensory, motor, and cognitive activities; therapeutic exercises; manual therapy; physical agent modalities; behavioral health services; and mental health services ~~Providing for the development of:~~

By Senator Bradley

5-00602A-21 2021990__

A bill to be entitled

An act relating to occupational therapy; amending s. 468.203, F.S.; revising and defining terms; amending s. 468.209, F.S.; revising the fieldwork experience requirement for certain persons to take the examination for licensure as an occupational therapist; amending s. 468.215, F.S.; authorizing licensed occupational therapists to use a specified title and initials; amending s. 468.223, F.S.; prohibiting certain persons from using a specified title and initials; providing criminal penalties; amending s. 468.225, F.S.; providing construction; reenacting ss. 1002.385(5)(c) and 1002.66(2)(c), F.S., relating to the Gardiner Scholarship and specialized instructional services for children with disabilities, respectively, to incorporate the amendment made to s. 468.203, F.S., in references thereto; providing an effective date.

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

Section 1. Subsection (4) of section 468.203, Florida Statutes, is amended to read:

468.203 Definitions.—As used in this act, the term:

(4) "Occupational therapy" means the therapeutic use of occupations with individuals, groups, or populations, along with their families or organizations to support participation, performance, and function in roles and situations in the home, at school, in the workplace, in the community, and in other

5-00602A-21 2021990__

settings. The term also includes services provided for habilitation, rehabilitation, and the promotion of health and wellness for clients with disability and nondisability-related needs, including, but not limited to, acquisition and preservation of occupational identity for clients who have or are at risk of developing an illness, injury, disease, disorder, condition, impairment, disability, activity limitation, or participation restriction. Through engagement in everyday activities, occupational therapy supports occupational performance in persons who have, or are at risk of experiencing, a range of developmental, physical, cognitive, behavioral, mental health, and other disorders and disabilities ~~purposeful activity or interventions to achieve functional outcomes~~.

(a) For the purposes of this subsection:

1. "Activities of daily living" means functions and tasks for self-care which are performed on a daily or routine basis, including functional mobility, bathing, dressing, eating and swallowing, personal hygiene and grooming, toileting, and other similar tasks ~~"Achieving functional outcomes" means to maximize the independence and the maintenance of health of any individual who is limited by a physical injury or illness, a cognitive impairment, a psychosocial dysfunction, a mental illness, a developmental or a learning disability, or an adverse environmental condition~~.

2. "Assessment" means the use of skilled observation or the administration and interpretation of standardized or nonstandardized tests and measurements to identify areas for occupational therapy services.

3. "Behavioral health services" means the promotion of

occupational performance and participation through services to support and facilitate the prevention and treatment of, and for the management of and recovery from, mental health and substance abuse disorders, within the scope of practice of occupational therapy. These include services to support positive mental health, prevention of mental health disorders, and direct individual and group interventions for the purpose of improving occupational participation and performance.

4. "Health management" means activities related to developing, managing, and maintaining health and wellness, including self-management, with the goal of improving or maintaining health to support participation in occupations.

5. "Instrumental activities of daily living" means daily or routine activities a person must perform to live independently within the home and community.

6. "Mental health services" means the promotion of occupational performance and participation related to mental health, coping, resilience, and well-being. These services include the treatment of mental health and substance abuse disorders by providing individual, group, and population level supports and services to those who are at risk of, experiencing, or in recovery from these conditions, along with their families and communities, within the scope of practice of occupational therapy.

7. "Occupations" means meaningful and purposeful everyday activities performed and engaged in by individuals, groups, populations, families, or communities which occur in contexts and over time, being broadly categorized as activities of daily living, instrumental activities of daily living, health

management, rest and sleep, education, work, play, leisure, and social participation. The term includes more specific occupations and execution of multiple activities that are influenced by performance patterns, performance skills, and client factors, resulting in varied outcomes.

8. "Occupational performance" means the ability to perceive, desire, recall, plan, and carry out roles, routines, tasks, and subtasks for the purpose of self-maintenance, self-preservation, productivity, leisure, and rest, for oneself or others, in response to internal or external demands of occupations and contexts.

(b) The practice of occupational therapy includes ~~services include~~, but is ~~are~~ not limited to:

1. Evaluation of factors that affect activities of daily living, instrumental activities of daily living, health management, rest and sleep, education, work, play, leisure, and social participation, including context, performance patterns, performance skills, and client factors ~~The assessment, treatment, and education of or consultation with the individual, family, or other persons~~.

2. Methods or approaches selected to direct the process of interventions, including, but not limited to:

a. Establishment, remediation, or restoration of a skill or ability that has not yet developed, is impaired, or is in decline.

b. Compensation, modification, or adaptation of activity contexts to improve or enhance performance.

c. Maintenance of capabilities without which performance in everyday life occupations would decline.

d. Health promotion and wellness, including the use of self-management strategies, to enable or enhance performance in everyday life activities and quality of life.

e. Prevention of the occurrence or emergence of barriers to performance and participation, including injury and disability prevention, and occupational deprivation ~~Interventions directed toward developing daily living skills, work readiness or work performance, play skills or leisure capacities, or enhancing educational performance skills~~.

3. Interventions and procedures to promote or enhance safety and performance in activities of daily living, instrumental activities of daily living, health management, rest and sleep, education, work, play, leisure, and social participation, including, but not limited to:

a. Therapeutic use of occupations, exercises, and activities.

b. Training in self-care, self-management, health management and maintenance, home management, community or work reintegration, and school activities and work performance.

c. Identification, development, remediation, or compensation of neuromusculoskeletal, sensory-perceptual, emotional regulation, visual, mental, and cognitive functions, pain tolerance and management, mental and behavioral health, praxis, developmental skills, and behavioral skills.

d. Education and training of individuals, including family members, caregivers, groups, and other populations.

e. Care coordination, case management, transition services, and consultative services to individuals, groups, or populations, along with their families and communities or

organizations.

f. Group interventions facilitating learning, skills acquisition, and occupational performance of groups, populations, or organizations across the life course.

g. Mental health services and behavioral health services for the promotion of occupational performance and participation.

h. Facilitating occupational performance of individuals, groups, or populations through modification of contexts and adaptation of processes, including the application of ergonomic principles.

i. Assessment, design, fabrication, application, fitting, and training in seating and positioning of assistive technology, adaptive devices, orthotic devices, and custom orthoses, and training in the use of prosthetic devices.

j. Assessment, recommendation, and training in techniques to enhance functional mobility, including management of wheelchairs and other mobility devices.

k. Remediation and compensation of visual deficits including low rehabilitation.

l. Driving skills rehabilitation and community mobility.

m. Management of feeding, eating, and swallowing to enable eating and feeding performance.

n. Application of physical agent and mechanical modalities and use of a range of therapeutic procedures to enhance performance skills.

o. Efforts directed toward promoting occupational justice and empowering clients to seek and obtain resources to fully participate in occupations ~~Providing for the development of: sensory-motor, perceptual, or neuromuscular functioning; range~~

~~of motion; or emotional, motivational, cognitive, or psychosocial components of performance~~.

~~These services may require assessment of the need for use of interventions such as the design, development, adaptation, application, or training in the use of assistive technology devices; the design, fabrication, or application of rehabilitative technology such as selected orthotic devices; training in the use of assistive technology; orthotic or prosthetic devices; the application of physical agent modalities as an adjunct to or in preparation for purposeful activity; the use of ergonomic principles; the adaptation of environments and processes to enhance functional performance; or the promotion of health and wellness.~~

(c) The use of devices subject to 21 C.F.R. s. 801.109 and identified by the board is expressly prohibited except by an occupational therapist or occupational therapy assistant who has received training as specified by the board. The board shall adopt rules to carry out the purpose of this provision.

Section 2. Subsection (2) of section 468.209, Florida Statutes, is amended to read:

468.209 Requirements for licensure.—

(2) An applicant who has practiced as a state-licensed or American Occupational Therapy Association-certified occupational therapy assistant for 4 years and who, before ~~prior to~~ January 24, 1988, completed a minimum of 24 weeks ~~6 months~~ of supervised occupational-therapist-level fieldwork experience may take the examination to be licensed as an occupational therapist without meeting the educational requirements for occupational therapists

made otherwise applicable under paragraph (1)(b).

Section 3. Subsection (2) of section 468.215, Florida Statutes, is amended to read:

468.215 Issuance of license.—

(2) Any person who is issued a license as an occupational therapist under the terms of this act may use the words "occupational therapist," "licensed occupational therapist," "occupational therapist doctorate," or "occupational therapist registered," or he or she may use the letters "O.T.," "L.O.T.," "O.T.D.," or "O.T.R.," in connection with his or her name or place of business to denote his or her registration hereunder.

Section 4. Section 468.223, Florida Statutes, is amended to read:

468.223 Prohibitions; penalties.—

(1) A person may not:

(a) Practice occupational therapy unless such person is licensed pursuant to ss. 468.201-468.225;

(b) Use, in connection with his or her name or place of business, the words "occupational therapist," "licensed occupational therapist," "occupational therapist doctorate," "occupational therapist registered," "occupational therapy assistant," "licensed occupational therapy assistant," "certified occupational therapy assistant"; the letters "O.T.," "L.O.T.," "O.T.D.," "O.T.R.," "O.T.A.," "L.O.T.A.," or "C.O.T.A."; or any other words, letters, abbreviations, or insignia indicating or implying that he or she is an occupational therapist or an occupational therapy assistant or, in any way, orally or in writing, in print or by sign, directly or by implication, to represent himself or herself as an

occupational therapist or an occupational therapy assistant unless the person is a holder of a valid license issued pursuant to ss. 468.201-468.225;

(c) Present as his or her own the license of another;

(d) Knowingly give false or forged evidence to the board or a member thereof;

(e) Use or attempt to use a license that ~~which~~ has been suspended, revoked, or placed on inactive or delinquent status;

(f) Employ unlicensed persons to engage in the practice of occupational therapy; or

(g) Conceal information relative to any violation of ss. 468.201-468.225.

(2) Any person who violates any provision of this section commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 5. Paragraph (e) is added to subsection (1) of section 468.225, Florida Statutes, to read:

468.225 Exemptions.—

(1) Nothing in this act shall be construed as preventing or restricting the practice, services, or activities of:

(e) Any person fulfilling an occupational therapy doctoral capstone experience that involves clinical practice or projects.

Section 6. For the purpose of incorporating the amendment made by this act to section 468.203, Florida Statutes, in a reference thereto, paragraph (c) of subsection (5) of section 1002.385, Florida Statutes, is reenacted to read:

1002.385 The Gardiner Scholarship.—

(5) AUTHORIZED USES OF PROGRAM FUNDS.—Program funds must be used to meet the individual educational needs of an eligible

student and may be spent for the following purposes:

(c) Specialized services by approved providers or by a hospital in this state which are selected by the parent. These specialized services may include, but are not limited to:

1. Applied behavior analysis services as provided in ss. 627.6686 and 641.31098.

2. Services provided by speech-language pathologists as defined in s. 468.1125.

3. Occupational therapy services as defined in s. 468.203.

4. Services provided by physical therapists as defined in s. 486.021.

5. Services provided by listening and spoken language specialists and an appropriate acoustical environment for a child who is deaf or hard of hearing and who has received an implant or assistive hearing device.

A provider of any services receiving payments pursuant to this subsection may not share, refund, or rebate any moneys from the Gardiner Scholarship with the parent or participating student in any manner. A parent, student, or provider of any services may not bill an insurance company, Medicaid, or any other agency for the same services that are paid for using Gardiner Scholarship funds.

Section 7. For the purpose of incorporating the amendment made by this act to section 468.203, Florida Statutes, in a reference thereto, paragraph (c) of subsection (2) of section 1002.66, Florida Statutes, is reenacted to read:

1002.66 Specialized instructional services for children with disabilities.—

(2) The parent of a child who is eligible for the prekindergarten program for children with disabilities may select one or more specialized instructional services that are consistent with the child's individual educational plan. These specialized instructional services may include, but are not limited to:

(c) Occupational therapy as defined in s. 468.203.

Section 8. This act shall take effect July 1, 2021.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR JENNIFER BRADLEY
5th District

COMMITTEES:
Community Affairs, *Chair*
Agriculture, *Vice Chair*
Appropriations Subcommittee on Agriculture, Environment, and General Government
Education
Ethics and Elections
Judiciary

SELECT COMMITTEE:
Select Committee on Pandemic Preparedness and Response

JOINT COMMITTEES:
Joint Legislative Auditing Committee
Joint Select Committee on Collective Bargaining

February 16, 2021

Senator Manny Diaz, Jr., Chairman
Senate Committee on Health Policy
306 Senate Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Mr. Chairman:

I respectfully request that Senate Bill 990 be placed on the committee's agenda at your earliest convenience. This bill relates to occupational therapy.

Thank you for your consideration.

Sincerely,

Jennifer Bradley

Jennifer Bradley

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

REPLY TO:
❒ 1279 Kingsley Avenue, Kingsley Center, Suite 117, Orange Park, Florida 32073 (904) 278-2085
❒ 324 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5005

Senate's Website: *www.flsenate.gov*

WILTON SIMPSON
President of the Senate

AARON BEAN
President Pro Tempore

YOU MUST PRINT AND DELIVER THIS FORM TO THE ASSIGNED TESTIMONY ROOM

THE FLORIDA SENATE

APPEARANCE RECORD

March 10, 2021
Meeting Date

SB 990
Bill Number (if applicable)

Topic SB 990 - Occupational Therapy

Amendment Barcode (if applicable)

Name Anita Berry

Job Title Associate

Address 21748 State Road 54, Suite 101
Street

Phone 301-524-0172

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Occupational Therapy Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 1140
INTRODUCER:	Senator Rodrigues
SUBJECT:	Unlawful Use of DNA
DATE:	March 9, 2021
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Favorable**
2.			CM	
3.			RC	

I. Summary:

SB 1140 establishes three new crimes related to the unlawful use of deoxyribose nucleic acid (DNA). The bill provides that:

- It is a first degree misdemeanor for a person to willfully, and without authorization, collect or retain another person's DNA sample with the intent to perform DNA analysis.
- It is a third degree felony for a person to willfully, and without authorization, submit another person's DNA sample for DNA analysis or to conduct or procure the conducting of another person's DNA analysis.
- It is a third degree felony for a person to willfully, and without authorization, disclose another person's DNA analysis results to a third party.

The bill specifies that each instance of the above crimes constitutes a separate violation which entails a separate penalty. The bill defines the terms "authorization," "DNA analysis," and "DNA sample" and provides exceptions for criminal investigations and prosecutions; determining paternity under ss. 409.256 or 742.12(1), F.S.; and performing any activity authorized in s. 943.325, F.S., pertaining to the criminal DNA database.

The bill also amends s. 760.40, F.S., which is the current law governing DNA privacy, to conform to the changes made by the bill.

The bill provides an effective date of October 1, 2021.

II. Present Situation:

What is DNA?

DNA, or deoxyribonucleic acid, is the hereditary material in humans and almost all other organisms. Nearly every cell in a person's body has the same DNA, unique to that person. Most

DNA is located in the cell nucleus (where it is called nuclear DNA), but a small amount of DNA can also be found in the mitochondria (where it is called mitochondrial DNA or mtDNA). Mitochondria are structures within cells that convert the energy from food into a form that cells can use.

The information in DNA is stored as a code made up of four chemical bases: adenine (A), guanine (G), cytosine (C), and thymine (T). Human DNA consists of about three billion bases, and more than 99 percent of those bases are the same in all people. The order, or sequence, of these bases determines the information available for building and maintaining an organism, similar to the way in which letters of the alphabet appear in a certain order to form words and sentences.

DNA bases pair-up with each other, A with T and C with G, to form units called base pairs. Each base is also attached to a sugar molecule and a phosphate molecule. Together, a base, sugar, and phosphate are called a nucleotide. Nucleotides are arranged in two long strands that form a spiral called a double helix. The structure of the double helix is somewhat like a ladder, with the base pairs forming the ladder's rungs and the sugar and phosphate molecules forming the vertical sidepieces of the ladder.

An important property of DNA is that it can replicate, or make copies of itself. Each strand of DNA in the double helix can serve as a pattern for duplicating the sequence of bases. This is critical when cells divide because each new cell needs to have an exact copy of the DNA present in the old cell.[1]

Genetics and Genomics

Genetics is a term that refers to the study of genes and their roles in inheritance – in other words, the way that certain traits or conditions are passed down from one generation to another. Genetics involves scientific studies of genes and their effects. Genes (units of heredity) carry the instructions for making proteins, which direct the activities of cells and functions of the body. Examples of genetic or inherited disorders include cystic fibrosis, Huntington's disease, and phenylketonuria.

Genomics is a more recent term that describes the study of all of a person's genes (the genome), including interactions of those genes with each other and with the person's environment. Genomics includes the scientific study of complex diseases such as heart disease, asthma, diabetes, and cancer because these diseases are typically caused more by a combination of genetic and environmental factors than by individual genes. Genomics is offering new possibilities for therapies and treatments for some complex diseases, as well as new diagnostic methods.[2]

[1] *What is DNA?*, MedlinePlus, *available at* https://medlineplus.gov/genetics/understanding/basics/dna/, (last visited Mar. 5, 2021).
[2] *Genetics vs. Genomics Fact Sheet*, National Human Genome Research Institute, *available at* https://www.genome.gov/about-genomics/fact-sheets/Genetics-vs-Genomics, (last visited Mar. 5, 2021).

Genetic Testing

Genetic testing is a type of medical test that identifies changes in chromosomes, genes, or proteins. The results of a genetic test can confirm or rule out a suspected genetic condition or help determine a person's chance of developing or passing on a genetic disorder. More than 1,000 genetic tests are currently in use, and more are being developed. Several methods can be used for genetic testing:

- Molecular genetic tests (or gene tests) study single genes or short lengths of DNA to identify variations or mutations that lead to a genetic disorder.
- Chromosomal genetic tests analyze whole chromosomes or long lengths of DNA to see if there are large genetic changes, such as an extra copy of a chromosome, that cause a genetic condition.
- Biochemical genetic tests study the amount or activity level of proteins; abnormalities in either can indicate changes to the DNA that result in a genetic disorder.[3]

Surreptitious Genetic Testing

Surreptitious genetic testing – testing without the knowledge of the person being tested – is a potential threat to the privacy of people's genomic information. Some companies offering DNA testing allow consumers to obtain genetic analyses of various biological samples without requiring the consent of the individual or individuals being tested. DNA samples may come from objects ranging from blood stains to a licked envelope. A variety of tests can be done using these DNA samples, including health-related testing and parentage determination. These tests can reveal sensitive or embarrassing personal information, which could be of significant concern for individuals in the public spotlight.

There is no federal law prohibiting surreptitious testing. Currently about half of the states in the U.S. have laws or regulations governing genomic privacy and illegitimate uses of genomic data.[4] However, there is great variation in these laws. While some states prohibit the unauthorized acquisition or analysis of genetic information, others prohibit only unauthorized disclosure. Whether genetic testing can be performed without the consent of the donor may depend on who conducts the test, what the test attempts to determine, how the results will be used, and in what state the testing takes place. The states also differ regarding the enforcement of these laws.[5]

Florida's DNA Privacy Law

Section 760.40, F.S., requires that, except for purposes of criminal prosecution; for the purposes of determining paternity as provided in s. 409.256, F.S., or 742.12(1), F.S.; and for purposes of acquiring specimens as provided in s. 943.325, F.S., DNA analysis[6] may be performed only with

[3] *What is Genetic Testing?*, MedlinePlus, *available at* https://medlineplus.gov/genetics/understanding/testing/genetictesting/, (last visited Mar. 5, 2021).
[4] For details on state laws regulating DNA usage *available at* https://www.genome.gov/about-genomics/policy-issues/Genome-Statute-Legislation-Database, (last visited Mar. 7, 2021).
[5] Privacy in Genomics, National Human Genome Research Institute, *available at* https://www.genome.gov/about-genomics/policy-issues/Privacy, (last visited Mar. 7, 2021).
[6] Defined as "the medical and biological examination and analysis of a person to identify the presence and composition of genes in that person's body. The term includes DNA typing and genetic testing."

the informed consent of the person to be tested. The section specifies that the results of a DNA analysis, whether held by a public or private entity, are the exclusive property of the person tested, are confidential, and may not be disclosed without the consent of the person tested. The information is also exempt from public records laws if held by a public entity. A violation of the above requirements is a misdemeanor of the third degree.[7]

The section also requires that a person who performs DNA analysis or receives records, results, or findings of a DNA analysis must provide the person tested with notice that the analysis was performed or that the information was received. The notice must state that, upon the request of the person tested, the information will be made available to his or her physician. The notice must also state whether the information was used in any decision to grant or deny any insurance, employment, mortgage, loan, credit, or educational opportunity. If the information was used in any decision that resulted in a denial, the analysis must be repeated to verify the accuracy of the first analysis, and if the first analysis is found to be inaccurate, the denial must be reviewed.

III. Effect of Proposed Changes:

SB 1140 creates s. 817.5655, F.S., to prohibit certain unlawful uses of DNA. The bill defines the terms:

- "Authorization" to mean the informed and written consent of the person whose DNA is to be extracted or analyzed, or the informed and written consent of the person's legal guardian or authorized representative.
- "DNA analysis" to mean the medical and biological examination and analysis of a person to identify the presence and composition of genes in that person's body. The term includes DNA typing and genetic testing.
- "DNA sample to mean any human biological specimen from which DNA can be extracted, or the DNA extracted from such specimen.

The bill establishes three new crimes as follows:

- It is a misdemeanor of the first degree[8] for a person to willfully, and without authorization, collect or retain another person's DNA sample with the intent to perform DNA analysis.
- It is a felony of the third degree[9] for a person to willfully, and without authorization, submit another person's DNA sample for DNA analysis or to conduct or procure the conducting of another person's DNA analysis.
- It is a felony of the third[10] degree for a person to willfully, and without authorization, disclose another person's DNA analysis results to a third party.

The bill specifies that each instance of collection, retention, submission, analysis, or disclosure constitutes a separate violation for which a separate penalty is authorized. The bill also provides exceptions to the prohibitions established in the bill for: a criminal investigation or prosecution; determining paternity under s. 409.256, F.S., or s. 742.12(1), F.S.; and for performing any activity authorized under s. 943.325, F.S., related to Florida's criminal DNA database.

[7] Punishable as provided in ss. 775.082 or 775.083, F.S.
[8] Id.
[9] Punishable as provided in ss. 775.082, 775.083, or 775.084, F.S.
[10] Id.

The bill amends s. 760.40, F.S., to conform to the changes made by the bill.

The bill provides an effective date of October 1, 2021.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

SB 1140 defines the term "authorization" to mean the informed and written consent of the person whose DNA is to be extracted or analyzed, or the informed and written consent of the person's legal guardian or authorized representative. However, the bill does not specify what information must be given to a person in order for that person to be informed before providing written

consent. Given that the failure to provide adequate information to the person who is providing written consent may constitute a criminal act, it may be advisable to specify what information must be given to a person prior to that person providing his or her consent.

SB 1140 prohibits as a third degree felony a person to willfully, and without authorization, disclose another person's DNA analysis results to a third party. Given the broad nature of this crime and the specific requirements for obtaining authorization established by the bill, it may be possible for a person to commit this crime unintentionally. For example, it is possible that a husband may have violated this section by disclosing his wife's DNA analysis results to their children even if the husband had his wife's prior authorization by spoken word.

VIII. Statutes Affected:

This bill substantially amends section 760.40 of the Florida Statutes.

This bill creates section 817.5655 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Rodrigues

27-01195A-21 20211140__

A bill to be entitled

An act relating to unlawful use of DNA; amending s. 760.40, F.S.; prohibiting DNA analysis and disclosure of DNA analysis results without authorization; removing criminal penalties; creating s. 817.5655, F.S.; defining terms; prohibiting the collection or retention of a DNA sample of another person without authorization for specified purposes; prohibiting specified DNA analysis and disclosure of DNA analysis results without authorization; providing criminal penalties; providing exceptions; providing an effective date.

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

Section 1. Subsection (2) of section 760.40, Florida Statutes, is amended to read:

760.40 Genetic testing; authorization ~~informed consent~~; confidentiality; penalties; notice of use of results.—

(2)~~(a) Except for purposes of criminal prosecution, except for purposes of determining paternity as provided in s. 409.256 or s. 742.12(1), and except for purposes of acquiring specimens as provided in s. 943.325,~~ DNA analysis may be performed only with authorization, as defined in s. 817.5655 ~~the informed consent of the person to be tested~~, and the results of such DNA analysis, whether held by a public or private entity, are the exclusive property of the person tested, are confidential, and may not be disclosed without authorization ~~the consent of the person tested~~. Such information held by a public entity is

27-01195A-21 20211140__

exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

~~(b) A person who violates paragraph (a) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.~~

Section 2. Section 817.5655, Florida Statutes, is created to read:

817.5655 Unlawful use of DNA; penalties; exceptions.—

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

(a) "Authorization" means the informed and written consent of the person whose DNA is to be extracted or analyzed, or the informed and written consent of the person's legal guardian or authorized representative.

(b) "DNA analysis" means the medical and biological examination and analysis of a person to identify the presence and composition of genes in that person's body. The term includes DNA typing and genetic testing.

(c) "DNA sample" means any human biological specimen from which DNA can be extracted, or the DNA extracted from such specimen.

(2) It is unlawful for a person to willfully, and without authorization, collect or retain another person's DNA sample with the intent to perform DNA analysis. A person who violates this subsection commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(3) It is unlawful for a person to willfully, and without authorization, submit another person's DNA sample for DNA analysis or to conduct or procure the conducting of another person's DNA analysis. A person who violates this subsection

commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083 or s. 775.084.

(4) It is unlawful for a person to willfully, and without authorization, disclose another person's DNA analysis results to a third party. A person who violates this subsection commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083 or s. 775.084.

(5) Each instance of collection or retention, submission or analysis or disclosure in violation of this section constitutes a separate violation for which a separate penalty is authorized.

(6) This section does not apply to a DNA sample, a DNA analysis, or the results of a DNA analysis used for the purposes of:

(a) Criminal investigation or prosecution;

(b) Determining paternity under s. 409.256 or s. 742.12(1); or

(c) Performing any activity authorized under s. 943.325.

Section 3. This act shall take effect October 1, 2021.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR RAY WESLEY RODRIGUES
27th District

COMMITTEES:
Governmental Oversight and Accountability, *Chair*
Appropriations Subcommittee on Agriculture, Environment, and General Government, *Vice Chair*
Appropriations Subcommittee on Health and Human Services
Banking and Insurance
Finance and Tax
Judiciary
Regulated Industries

JOINT COMMITTEES:
Joint Select Committee on Collective Bargaining, *Alternating Chair*
Joint Committee on Public Counsel Oversight

February 18, 2021

The Honorable Manny Diaz, Jr.
Senate Health Policy, Chair
530 Knott Building
404 South Monroe Street
Tallahassee, FL 32399

RE: SB 1140 – Unlawful Use of DNA

Dear Mr. Chair:

Please allow this letter to serve as my respectful request to place SB 1140, relating to Unlawful Use of DNA, on the next committee agenda.

Your kind consideration of this request is greatly appreciated. Please feel free to contact my office for any additional information.

Sincerely,

Ray Rodrigues

Ray Rodrigues
Senate District 27

Cc: Allen Brown, Staff Director
Lynn Wells, Administrative Assistant

REPLY TO:
❒ 2000 Main Street, Suite 401, Fort Myers, Florida 33901 (239) 338-2570
❒ 305 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5027

Senate's Website: *www.flsenate.gov*

WILTON SIMPSON
President of the Senate

AARON BEAN
President Pro Tempore

YOU MUST PRINT AND DELIVER THIS FORM TO THE ASSIGNED TESTIMONY ROOM

THE FLORIDA SENATE

APPEARANCE RECORD

March 10, 2021
Meeting Date

SB 1140
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Genetic Privacy

Name Alli Liby-Schoonover

Job Title

Address 119 S Monroe Street, Suite 200
Street

Phone 850-205-9000

Tallahassee FL 32301
City *State* *Zip*

Email ALS@mhdfirm.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Ancestry.com and 23andMe

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 1084
INTRODUCER:	Health Policy Committee and Senator Pizzo
SUBJECT:	Volunteer Ambulance Services
DATE:	March 10, 2021
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1084:

- Authorizes vehicles of certain faith-based volunteer ambulance services, as authorized by the chief of police of an incorporated city or any sheriff of any county, to display red lights and operate emergency lights and sirens while responding to an emergency.
- Authorizes privately owned vehicles belonging to medical staff physicians and technicians of certain faith-based volunteer ambulance services to use red lights on privately owned vehicles and to disregard specified traffic laws and ordinances while responding to an emergency.
- Exempts certain faith-based volunteer first responder agencies who have been operating in this state for at least 10 years from certificate of public convenience and necessity requirements.
- Prohibits county and municipal governments from:
  - Limiting, prohibiting, or preventing certain faith-based volunteer ambulance services from responding to emergencies or providing emergency medical services or transport.
  - Requiring certain faith-based volunteer ambulance services to obtain a license or certificate or pay a fee.

The bill provides an effective date of July 1, 2021.

II. Present Situation:

Emergency Vehicles

Chapter 316, F.S., is known as the "Florida Uniform Traffic Control Law"[1] which exists for the purpose of making uniform traffic laws and ordinances apply throughout the state.[2] For purposes of that chapter, an "authorized emergency vehicle" includes all of the following vehicles, as designated or authorized by their respective department or the chief of police of an incorporated city or any sheriff of any of the various counties:

- Vehicles of the fire department (fire patrol);
- Police vehicles; and
- Such ambulances and emergency vehicles of:
  - Municipal departments;
  - Public service corporations operated by private corporations;
  - The Fish and Wildlife Conservation Commission;
  - The Department of Environmental Protection;
  - The Department of Health;
  - The Department of Transportation; and
  - The Department of Corrections.[3]

Traffic Laws and Ordinances – Privileges

Section 316.072(5), F.S., authorizes the drivers of certain vehicles to exercise a privilege and disregard specified traffic laws and ordinances while responding to an emergency. Under that section, all of the following drivers may exercise the privilege:

- The driver of an "authorized emergency vehicle" when responding to an emergency call, when in the pursuit of an actual or suspected violator of the law, or when responding to a fire alarm, but not upon returning from a fire;
- A medical staff physician or technician of a medical facility licensed by the state when responding to an emergency in the line of duty in his or her privately owned vehicle, using red lights as authorized in s. 316.2398, F.S.; or
  The driver of an authorized law enforcement vehicle, when conducting a nonemergency escort, to warn the public of an approaching motorcade.

Under those conditions, and unless otherwise directed by a police officer, those drivers may:

- Park or stand, regardless of traffic laws or ordinances.
- Proceed past a red or stop signal or stop sign, but only after slowing down as may be necessary for safe operation.
- Exceed the maximum speed limits, so long as the driver does not endanger life or property.
- Disregard regulations governing direction or movement or turning in specified directions, so long as the driver does not endanger life or property.

[1] Section 316.001, F.S.
[2] Section 316.002, F.S.
[3] Section 316.003(1), F.S.

Under the conditions above, the driver has a duty to drive with due regard to the safety of all persons. The driver is not protected from the consequences of his or her reckless disregard for the safety of others.

***Red Lights, Red and White Lights, Emergency Lights, Sirens*[4]**

Under the Florida Uniform Traffic Control Law, a person may not drive or move or cause to be moved any vehicle or equipment upon any highway within this state with any lamp or device thereon showing or displaying certain colors of lights unless they are explicitly authorized. For example, only police vehicles and certain vehicles owned, operated, or leased by the Department of Corrections may show or display blue lights when responding to emergencies. Additionally, amber lights are reserved for wreckers, mosquito control fog and spray vehicles, and emergency vehicles of governmental departments or public service corporations; and green and amber lights are reserve for vehicles owned or leased by private security agencies.

Red or red and white lights may be shown or displayed by vehicles of the fire department and fire patrol, and by a privately owned vehicle belonging to an active firefighter member of a regularly organized volunteer firefighting company or association, while en route to the fire station for the purpose of proceeding to the scene of a fire or other emergency or while en route to the scene of a fire or other emergency in the line of duty as an active firefighter member of a regularly organized firefighting company or association.[5]

Red lights may be shown or displayed by privately owned vehicles of medical staff physicians or technicians of medical facilities licensed by the state while responding to an emergency in the line of duty, certain ambulances, and certain buses and taxicabs.[6]

Flashing red lights may be used by emergency response vehicles of the Fish and Wildlife Conservation Commission, the Department of Environmental Protection, and the Department of Health when responding to an emergency in the line of duty.

Under s. 316.271, F.S., every "authorized emergency vehicle" is required to be equipped with a siren that meets certain specifications. The siren may only be operated in an emergency.

Basic and Advanced Life Support Services

Part III of ch. 401, F.S., consisting of ss. 401.2101-401.465, F.S., provides for the regulation of emergency medical services by the Department of Health (DOH). The DOH website reflects that its Emergency Medical Services Section is responsible for the licensure and oversight of over 60,000 emergency medical technicians and paramedics, 270+ advanced and basic life support agencies, and over 4,500 EMS vehicles.[7] The DOH licenses three types of emergency medical services: air ambulance,[8] basic life support, and advanced life support services.

[4] Section 316.2397, F.S.
[5] Section 316.2398, F.S.
[6] *Id.*
[7] Florida Department of Health, Emergency Medical Services System, *available at* http://www.floridahealth.gov/licensing-and-regulation/ems-system/index.html (last visited Mar. 5, 2021).
[8] Sections 401.23(3) and (4) and 401.251, F.S.

A basic life support service is an emergency medical service which uses *only* basic life support techniques.[9] In contrast, an advanced life support service is an emergency medical transport or non-transport service which uses advanced life support techniques.[10] Similarly, an emergency medical technician (EMT) is certified to perform basic life support,[11] but a paramedic is certified to perform basic and advanced life support.[12]

"Basic life support" is the assessment or treatment through the use of techniques described in the EMT-Basic National Standard Curriculum or the National EMS Education Standards of the United States Department of Transportation and approved by the DOH. The term includes the administration of oxygen and other techniques that have been approved by the DOH.[13] When transporting a person who is sick, injured, wounded, incapacitated, or helpless, each basic life support ambulance must be occupied by at least two persons:

- One patient attendant who is a certified emergency medical technician, certified paramedic, or licensed physician; and
- One ambulance driver who meets the requirements of s. 401.281, F.S.[14]

"Advanced life support" is assessment or treatment through the use of techniques such as endotracheal intubation, the administration of drugs or intravenous fluids, telemetry, cardiac monitoring, cardiac defibrillation, and other techniques described in the EMT-Paramedic National Standard Curriculum or the National EMS Education Standards, pursuant to DOH rules.[15] When transporting a person who is sick, injured, wounded, incapacitated, or helpless, each advanced life support ambulance must be occupied by at least two persons:

- One certified paramedic or licensed physician; and
- One certified emergency medical technician, certified paramedic, or licensed physician who also meets the requirements of s. 401.281, F.S., for drivers.[16]

The person occupying the advanced life support ambulance with the highest medical certifications is in charge of patient care.[17]

Section 401.25, F.S., provides requirements for licensure as basic and advanced life support services. Every licensee must possess a valid permit for each vehicle in use.[18]

Certificate of Public Convenience and Necessity Requirement

Section 401.25(2)(d), F.S., requires an applicant for licensure to obtain a certificate of public convenience and necessity from each county in which the applicant will operate. In issuing the certificate of public convenience and necessity, the governing body of each county must consider the recommendations of municipalities within its jurisdiction.

[9] Section 401.23(8), F.S.
[10] Section 401.23(2), F.S.
[11] Section 401.23(11), F.S.
[12] Section 401.23(17), F.S.
[13] Section 401.23(7), F.S.
[14] Section 401.25(7)(a), F.S.
[15] Section 401.23(1), F.S.
[16] Section 401.25(7)(b), F.S.
[17] *Id.*
[18] Section 401.26, F.S.

DOH Rule 64J-1.001, F.A.C., defines a "certificate of public convenience and necessity" as "a written statement or document, issued by the governing board of a county, granting permission for an applicant or licensee to provide services authorized by a license issued under ch. 401, part III, F.S., for the benefit of the population of that county or the benefit of the population of some geographic area of that county. No certificate of public need from one county may interfere with the prerogatives asserted by another county regarding certificate of public need."

Insurance Requirement

Section 401.25(2)(c), F.S., requires an applicant for licensure as a basic life support service or an advanced life support service to furnish evidence of adequate insurance coverage for claims arising out of injury to or death of persons and damage to the property of others resulting from any cause for which the owner the service would be liable. In lieu of such insurance, the applicant may furnish a certificate of self-insurance evidencing that the applicant has established an adequate self-insurance plan to cover such risks and that the plan has been approved by the Office of Insurance Regulation of the Financial Services Commission.

DOH Rule 64J-1.002, F.A.C., requires each non-government-operated ground ambulance vehicle to be insured for the sum of at least $100,000.00 for injuries to or death of any one person arising out of any one accident; the sum of at least $300,000.00 for injuries to or death of more than one person in any one accident; and, for the sum of at least $50,000.00 for damage to property arising from any one accident. The rule requires government operated service vehicles to be insured for the sum of at least $100,000.00 for any claim or judgment and the sum of $200,000.00 total for all claims or judgments arising out of the same occurrence.

Some counties and municipal governments throughout the state have minimum insurance limits within their ordinances that exceed those required by DOH rule.

III. Effect of Proposed Changes:

Section 1 of the bill amends s. 316.003, F.S., to define the term "volunteer ambulance services" for purposes of ch. 316, F.S., as a faith-based, not-for-profit corporation (registered under ch. 617, F.S.) which is licensed by as a basic life support service or an advanced life support service and which has no for-profit subsidiaries, uses volunteers to provide services, is not operating for pecuniary profit or financial gain, and does not distribute to or inure to the benefit of its directors, members, or officers, any part of its assets or income."

The bill expands the definition of the term "authorized emergency vehicles" to include volunteer ambulance services that are designated or authorized by the chief of police of an incorporated city or any sheriff of any of the various counties, for purposes of ch. 316, F.S.

A volunteer ambulance services vehicle that qualifies as an authorized emergency vehicle under the bill may disregard specified traffic laws and ordinances when responding to an emergency (pursuant to s. 316.072, F.S.) and may operate emergency lights and sirens which signal to the drivers of every other vehicle to yield the right of way to the emergency vehicle and to steer to the edge of the roadway when the authorized emergency vehicle is in motion, or to slow their speed and vacate the lane closest to the emergency vehicle, in accordance with s. 316.126, F.S.

Section 2 of the bill amends s. 316.072, F.S., to authorize a medical staff physician or technician of a volunteer ambulance service when responding to an emergency in the line of duty in his or her privately owned vehicle and using red lights (as authorized in s. 316.2398, F.S., as amended by section 4 of the bill) to disregard specified traffic laws and ordinances. Under those conditions, and unless otherwise directed by a police officer, a medical staff physician or a technician of the volunteer ambulance service (and the driver of a volunteer ambulance service that meets the definition of an "authorized emergency vehicle") may:

- Park or stand, regardless of traffic laws or ordinances.
- Proceed past a red or stop signal or stop sign, but only after slowing down as may be necessary for safe operation.
- Exceed the maximum speed limits, so long as the driver does not endanger life or property.
- Disregard regulations governing direction or movement or turning in specified directions, so long as the driver does not endanger life or property.

The driver has a duty to drive with due regard to the safety of all persons. The driver is not protected from the consequences of his or her reckless disregard for the safety of others.

Section 3 of the bill amends s. 316.2397, F.S., to authorize vehicles of medical staff physicians or a technician of a volunteer ambulance service, as authorized by s. 316.2398, F.S., as amended by section 4 of the bill, to show or display red lights. The bill authorizes ambulances and emergency service vehicles of volunteer ambulance services, as designated or authorized by the chief of police of an incorporated city or any sheriff of any county, to operate emergency lights and sirens in an emergency.

Section 4 of the bill amends s. 316.2398, F.S., to authorize a privately owned vehicle belonging to a medical staff physician or a technician of a volunteer ambulance service to show or display or use red warning signals while responding to an emergency. The red warning signals must be visible from the front and from the rear of the vehicle. No more than two red or red and white warning signals may be displayed on the vehicle. No inscription of any kind may appear across the face of the lens of the red or red and white warning signal. The bill prohibits the medical staff physician or technician from operating the red warning signals except when responding to an emergency in the line of duty. Any violation of this section of statute is a nonmoving violation, punishable as provided in ch. 318, F.S.

Section 5 of the bill amends s. 401.211, F.S., to provide a legislative finding that it is in the public interest to foster the development of emergency medical services that address religious sensitivities and to recognize, in accordance with the Florida Volunteer and Community Service Act of 2001, the value of augmenting existing county and municipal emergency medical services with those provided by volunteer service organizations.

Section 6 of the bill amends s. 401.23, F.S., to define the term "volunteer ambulance service" for purposes of part III of ch. 401, F.S.

"Volunteer ambulance service" means a faith-based, not-for-profit corporation (registered under ch. 617, F.S.) which is licensed by the DOH as a basic life support service or an advanced life support service and which has no for-profit subsidiaries, uses volunteers to provide services, is

not operating for pecuniary profit or financial gain, and does not distribute to or inure to the benefit of its directors, members, or officers any part of its assets or income.

Section 7 of the bill amends s. 401.25, F.S., to exempt a first responder agency[19] which is a faith-based, not-for-profit corporation (registered under ch. 617, F.S.) which has been operating in this state for at least 10 consecutive years, has no for-profit subsidiaries, uses volunteers to provide services, is not operating for pecuniary profit or financial gain, and does not distribute to or inure to the benefit of its directors, members, or officers any part of its assets or income, from needing to obtain a certificate of public convenience and necessity to be licensed as a basic life support service or as an advanced life support service.

The bill prohibits a county or municipal government from:

- Limiting, prohibiting, or preventing a volunteer ambulance service from responding to an emergency or from providing emergency medical services or transport within its jurisdiction.
- Requiring a volunteer ambulance service to obtain a license or a certificate or pay a fee to provide ambulance or air ambulance services within its jurisdiction, except that a county of municipal government may impose, collect, or enforce payment of any occupational license tax authorized by law.

Section 8 of the bill amends s. 316.306, F.S., to conform a cross-reference.

Section 9 of the bill provides an effective date of July 1, 2021.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

[19] Section 401.435(2), F.S., "First responder agency" includes a law enforcement agency, a fire service agency not licensed under this part, a lifeguard agency, and a volunteer organization that renders, as part of its routine functions, on-scene patient care before emergency medical technicians or paramedics arrive.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

The bill defines the term "volunteer ambulance service" as a certain faith-based, not-for-profit corporation. Other areas of the statutes[20] suggest that not all volunteer organizations providing ambulance services are faith-based. The terminology used in the bill could be misleading and an amendment should be considered to define these entities as "faith-based volunteer ambulance services." It is unclear from the definition provided (and in line 230 pertaining to an exemption for certain first responder agencies) if *only* volunteers may be used to provide services.

VII. Related Issues:

The bill authorizes medical staff physicians and technicians of certain faith-based volunteer ambulance services to use red lights and warning signals and to disregard specified traffic laws and ordinances while responding to an emergency in their privately owned vehicles. The bill does not authorize these individuals to carry a permit or any identifiable means of verification, such as required for an active volunteer firefighter. For an active volunteer firefighter to display such red or red and white warning signals on his or her vehicle, s. 316.2398, F.S., requires the volunteer firefighter to secure a written permit from the chief executive officer of the firefighting organization to use the red or red and white warning signals, and to carry the permit at all times while the red or red and white warning signals are displayed. A volunteer firefighter who violates that section must be dismissed from the firefighting organization by the organization's chief executive officer. The bill does not create a similar requirement for a medical staff physician or a technician of a volunteer ambulance service. This could present challenges for law enforcement at the local, state, and federal levels.

The bill may also present challenges for a county or municipal government (especially during a disaster or mass casualty event) because a volunteer ambulance service is not required to report to or communicate with the county or municipal government. The county or municipal government would have no ability to respond or control the scene in terms of traffic management and staging areas.

[20] *See* s. 401.121, F.S.

Some counties and municipal governments have adopted ordinances requiring basic and advanced life support services to carry insurance in excess of what is required by DOH rule[21] would not apply to volunteer ambulance services within its jurisdiction. Changes made to s. 401.25, F.S., in section 7 of the bill could be interpreted to prevent the enforcement of such ordinances.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 316.003, 316.072, 316.2397, 316.2398, 316.306, 401.211, 401.23, and 401.25.

IX. Additional Information:

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

CS by Health Policy on March 10, 2021:
The CS corrects technical deficiencies in the underlying bill regarding the licensure of basic and advanced life support services, which are currently licensed by the DOH under part III of chapter 401, F.S., and clarifies that volunteer ambulance services must be licensed as basic or advanced life support services. The CS removes the definition of the term "volunteer first responder agency."

B. Amendments:

None.

[21] *See* Section II of this analysis.

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/10/2021	.	
	.	
	.	
	.	

The Committee on Health Policy (Pizzo) recommended the following:

Senate Amendment (with title amendment)

Delete lines 62 - 235

and insert:

licensed under part III of chapter 401 as a basic life support service or an advanced life support service and which has no for-profit subsidiaries, uses volunteers to provide services, is not operating for pecuniary profit or financial gain, and does not distribute to or inure to the benefit of its directors, members, or officers any part of its assets or income.

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Section 2. Paragraph (a) of subsection (5) of section 316.072, Florida Statutes, is amended to read:

316.072 Obedience to and effect of traffic laws.—

(5) AUTHORIZED EMERGENCY VEHICLES.—

(a)1. The driver of an authorized emergency vehicle, when responding to an emergency call, when in the pursuit of an actual or suspected violator of the law, or when responding to a fire alarm, but not upon returning from a fire;

2. A medical staff physician or technician of a medical facility licensed by the state or of a volunteer ambulance service when responding to an emergency in the line of duty in his or her privately owned vehicle, using red lights as authorized in s. 316.2398; or

3. The driver of an authorized law enforcement vehicle, when conducting a nonemergency escort, to warn the public of an approaching motorcade;

may exercise the privileges set forth in this section, but subject to the conditions herein stated.

Section 3. Subsection (3) of section 316.2397, Florida Statutes, is amended to read:

316.2397 Certain lights prohibited; exceptions.—

(3) Vehicles of the fire department and fire patrol, including vehicles of volunteer firefighters as permitted under s. 316.2398, may show or display red or red and white lights. Vehicles of medical staff physicians or technicians of medical facilities licensed by the state or of volunteer ambulance services as authorized under s. 316.2398, ambulances as authorized under this chapter, and buses and taxicabs as

authorized under s. 316.2399 may show or display red lights. Vehicles of the fire department, fire patrol, police vehicles, and such ambulances and emergency vehicles of municipal and county departments, volunteer ambulance services, public service corporations operated by private corporations, the Fish and Wildlife Conservation Commission, the Department of Environmental Protection, the Department of Transportation, the Department of Agriculture and Consumer Services, and the Department of Corrections as are designated or authorized by their respective department or the chief of police of an incorporated city or any sheriff of any county may operate emergency lights and sirens in an emergency. Wreckers, mosquito control fog and spray vehicles, and emergency vehicles of governmental departments or public service corporations may show or display amber lights when in actual operation or when a hazard exists provided they are not used going to and from the scene of operation or hazard without specific authorization of a law enforcement officer or law enforcement agency. Wreckers must use amber rotating or flashing lights while performing recoveries and loading on the roadside day or night, and may use such lights while towing a vehicle on wheel lifts, slings, or under reach if the operator of the wrecker deems such lights necessary. A flatbed, car carrier, or rollback may not use amber rotating or flashing lights when hauling a vehicle on the bed unless it creates a hazard to other motorists because of protruding objects. Further, escort vehicles may show or display amber lights when in the actual process of escorting overdimensioned equipment, material, or buildings as authorized by law. Vehicles owned or leased by private security agencies

may show or display green and amber lights, with either color being no greater than 50 percent of the lights displayed, while the security personnel are engaged in security duties on private or public property.

Section 4. Subsections (1), (2), and (4) of section 316.2398, Florida Statutes, are amended to read:

316.2398 Display or use of red or red and white warning signals; motor vehicles of volunteer firefighters or medical staff.—

(1) A privately owned vehicle belonging to an active firefighter member of a regularly organized volunteer firefighting company or association, while en route to the fire station for the purpose of proceeding to the scene of a fire or other emergency or while en route to the scene of a fire or other emergency in the line of duty as an active firefighter member of a regularly organized firefighting company or association, may display or use red or red and white warning signals. A privately owned vehicle belonging to a medical staff physician or technician of a medical facility licensed by the state or of a volunteer ambulance service, while responding to an emergency in the line of duty, may display or use red warning signals. Warning signals must be visible from the front and from the rear of such vehicle, subject to the following restrictions and conditions:

(a) No more than two red or red and white warning signals may be displayed.

(b) No inscription of any kind may appear across the face of the lens of the red or red and white warning signal.

(c) In order for an active volunteer firefighter to display

such red or red and white warning signals on his or her vehicle, the volunteer firefighter must first secure a written permit from the chief executive officers of the firefighting organization to use the red or red and white warning signals, and this permit must be carried by the volunteer firefighter at all times while the red or red and white warning signals are displayed.

(2) A person who is not an active firefighter member of a regularly organized volunteer firefighting company or association or a physician or technician of the medical staff of a medical facility licensed by the state or of a volunteer ambulance service may not display on any motor vehicle owned by him or her, at any time, any red or red and white warning signals as described in subsection (1).

(4) A physician or technician of the medical staff of a medical facility licensed by the state or of a volunteer ambulance service may not operate any red warning signals as authorized in subsection (1), except when responding to an emergency in the line of duty.

Section 5. Section 401.211, Florida Statutes, is amended to read:

401.211 Legislative intent.—The Legislature recognizes that the systematic provision of emergency medical services saves lives and reduces disability associated with illness and injury. In addition, that system of care must be equally capable of assessing, treating, and transporting children, adults, and frail elderly persons. Further, it is the intent of the Legislature to encourage the development and maintenance of emergency medical services because such services are essential

to the health and well-being of all citizens of the state. The Legislature finds that it is in the public interest to foster the development of emergency medical services that address religious sensitivities. In accordance with the Florida Volunteer and Community Service Act of 2001, the Legislature further recognizes the value of augmenting existing county and municipal emergency medical services with those provided by volunteer service organizations. The Legislature also recognizes that the establishment of a comprehensive statewide injury-prevention program supports state and community health systems by further enhancing the total delivery system of emergency medical services and reduces injuries for all persons. The purpose of this part is to protect and enhance the public health, welfare, and safety through the establishment of an emergency medical services state plan, an advisory council, a comprehensive statewide injury-prevention program, minimum standards for emergency medical services personnel, vehicles, services and medical direction, and the establishment of a statewide inspection program created to monitor the quality of patient care delivered by each licensed service and appropriately certified personnel.

Section 6. Subsection (22) is added to section 401.23, Florida Statutes, to read:

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

(22) "Volunteer ambulance service" means a faith-based, not-for-profit corporation registered under chapter 617 which is licensed by the department as a basic life support service or an advanced life support service and which has no for-profit subsidiaries, uses volunteers to provide services, is not

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operating for pecuniary profit or financial gain, and does not distribute to or inure to the benefit of its directors, members, or officers any part of its assets or income.

Section 7. Paragraph (d) of subsection (2) and subsection (6) of section 401.25, Florida Statutes, are amended to read:

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

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

(d) The applicant has obtained a certificate of public convenience and necessity from each county in which the applicant will operate. In issuing the certificate of public convenience and necessity, the governing body of each county shall consider the recommendations of municipalities within its jurisdiction. An applicant that is a first responder agency is exempt from this requirement if it is a faith-based, not-for-profit corporation registered under chapter 617 which has been operating in this state for at least 10 consecutive years, has no for-profit subsidiaries, uses volunteers to provide services, is not operating for pecuniary profit or financial gain, and does not distribute to or inure to the benefit of its directors, members, or officers any part of its assets or income.

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

And the title is amended as follows:

Delete lines 22 - 24

and insert:

the term "volunteer ambulance service"; amending s. 401.25, F.S.; exempting certain first responder

446228

185 agencies from

By Senator Pizzo

38-00809A-21 20211084__

A bill to be entitled

An act relating to volunteer ambulance services; amending s. 316.003, F.S.; revising the definition of the term "authorized emergency vehicles" and defining the term "volunteer ambulance service"; amending s. 316.072, F.S.; authorizing certain medical staff of a volunteer ambulance service to use red lights on a privately owned vehicle under certain circumstances; amending s. 316.2397, F.S.; authorizing vehicles of volunteer ambulance services to show or display red lights and operate emergency lights and sirens under certain circumstances; amending s. 316.2398, F.S.; authorizing privately owned vehicles belonging to certain medical staff of a volunteer ambulance service to display or use red warning signals under certain circumstances; conforming a provision to changes made by the act; prohibiting certain medical staff of volunteer ambulance services from operating red warning signals when not responding to an emergency in the line of duty; amending s. 401.211, F.S.; revising legislative intent; amending s. 401.23, F.S.; defining the terms "volunteer ambulance service" and "volunteer first responder agency"; amending s. 401.25, F.S.; exempting volunteer first responder agencies from certificate of public convenience and necessity requirements; providing that county and municipal governments may not limit, prohibit, or prevent volunteer ambulance services from responding to emergencies or providing emergency medical services or

38-00809A-21 20211084__

transport within their respective jurisdictions; prohibiting county and municipal governments from requiring volunteer ambulance services to obtain a license or certificate or pay a fee to provide ambulance or air ambulance services within their respective jurisdictions, with an exception; amending s. 316.306, F.S.; conforming a cross-reference; providing an effective date.

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

Section 1. Present subsection (105) of section 316.003, Florida Statutes, is redesignated as subsection (106), a new subsection (105) is added to that section, and subsection (1) of that section is amended, to read:

316.003 Definitions.—The following words and phrases, when used in this chapter, shall have the meanings respectively ascribed to them in this section, except where the context otherwise requires:

(1) AUTHORIZED EMERGENCY VEHICLES.—Vehicles of the fire department (fire patrol), police vehicles, and such ambulances and emergency vehicles of municipal departments, volunteer ambulance services, public service corporations operated by private corporations, the Fish and Wildlife Conservation Commission, the Department of Environmental Protection, the Department of Health, the Department of Transportation, and the Department of Corrections as are designated or authorized by their respective departments ~~department~~ or the chief of police of an incorporated city or any sheriff of any of the various

counties.

(105) VOLUNTEER AMBULANCE SERVICE.—A faith-based, not-for-profit corporation registered under chapter 617 which is licensed by the department as a basic life support service or an advanced life support service and which has no for-profit subsidiaries, uses volunteers to provide services, is not operating for pecuniary profit or financial gain, and does not distribute to or inure to the benefit of its directors, members, or officers any part of its assets or income.

Section 2. Paragraph (a) of subsection (5) of section 316.072, Florida Statutes, is amended to read:

316.072 Obedience to and effect of traffic laws.—

(5) AUTHORIZED EMERGENCY VEHICLES.—

(a)1. The driver of an authorized emergency vehicle, when responding to an emergency call, when in the pursuit of an actual or suspected violator of the law, or when responding to a fire alarm, but not upon returning from a fire;

2. A medical staff physician or technician of a medical facility or a volunteer ambulance service licensed by the state when responding to an emergency in the line of duty in his or her privately owned vehicle, using red lights as authorized in s. 316.2398; or

3. The driver of an authorized law enforcement vehicle, when conducting a nonemergency escort, to warn the public of an approaching motorcade;

may exercise the privileges set forth in this section, but subject to the conditions herein stated.

Section 3. Subsection (3) of section 316.2397, Florida

Statutes, is amended to read:

316.2397 Certain lights prohibited; exceptions.—

(3) Vehicles of the fire department and fire patrol, including vehicles of volunteer firefighters as permitted under s. 316.2398, may show or display red or red and white lights. Vehicles of medical staff physicians or technicians of medical facilities or volunteer ambulance services licensed by the state as authorized under s. 316.2398, ambulances as authorized under this chapter, and buses and taxicabs as authorized under s. 316.2399 may show or display red lights. Vehicles of the fire department, fire patrol, police vehicles, and such ambulances and emergency vehicles of municipal and county departments, volunteer ambulance services, public service corporations operated by private corporations, the Fish and Wildlife Conservation Commission, the Department of Environmental Protection, the Department of Transportation, the Department of Agriculture and Consumer Services, and the Department of Corrections as are designated or authorized by their respective department or the chief of police of an incorporated city or any sheriff of any county may operate emergency lights and sirens in an emergency. Wreckers, mosquito control fog and spray vehicles, and emergency vehicles of governmental departments or public service corporations may show or display amber lights when in actual operation or when a hazard exists provided they are not used going to and from the scene of operation or hazard without specific authorization of a law enforcement officer or law enforcement agency. Wreckers must use amber rotating or flashing lights while performing recoveries and loading on the roadside day or night, and may use such lights while towing a vehicle on

wheel lifts, slings, or under reach if the operator of the wrecker deems such lights necessary. A flatbed, car carrier, or rollback may not use amber rotating or flashing lights when hauling a vehicle on the bed unless it creates a hazard to other motorists because of protruding objects. Further, escort vehicles may show or display amber lights when in the actual process of escorting overdimensioned equipment, material, or buildings as authorized by law. Vehicles owned or leased by private security agencies may show or display green and amber lights, with either color being no greater than 50 percent of the lights displayed, while the security personnel are engaged in security duties on private or public property.

Section 4. Subsections (1), (2), and (4) of section 316.2398, Florida Statutes, are amended to read:

316.2398 Display or use of red or red and white warning signals; motor vehicles of volunteer firefighters or medical staff.—

(1) A privately owned vehicle belonging to an active firefighter member of a regularly organized volunteer firefighting company or association, while en route to the fire station for the purpose of proceeding to the scene of a fire or other emergency or while en route to the scene of a fire or other emergency in the line of duty as an active firefighter member of a regularly organized firefighting company or association, may display or use red or red and white warning signals. A privately owned vehicle belonging to a medical staff physician or technician of a medical facility or a volunteer ambulance service licensed by the state, while responding to an emergency in the line of duty, may display or use red warning

signals. Warning signals must be visible from the front and from the rear of such vehicle, subject to the following restrictions and conditions:

(a) No more than two red or red and white warning signals may be displayed.

(b) No inscription of any kind may appear across the face of the lens of the red or red and white warning signal.

(c) In order for an active volunteer firefighter to display such red or red and white warning signals on his or her vehicle, the volunteer firefighter must first secure a written permit from the chief executive officers of the firefighting organization to use the red or red and white warning signals, and this permit must be carried by the volunteer firefighter at all times while the red or red and white warning signals are displayed.

(2) A person who is not an active firefighter member of a regularly organized volunteer firefighting company or association or a physician or technician of the medical staff of a medical facility or a volunteer ambulance service licensed by the state may not display on any motor vehicle owned by him or her, at any time, any red or red and white warning signals as described in subsection (1).

(4) A physician or technician of the medical staff of a medical facility or a volunteer ambulance service may not operate any red warning signals as authorized in subsection (1), except when responding to an emergency in the line of duty.

Section 5. Section 401.211, Florida Statutes, is amended to read:

401.211 Legislative intent.—The Legislature recognizes that

the systematic provision of emergency medical services saves lives and reduces disability associated with illness and injury. In addition, that system of care must be equally capable of assessing, treating, and transporting children, adults, and frail elderly persons. Further, it is the intent of the Legislature to encourage the development and maintenance of emergency medical services because such services are essential to the health and well-being of all citizens of the state. The Legislature finds that it is in the public interest to foster the development of emergency medical services that address religious sensitivities. In accordance with the Florida Volunteer and Community Service Act of 2001, the Legislature further recognizes the value of augmenting existing county and municipal emergency medical services with those provided by volunteer service organizations. The Legislature also recognizes that the establishment of a comprehensive statewide injury-prevention program supports state and community health systems by further enhancing the total delivery system of emergency medical services and reduces injuries for all persons. The purpose of this part is to protect and enhance the public health, welfare, and safety through the establishment of an emergency medical services state plan, an advisory council, a comprehensive statewide injury-prevention program, minimum standards for emergency medical services personnel, vehicles, services and medical direction, and the establishment of a statewide inspection program created to monitor the quality of patient care delivered by each licensed service and appropriately certified personnel.

Section 6. Subsections (22) and (23) are added to section

401.23, Florida Statutes, to read:

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

(22) "Volunteer ambulance service" means a faith-based, not-for-profit corporation registered under chapter 617 which is licensed by the department as a basic life support service or an advanced life support service and which has no for-profit subsidiaries, uses volunteers to provide services, is not operating for pecuniary profit or financial gain, and does not distribute to or inure to the benefit of its directors, members, or officers any part of its assets or income.

(23) "Volunteer first responder agency" means a first responder agency as defined in s. 401.435(2) which is a faith-based, not-for-profit corporation registered under chapter 617, has been operating in this state for at least 10 consecutive years, has no for-profit subsidiaries, uses volunteers to provide services, is not operating for pecuniary profit or financial gain, and does not distribute to or inure to the benefit of its directors, members, or officers any part of its assets or income.

Section 7. Paragraph (d) of subsection (2) and subsection (6) of section 401.25, Florida Statutes, are amended to read:

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

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

(d) The applicant has obtained a certificate of public convenience and necessity from each county in which the applicant will operate. In issuing the certificate of public convenience and necessity, the governing body of each county

shall consider the recommendations of municipalities within its jurisdiction. An applicant that is a volunteer first responder agency is exempt from this requirement.

(6)(a) The governing body of each county may adopt ordinances that provide reasonable standards for certificates of public convenience and necessity for basic or advanced life support services and air ambulance services. In developing standards for certificates of public convenience and necessity, the governing body of each county must consider state guidelines, recommendations of the local or regional trauma agency created under chapter 395, and the recommendations of municipalities within its jurisdiction.

(b) A county or municipal government may not limit, prohibit, or prevent a volunteer ambulance service from responding to an emergency or from providing emergency medical services or transport within its jurisdiction.

(c) A county or municipal government may not require a volunteer ambulance service to obtain a license or certificate or pay a fee to provide ambulance or air ambulance services within its jurisdiction, except that a county or municipal government may impose, collect, or enforce payment of any occupational license tax authorized by law.

Section 8. Paragraph (a) of subsection (3) of section 316.306, Florida Statutes, is amended to read:

316.306 School and work zones; prohibition on the use of a wireless communications device in a handheld manner.—

(3)(a)1. A person may not operate a motor vehicle while using a wireless communications device in a handheld manner in a designated school crossing, school zone, or work zone area as

defined in s. 316.003(106) ~~s. 316.003(105)~~. This subparagraph shall only be applicable to work zone areas if construction personnel are present or are operating equipment on the road or immediately adjacent to the work zone area. For the purposes of this paragraph, a motor vehicle that is stationary is not being operated and is not subject to the prohibition in this paragraph.

2.a. During the period from October 1, 2019, through December 31, 2019, a law enforcement officer may stop motor vehicles to issue verbal or written warnings to persons who are in violation of subparagraph 1. for the purposes of informing and educating such persons of this section. This sub-subparagraph shall stand repealed on October 1, 2020.

b. Effective January 1, 2020, a law enforcement officer may stop motor vehicles and issue citations to persons who are driving while using a wireless communications device in a handheld manner in violation of subparagraph 1.

Section 9. This act shall take effect July 1, 2021.

The Florida Senate

Committee Agenda Request

To: Senator Manny Diaz, Jr., Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: February 10, 2021

I respectfully request that **Senate Bill #1084**, relating to Volunteer Ambulance Services, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

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

File signed original with committee office

S-020 (03/2004)

YOU MUST PRINT AND DELIVER THIS FORM TO THE ASSIGNED TESTIMONY ROOM

Duplicate

THE FLORIDA SENATE

APPEARANCE RECORD

March 10, 2021
Meeting Date

SB 1084
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Volunteer Ambulance Services

Name Chief Ray Colburn

Job Title Executive Director

Address 5289 Palm Dr.
Street

Melbourne Beach FL 32951
City *State* *Zip*

Phone 407-468-6622

Email ray@ffca.org

Speaking: ☐ For ☑ Against ☐ Information

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

Representing Florida Fire Chiefs' Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/10/20201
Meeting Date

1084
Bill Number (if applicable)

Topic HATZALAH

Amendment Barcode (if applicable)

Name Schneur Oirechman

Job Title Rabbi

Address 224 Chapel Drive
Street

Phone 850-523-9294

Tall FL 32304
City *State* *Zip*

Email

Speaking: ☒ For ☐ Against ☐ Information

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

Representing HATZALAH

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/10/2021
Meeting Date

SB 1084
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Volunteer Ambulance Services

Name Andre Reitman (Nicole Fumarola on his behalf)

Job Title Emergency Medical Technician

Address _____ Phone 305-803-8302
Street

_____ Email areitman@hatzalah
City *State* *Zip* southflorida.org

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Hatzalah

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 634
INTRODUCER:	Health Policy Committee and Senators Gibson and Baxley
SUBJECT:	Dementia-related Staff Training
DATE:	March 10, 2021
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 634 creates s. 430.5025, F.S., to establish the Florida Alzheimer's Disease and Dementia Training Act. The bill establishes universal Alzheimer's disease and related disorder (ADRD) training requirements to be used by nursing homes, home health agencies, hospice providers, assisted living facilities, adult family-care homes, and adult day care centers to replace each license type's individual training requirements on that topic.

The bill requires a licensee, as defined in the bill, to provide each of its employees one hour of dementia-related training within 30 days of his or her employment. Additionally, each licensee must require employees who are direct care workers, as defined by the bill, and who are expected to or required to have direct contact with clients, patients, or residents with ADRD to receive at least three hours of initial training within the first three months of employment and four hours of continuing education annually. If the licensee advertises that it provides special care for individuals with Alzheimer's disease, the licensee must require each of its direct care workers to complete four additional hours of training.

The bill requires the Department of Elder Affairs (DOEA) or its designee to approve the courses that may be used to satisfy the training requirements in the bill and to develop an assessment for each required topic. The DOEA is required to adopt rules for implementation.

The bill also amends ss. 400.1755, 400.4785, 400.6045, 429.178, 429.52, 429.83, and 429.917, F.S., to eliminate individual ADRD training requirements for nursing homes, home health

service providers, hospice providers, assisted living facilities (ALF), adult family-care homes, and adult day care centers in favor of the uniform requirements established by the bill.

The bill provides an effective date of July 1, 2021.

II. Present Situation:

Dementia and Alzheimer's Disease

Dementia is the loss of cognitive functioning—thinking, remembering, and reasoning—and behavioral abilities to such an extent that it interferes with a person's daily life and activities. These functions include memory, language skills, visual perception, problem solving, self-management, and the ability to focus and pay attention. Some people with dementia cannot control their emotions, and their personalities may change. Dementia ranges in severity from the mildest stage, when it is just beginning to affect a person's functioning, to the most severe stage, when the person must depend completely on others for basic activities of living.[1]

Alzheimer's disease is the most common type of dementia. It is a progressive disease that begins with mild memory loss and can lead to loss of the ability to carry on a conversation and respond to one's environment. Alzheimer's disease affects parts of the brain that control thought, memory, and language. It can seriously affect a person's ability to carry out daily activities. Although scientists are studying the disease, what causes Alzheimer's disease is unknown.[2]

There are an estimated 580,000 individuals living with Alzheimer's disease in the state of Florida.[3] By 2025, it is projected that 720,000 Floridians will have Alzheimer's disease.[4] Most individuals with Alzheimer's can live in the community with support, often provided by spouses or other family members. In the late stages of the disease, many patients require care 24 hours per day and are often served in long-term care facilities.

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[1] *What is Dementia? Symptoms, Types, and Diagnosis*, National Institute on Aging, *available at* https://www.nia.nih.gov/health/what-dementia-symptoms-types-and-diagnosis, (last visited on Mar. 2, 2021).
[2] Centers for Disease Control and Prevention, Alzheimer's Disease and Healthy Aging website *available at* https://www.cdc.gov/aging/aginginfo/alzheimers.htm#AlzheimersDisease, (last visited Mar. 2, 2021).
[3] Alzheimer's Association *available at* https://www.alz.org/media/Documents/florida-alzheimers-facts-figures-2018.pdf, (last visited Mar. 2, 2021).
[4] *Id.*

Dementia and Alzheimer's Disease Training

Overview by Facility Type

	All Employees	Employees with Expected or Required Direct Contact	Employees Providing Direct Care	Health Care Practitioner Continuing Education Sufficient?	Training Approved?	Additional Reqs.
Nursing Homes	Provided with basic written information about interacting with persons with ADRD upon beginning employment.	1 hour of training within the first 3 months of employment.	Additional 3 hours of training within the first 9 months of employment.	Yes	By DOEA.	
Home Health Agencies		Not specified.	2 hours of training within the first 9 months of employment.	Yes	By DOEA.	HHA's that serve 90% individuals under age 21 are exempt.
Hospice Providers	ADRD upon beginning employment.	1 hour of training within the first 3 months of employment.	Additional 3 hours of training within the first 9 months of employment.	Yes	By DOEA.	
ALFs[5]	Employees with incidental contact must be given information within 3 months.	4 hours within 3 months of employment	4 additional hours within 9 months of employment + 4 hours CE annually	Not specified.	By DOEA	
Adult Day Care Centers	Same as nursing homes, home health agencies, and Hospice.	1 hour of training within the first 3 months of employment.	Additional 3 hours of training within the first 9 months of employment.	Yes	By DOEA	
Adult Family-Care Homes	None	None	None	Not Specified	By the Agency for Health Care Administration (AHCA)	

Details for each facility type are below:

[5] Training is required only if the ALF advertises that it provides special care for persons with Alzheimer's disease or related disorders.

Nursing Homes

Section 400.1755, F.S., requires each nursing home to provide the following training:

- Provide each of its employee's basic written information about interacting with persons with ADRD upon beginning employment.
- All employees who are expected to, or whose responsibilities require them to, have direct contact with residents with ADRD must also have an initial training of at least one hour completed in the first three months after beginning employment. This training must include, but is not limited to, an overview of dementias and must provide basic skills in communicating with persons with dementia.
- An individual who provides direct care must complete the required initial training and an additional three hours of training within nine months after beginning employment. This training must include, but is not limited to, managing problem behaviors, promoting the resident's independence in activities of daily living, and skills in working with families and caregivers. Health care practitioners' continuing education can be counted toward the required training hours.
- The DOEA or its designee must approve the initial and continuing training provided in the facilities. The DOEA must approve training offered in a variety of formats, including, but not limited to, Internet-based training, videos, teleconferencing, and classroom instruction. The DOEA must keep a list of current providers who are approved to provide initial and continuing training. The DOEA must adopt rules to establish standards for the trainers and the training required in this section of statute.
- Upon completing any training listed in the section, the employee or direct caregiver must be issued a certificate that includes the name of the training provider, the topic covered, and the date and signature of the training provider. The certificate is evidence of completion of training in the identified topic, and the employee or direct caregiver is not required to repeat training in that topic if the employee or direct caregiver changes employment to a different facility or to an assisted living facility, home health agency, adult day care center, or adult family-care home. The direct caregiver must comply with other applicable continuing education requirements.

Home Health Agencies

Section 400.4785, F.S., requires a home health agency to provide the following staff training:

- Upon beginning employment with the agency, each employee must receive basic written information about interacting with participants who have ADRD.
- Newly-hired home health agency personnel who will be providing direct care to patients must complete two hours of training in ADRD within nine months after beginning employment with the agency. This training must include, but is not limited to, an overview of dementia, a demonstration of basic skills in communicating with persons who have dementia, the management of problem behaviors, information about promoting the client's independence in activities of daily living, and instruction in skills for working with families and caregivers.
- For certified nursing assistants, the required two hours of training are part of the total hours of training required annually.
- For a health care practitioner, as defined in s. 456.001, F.S., continuing education hours taken as required by that practitioner's licensing board are counted toward the total of two hours.

- For an employee who is a licensed health care practitioner, training that is sanctioned by that practitioner's licensing board must be considered to be approved by the DOEA.
- The DOEA, or its designee, must approve the required training. The DOEA must consider for approval training offered in a variety of formats. The DOEA must keep a list of current providers who are approved to provide the two-hour training. The DOEA must adopt rules to establish standards for the employees who are subject to this training, for the trainers, and for the training required in this section of statute.
- Upon completing the training listed in the section, the employee must be issued a certificate that states that the training mandated under the section has been received. The certificate must be dated and signed by the training provider. The certificate is evidence of completion of this training, and the employee is not required to repeat this training if the employee changes employment to a different home health agency.
- A licensed home health agency whose unduplicated census during the most recent calendar year was composed of at least 90 percent of individuals aged 21 years or younger at the date of admission, is exempt from the training requirements in this section of statute.

Hospice Providers

Section 400.6045, F.S., requires a hospice provider to provide the following staff training:

- Upon beginning employment with the agency, each employee must receive basic written information about interacting with persons who have ADRD.
- Employees who are expected to, or whose responsibilities require them to, have direct contact with participants who have ADRD must complete initial training of at least one hour within the first three months after beginning employment. The training must include an overview of dementias and must provide instruction in basic skills for communicating with persons who have dementia.
- In addition, an employee who will be providing direct care to a participant who has ADRD must complete an additional three hours of training within nine months after beginning employment. This training must include, but is not limited to, the management of problem behaviors, information about promoting the patient's independence in activities of daily living, and instruction in skills for working with families and caregivers.
- For certified nursing assistants, the required four hours of training is part of the total hours of training required annually.
- For a health care practitioner as defined in s. 456.001, F.S., continuing education hours taken as required by that practitioner's licensing board are counted toward the total of four hours.
- For an employee who is a licensed health care practitioner as defined in s. 456.001, F.S., training that is sanctioned by that practitioner's licensing board is considered to be approved by the DOEA.
- The DOEA or its designee must approve the required one-hour and three-hour training provided to employees or direct caregivers under this section of statute. The DOEA must consider for approval training offered in a variety of formats. The DOEA must keep a list of current providers who are approved to provide the one-hour and three-hour training. The DOEA must adopt rules to establish standards for the employees who are subject to this training, for the trainers, and for the training required in this section of statute.
- Upon completing any training described in the section, the employee or direct caregiver must be issued a certificate that includes the name of the training provider, the topic covered, and the date and signature of the training provider. The certificate is evidence of completion of

training in the identified topic, and the employee or direct caregiver is not required to repeat training in that topic if the employee or direct caregiver changes employment to a different hospice or to a home health agency, assisted living facility, nursing home, or adult day care center.

- A hospice that claims it provides special care for persons who have ADRD must disclose in its advertisements or in a separate document those services that distinguish the care as being especially applicable to, or suitable for, such persons. The hospice must give a copy of all such advertisements or a copy of the document to each person who requests information about programs and services for persons with ADRD offered by the hospice and must maintain a copy of all such advertisements and documents in its records. The Agency for Health Care Administration (AHCA) must examine all such advertisements and documents in the hospice's records as part of the license renewal procedure.

Assisted Living Facilities

Section 429.178, F.S., requires an ALF that advertises it provides special care for persons with ADRD to provide the following training:

- An employee who has regular contact with such residents must complete up to four hours of initial dementia-specific training developed or approved by the DOEA. The training must be completed within three months after beginning employment and satisfy the core training requirements of s. 429.52(3)(g), F.S.
- A direct caregiver who provides direct care to such residents must complete the required initial training and four additional hours of training developed or approved by the DOEA. The training must be completed within nine months after beginning employment and satisfy the core training requirements of s. 429.52(3)(g), F.S.
- An individual who is employed by a facility that provides special care for residents with ADRD, but who only has incidental contact with such residents, must be given, at a minimum, general information on interacting with individuals with ADRD, within three months after beginning employment.
- A direct caregiver must also participate in a minimum of four contact hours of continuing education each calendar year. The continuing education must include one or more topics included in the dementia-specific training, developed or approved by the DOEA, in which the caregiver has not received previous training.
- Upon completing any specified training, the employee or direct caregiver must be issued a certificate that includes the name of the training provider, the topic covered, and the date and signature of the training provider. The certificate is evidence of completion of training in the identified topic, and the employee or direct caregiver is not required to repeat training in that topic if the employee or direct caregiver changes employment to a different facility. The employee or direct caregiver must comply with other applicable continuing education requirements.
- The DOEA, or its designee, must approve the initial and continuing education courses and providers.
- The DOEA must keep a current list of providers who are approved to provide initial and continuing education for staff of facilities that provide special care for persons with ADRD.

Adult Family-Care Homes

Adult family-care home providers are required to undergo 12 hours of training some of which must be related to Identifying and meeting the special needs of disabled adults and frail elders. However, providers are not currently required to undergo training specific to ADRD.[6]

Adult Day Care Centers

Section 49.917, F.S., requires an adult day care center to provide the following staff training:

- Upon beginning employment with the facility, each employee must receive basic written information about interacting with participants who have ADRD.
- In addition to the information provided, newly-hired adult day care center personnel who are expected to, or whose responsibilities require them to, have direct contact with participants who have ADRD must complete initial training of at least one hour within the first three months after beginning employment. The training must include an overview of dementias and must provide instruction in basic skills for communicating with persons who have dementia.
- In addition to the previous requirements, an employee who will be providing direct care to a participant who has ADRD must complete an additional three hours of training within nine months after beginning employment. This training must include, but is not limited to, the management of problem behaviors, information about promoting the participant's independence in activities of daily living, and instruction in skills for working with families and caregivers.
- For certified nursing assistants, the required four hours of training is part of the total hours of training required annually.
- For a health care practitioner as defined in s. 456.001, F.S., continuing education hours taken as required by that practitioner's licensing board are counted toward the total of four hours.
- For an employee who is a licensed health care practitioner as defined in s. 456.001, F.S., training that is sanctioned by that practitioner's licensing board is considered to be approved by the DOEA.
- The DOEA or its designee must approve the one-hour and three-hour training provided to employees and direct caregivers under this section of statute. The DOEA must consider for approval training offered in a variety of formats. The DOEA must keep a list of current providers who are approved to provide the one-hour and three-hour training. The DOEA must adopt rules to establish standards for the employees who are subject to this training, for the trainers, and for the training required in this section of statute.
- Upon completing any training described in the section, the employee or direct caregiver must be issued a certificate that includes the name of the training provider, the topic covered, and the date and signature of the training provider. The certificate is evidence of completion of training in the identified topic, and the employee or direct caregiver is not required to repeat training in that topic if the employee or direct caregiver changes employment to a different adult day care center or to an assisted living facility, nursing home, home health agency, or hospice. The direct caregiver must comply with other applicable continuing education requirements.

[6] *See* s. 429.75, F.S., and Fla. Admin. Code R. 59A-37.007 (2020).

Current Administration of ADRD Training

The DOEA has authority for administering the existing ADRD training[7] and currently does so through a contract with the University of South Florida (USF).[8] USF, through its Training Academy on Aging, reviews and approves ADRD Training Providers and Training Curriculum Programs for the DOEA. The mission of the ADRD training program is to improve the care of individuals with ADRDs who receive services from nursing homes, assisted living facilities, home health agencies, adult day care centers, and hospice care facilities. The ADRD training program is designed to ensure that agency and facility staff members who have regular contact with or provide direct care to, persons with ADRD receive the relevant ADRD training.[9]

III. Effect of Proposed Changes:

Sections 1 and 2 of CS/SB 634 establish the Florida Alzheimer's Disease and Dementia Training Act. The bill creates s. 430.5025, F.S., to establish universal ADRD training requirements for nursing homes, home health agencies, hospice providers, ALFs, and adult day care centers. The bill defines the following terms:

- "Department" means the Department of Elderly Affairs.[10]
- "Direct care worker" means an individual who, as part of his or her employment duties, provides or has access to provide direct contact assistance with personal care or activities of daily living to clients, patients, or residents of any facility licensed under part II, part III, or part IV of ch. 400, F.S., or part I or part III of ch. 429, F.S.
- "Employee" means any staff member who has regular contact or incidental contact on a recurring basis with clients, patients, or residents of a facility licensed under part II, part III, or part IV of ch. 400, F.S., or part I or part III of ch. 429, F.S. The term includes, but is not limited to, direct care workers; staff responsible for housekeeping, the front desk, maintenance, and other administrative functions; and any other individuals who may have regular contact or incidental contact on a recurring basis with clients, patients, or residents.
- "Licensee" means a person or an entity licensed under part II, part III, or part IV of ch. 400, F.S., or part I or part III of ch. 429, F.S.

The bill requires that, as a condition of licensure, each licensee must provide one hour of dementia-related training to each of its employees within 30 days of their employment. The training must include methods for interacting with persons with ADRD and for identifying warning signs of dementia.

Any employee who is a direct care worker, as defined, must receive at least three hours of additional training within the first three months of employment if the direct care worker is expected or required to have direct contact with clients, patients, or residents with ADRD or with populations that are at a greater risk for ADRD. The three hours of training must include, but need not be limited to, an overview of ADRDs and person-centered care, assessment and care

[7] Fla. Admin. Code R. 58A-5.0194 (2020).
[8] Contract XQ092, effective July 1, 2020, and AHCA Agreement AA412, effective July 21, 2020, between Department of Elder Affairs, USF Board of Trustees, and the Agency for Health Care Administration (Agency).
[9] Department of Elder Affairs, *Senate Bill 634 Fiscal Analysis* (Feb. 2, 2021) (on file with the Senate Committee on Health Policy).
[10] Also known as the Department of Elder Affairs (DOEA).

planning, activities of daily living, and dementia-related behaviors and communication for clients, patients, and residents with ADRD. Each such employee must also receive at least four hours of continuing education, approved by the DOEA, annually on the above topics and any related changes in state or federal law.

If the licensee advertises that it provides special care for individuals with ADRD, the licensee must require its direct care workers to complete four additional hours of initial training with a curriculum developed or approved by the DOEA. This training will count toward a certified nursing assistant's annual training requirements.

If the employee is a health care practitioner, as defined in 456.001, F.S., the employee may count his or her continuing education hours for licensure to satisfy the three-hour and four-hour training requirements if his or her continuing education covers the required topics and the hours are approved by the DOEA.

The DOEA or its designee is required to approve the courses that licensees may use to satisfy the training requirements in the bill, and the approved courses must be in a variety of formats, including but not limited to, Internet-based training, videos, teleconferencing, and classroom instruction. The DOEA or its designee must develop a process for registering training providers and maintaining a list of those providers approved to provide training required under the bill. To be approved, a training provider must have at least two years of experience related to ADRD, gerontology, health care, or a related field. The DOEA or its designee must issue each approved training provider a unique registration identifier.

The DOEA or its designee is also required to develop an assessment for each training topic required by the bill. Upon completion of any such training, the employee or direct care worker must pass the related assessment. If an employee or a direct care worker completes a training and passes the related assessment, the training provider must issue the employee or direct care worker a certificate that includes the training provider's name and unique identifier, the topic covered in the training, the date of completion, and the signature of the training provider. The certificate is evidence of completion of the training and assessment in the identified topic, and the employee or direct care worker is not required to repeat training in that topic if he or she changes employment to a different licensee, but he or she must comply with any applicable continuing education requirements.

The DOEA is required to adopt rules to implement section 2 of the bill.

Sections 7 and 8 amend ss. 429.52 and 429.83, F.S., to require all adult family-care homes and ALFs to provide ADRD staff training pursuant to the requirements established in the bill. Currently, no adult family-care homes and only ALFs who advertise they provide special care for patients with ADRD are required to provide such training.

Sections 3 through 6 and section 9 amend ss. 400.1755, 400.4785, 400.6045, 429.178, and 429.917, F.S., respectively, to repeal the individual ADRD training requirements in the licensure statutes for nursing homes, home health agencies, hospice providers, ALFs, and adult day care centers in favor of the uniform training requirements established by the bill.

Section 10 provides an effective date of July 1, 2021.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 634 may have an indeterminate negative fiscal impact on a facility required to provide ADRD training by the bill if such training is more extensive than what is required to be provided by the facility under current law.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 400.1755, 400.4785, 400.6045, 429.178, 429.52, 429.83, and 429.917.

This bill creates section 430.5025 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on March 10, 2021:
The CS adds adult family-care homes to the list of providers who are required to comply with the ADRD training requirements established by the bill and removes the authority for the DOEA to establish a uniform curriculum for ADRD training.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/10/2021	.	
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	.	

The Committee on Health Policy (Gibson) recommended the following:

Senate Amendment (with title amendment)

Delete lines 72 - 180

and insert:

chapter 400 or chapter 429.

(c) "Employee" means any staff member who has regular contact or incidental contact on a recurring basis with clients, patients, or residents of a facility licensed under part II, part III, or part IV of chapter 400 or chapter 429. The term includes, but is not limited to, direct care workers; staff

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responsible for housekeeping, the front desk, maintenance, and other administrative functions; and any other individuals who may have regular contact or incidental contact on a recurring basis with clients, patients, or residents.

(d) "Licensee" means a person or an entity licensed under part II, part III, or part IV of chapter 400 or chapter 429.

(2) As a condition of licensure, licensees must provide to each of their employees, within 30 days after their employment begins, 1 hour of dementia-related training, which must include methods for interacting with persons with Alzheimer's disease or a related disorder and for identifying warning signs of dementia.

(3) In addition to the training requirements of subsection (2), licensees must require all employees who are direct care workers to receive at least 3 hours of evidence-based training if the direct care workers are expected to, or their responsibilities require them to, have direct contact with clients, patients, or residents with Alzheimer's disease or a related disorder or with populations that are at a greater risk for Alzheimer's disease or a related disorder. The training must be completed within the first 3 months after employment begins and must include, but need not be limited to, an overview of Alzheimer's disease and related disorders and person-centered care, assessment and care planning, activities of daily living, and dementia-related behaviors and communication for clients, patients, and residents with Alzheimer's disease or a related disorder. Each calendar year thereafter, the licensee must require all of its direct care workers to receive at least 4 hours of continuing education, approved by the department, on

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these topics and any related changes in state or federal law.

(4) If a licensee advertises that it provides special care for individuals with Alzheimer's disease or a related disorder which includes direct care to such individuals, the licensee must require its direct care workers to complete 4 hours of training developed or approved by the department. This training is in addition to the training requirements of subsections (2) and (3) and must be completed within 4 months after employment begins.

(5) Completion of the 4 hours of training developed or approved by the department under subsection (4) shall count toward a certified nursing assistant's annual training requirements.

(6) If a health care practitioner as defined in s. 456.001 completes continuing education hours as required by that practitioner's licensing board, he or she may count those continuing education hours toward satisfaction of the training requirements of subsections (3) and (4) if the course curriculum covers the topics required under those subsections. The department must approve such continuing education hours for purposes of satisfying the training requirements of subsections (3) and (4).

(7) The department or its designee shall develop a process for registering training providers and maintain a list of those providers approved to provide training required under this section. To be approved, a training provider must have at least 2 years of experience related to Alzheimer's disease or related disorders, gerontology, health care, or a related field. The department or its designee shall issue each approved training

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provider a unique registration identifier.

(8) The department or its designee shall approve the courses that licensees may use to satisfy the training requirements under this section. The department or its designee must approve training offered in a variety of formats, including, but not limited to, Internet-based training, videos, teleconferencing, and classroom instruction.

(9) For each training topic required under this section, the training provider shall develop an assessment that measures an individual's understanding of the topic and indicate a minimum required score to pass the assessment. Upon completion of any training under this section, the employee or direct care worker must pass the related assessment. If an employee or a direct care worker completes a training and passes the related assessment, the training provider must issue the employee or direct care worker a certificate that includes the training provider's name and unique identifier, the topic covered in the training, the date of completion, and the signature of the training provider. The certificate is evidence of completion of the training and assessment in the identified topic, and the employee or direct care worker is not required to repeat training in that topic if he or she changes employment to a different licensee, but he or she must comply with any applicable continuing education requirements under this section. Licensees must maintain copies of certificates issued to each of their employees or direct care workers under this section and must make them available for inspection to meet the requirements of licensure.

(10) The department shall adopt rules to implement this

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section.

Section 3. Section 429.83, Florida Statutes, is amended to read:

429.83 Residents with Alzheimer's disease or other related disorders; training; certain disclosures.—

(1) An adult family-care home licensed under this part must provide staff training as required in s. 430.5025.

(2) An adult family-care home licensed under this part which claims that it provides special care for persons who have Alzheimer's disease or other related disorders must Disclose in its advertisements or in a separate document those services that distinguish the care as being especially applicable to, or suitable for, such persons. The home must give a copy of all such advertisements or a copy of the document to each person who requests information about programs and services for persons with Alzheimer's disease or other related disorders offered by the home and must maintain a copy of all such advertisements and documents in its records. The agency shall examine all such advertisements and documents in the home's records as part of the license renewal procedure.

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

And the title is amended as follows:

Delete lines 22 - 54

and insert:

dementia-related training requirements; requiring the department or its designee to develop a registration process for training providers; specifying requirements for such registration; requiring the

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department or its designee to issue unique identifiers to approved training providers; requiring the department or its designee to approve courses used to satisfy the dementia-related training requirements; requiring such courses to be approved in various; requiring training providers to develop certain assessments and passing scores for a specified purpose; requiring certain employees to take and pass such assessments upon completion of the training; requiring training providers to issue such employees a certificate upon completing the training and passing the assessments; providing requirements for the certificate; providing that certain employees do not need to repeat certain training when changing employment, under certain circumstances; requiring licensees to maintain copies of training certifications for each of their employees and direct care workers; requiring licensees to make such copies available for inspection for a specified purpose; requiring the department to adopt rules; amending ss. 400.1755, 400.4785, 400.6045, 429.178, 429.52, 429.83, and 429.917, F.S.; revising dementia-related staff training requirements for nursing homes, home health agencies, hospices, facilities that provide special care for persons with Alzheimer’s disease or related disorders, assisted living facilities, adult family-care homes, and adult day care centers, respectively, to conform to changes made by

By Senator Gibson

6-00395-21 2021634__

A bill to be entitled

An act relating to dementia-related staff training; providing a short title; creating s. 430.5025, F.S.; defining terms; requiring certain entities, as a condition of licensure, to provide specified dementia-related training for new employees within a specified timeframe; requiring certain employees to receive additional dementia-related training under certain circumstances within a specified timeframe; providing requirements for the training; requiring annual dementia-related training for certain employees; requiring certain employees to receive additional training developed or approved by the Department of Elderly Affairs under certain circumstances; providing that such additional training counts toward a certified nursing assistant's total annual training; authorizing certain health care practitioners to count certain continuing education hours toward the dementia-related training requirements under certain circumstances; requiring the department to approve such continuing education hours to satisfy the dementia-related training requirements; authorizing the department to develop a curriculum for the dementia-related training requirements and to review the curriculum at least every 4 years for a specified purpose; encouraging the department to consult with certain nationally recognized organizations; providing requirements for the curriculum; requiring the department or its designee to approve courses used to

6-00395-21 2021634__

satisfy the dementia-related training requirements; requiring such courses to be approved in various formats; requiring the department or its designee to develop a registration process for training providers; providing requirements for such registration; requiring the department or its designee to issue unique identifiers to approved training providers; requiring the department or its designee to develop certain assessments and passing scores for a specified purpose; requiring certain employees to take and pass such assessments upon completion of the training; requiring training providers to issue such employees a certificate upon completing the training and passing the assessments; providing requirements for the certificate; providing that certain employees do not need to repeat certain training when changing employment, under certain circumstances; requiring the department to adopt rules; amending ss. 400.1755, 400.4785, 400.6045, 429.178, 429.52, and 429.917, F.S.; revising dementia-related staff training requirements for nursing homes, home health agencies, hospices, facilities that provide special care for persons with Alzheimer's disease or related disorders, assisted living facilities, and adult day care centers, respectively, to conform to changes made by the act; providing an effective date.

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

Section 1. This act may be cited as the "Florida Alzheimer's Disease and Dementia Training Act."

Section 2. Section 430.5025, Florida Statutes, is created to read:

430.5025 Care for persons with Alzheimer's disease or a related disorder; staff training.—

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

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

(b) "Direct care worker" means an individual who, as part of his or her employment duties, provides or has access to provide direct contact assistance with personal care or activities of daily living to clients, patients, or residents of any facility licensed under part II, part III, or part IV of chapter 400 or part I or part III of chapter 429.

(c) "Employee" means any staff member who has regular contact or incidental contact on a recurring basis with clients, patients, or residents of a facility licensed under part II, part III, or part IV of chapter 400 or part I or part III of chapter 429. The term includes, but is not limited to, direct care workers; staff responsible for housekeeping, the front desk, maintenance, and other administrative functions; and any other individuals who may have regular contact or incidental contact on a recurring basis with clients, patients, or residents.

(d) "Licensee" means a person or an entity licensed under part II, part III, or part IV of chapter 400 or part I or part III of chapter 429.

(2) As a condition of licensure, licensees must provide to each of their employees, within 30 days after their employment

begins, 1 hour of dementia-related training, which must include methods for interacting with persons with Alzheimer's disease or a related disorder and for identifying warning signs of dementia.

(3) In addition to the training requirements of subsection (2), licensees must require all employees who are direct care workers to receive at least 3 hours of training if the direct care workers are expected to, or their responsibilities require them to, have direct contact with clients, patients, or residents with Alzheimer's disease or a related disorder or with populations that are at a greater risk for Alzheimer's disease or a related disorder. The training must be completed within the first 3 months after employment begins and must include, but need not be limited to, an overview of Alzheimer's disease and related disorders and person-centered care, assessment and care planning, activities of daily living, and dementia-related behaviors and communication for clients, patients, and residents with Alzheimer's disease or a related disorder. Each calendar year thereafter, the licensee must require all of its direct care workers to receive at least 4 hours of continuing education, approved by the department, on these topics and any related changes in state or federal law.

(4) If a licensee advertises that it provides special care for individuals with Alzheimer's disease or a related disorder which includes direct care to such individuals, the licensee must require its direct care workers to complete 4 hours of training developed or approved by the department. This training is in addition to the training requirements of subsections (2) and (3) and must be completed within 3 months after employment

begins.

(5) Completion of the 4 hours of training developed or approved by the department under subsection (4) shall count toward a certified nursing assistant's annual training requirements.

(6) If a health care practitioner as defined in s. 456.001 completes continuing education hours as required by that practitioner's licensing board, he or she may count those continuing education hours toward satisfaction of the training requirements of subsections (3) and (4) if the course curriculum covers the topics required under those subsections. The department must approve such continuing education hours for purposes of satisfying the training requirements of subsections (3) and (4).

(7)(a) The department may develop an evidence-based curriculum for the training requirements of this section and review the curriculum at least every 4 years to make any necessary revisions based on current research and best practices. The department is encouraged to consult with a nationally recognized organization that has expertise in the care of individuals with Alzheimer's disease or a related disorder to develop the curriculum. The curriculum must include, at a minimum, all of the following topics related to clients, patients, and residents with Alzheimer's disease or a related disorder:

1. An overview of Alzheimer's disease and related disorders.

2. Person-centered care.

3. Assessment care and planning.

4. Activities of daily living.

5. Dementia-related behaviors and communication.

(b) The department or its designee shall approve the courses that licensees may use to satisfy the training requirements under this section. The department or its designee must approve training offered in a variety of formats, including, but not limited to, Internet-based training, videos, teleconferencing, and classroom instruction.

(8) The department or its designee shall develop a process for registering training providers and maintain a list of those providers approved to provide training required under this section. To be approved, a training provider must have at least 2 years of experience related to Alzheimer's disease or related disorders, gerontology, health care, or a related field. The department or its designee shall issue each approved training provider a unique registration identifier.

(9) For each training topic required under this section, the department or its designee shall develop an assessment that measures an individual's understanding of the topic and indicate a minimum required score to pass the assessment. Upon completion of any training under this section, the employee or direct care worker must pass the related assessment. If an employee or a direct care worker completes a training and passes the related assessment, the training provider must issue the employee or direct care worker a certificate that includes the training provider's name and unique identifier, the topic covered in the training, the date of completion, and the signature of the training provider. The certificate is evidence of completion of the training and assessment in the identified topic, and the

employee or direct care worker is not required to repeat training in that topic if he or she changes employment to a different licensee, but he or she must comply with any applicable continuing education requirements under this section.

(10) The department shall adopt rules to implement this section.

Section 3. Section 400.1755, Florida Statutes, is amended to read:

400.1755 Care for persons with Alzheimer's disease or related disorders; staff training requirements.—

~~(1)~~ As a condition of licensure, facilities licensed under this part must provide to each of their employees training as required in s. 430.5025~~, upon beginning employment, basic written information about interacting with persons with Alzheimer's disease or a related disorder.~~

~~(2) All employees who are expected to, or whose responsibilities require them to, have direct contact with residents with Alzheimer's disease or a related disorder must, in addition to being provided the information required in subsection (1), also have an initial training of at least 1 hour completed in the first 3 months after beginning employment. This training must include, but is not limited to, an overview of dementias and must provide basic skills in communicating with persons with dementia.~~

~~(3) An individual who provides direct care shall be considered a direct caregiver and must complete the required initial training and an additional 3 hours of training within 9 months after beginning employment. This training shall include, but is not limited to, managing problem behaviors, promoting the~~

~~resident's independence in activities of daily living, and skills in working with families and caregivers.~~

~~(a) The required 4 hours of training for certified nursing assistants are part of the total hours of training required annually.~~

~~(b) For a health care practitioner as defined in s. 456.001, continuing education hours taken as required by that practitioner's licensing board shall be counted toward this total of 4 hours.~~

~~(4) For an employee who is a licensed health care practitioner as defined in s. 456.001, training that is sanctioned by that practitioner's licensing board shall be considered to be approved by the Department of Elderly Affairs.~~

~~(5) The Department of Elderly Affairs or its designee must approve the initial and continuing training provided in the facilities. The department must approve training offered in a variety of formats, including, but not limited to, Internet-based training, videos, teleconferencing, and classroom instruction. The department shall keep a list of current providers who are approved to provide initial and continuing training. The department shall adopt rules to establish standards for the trainers and the training required in this section.~~

~~(6) Upon completing any training listed in this section, the employee or direct caregiver shall be issued a certificate that includes the name of the training provider, the topic covered, and the date and signature of the training provider. The certificate is evidence of completion of training in the identified topic, and the employee or direct caregiver is not~~

~~required to repeat training in that topic if the employee or direct caregiver changes employment to a different facility or to an assisted living facility, home health agency, adult day care center, or adult family-care home. The direct caregiver must comply with other applicable continuing education requirements~~.

Section 4. Section 400.4785, Florida Statutes, is amended to read:

400.4785 Patients with Alzheimer's disease or other related disorders; staff training requirements; certain disclosures.—

(1) A home health agency must provide ~~the following~~ staff training as required in s. 430.5025~~:~~

~~(a) Upon beginning employment with the agency, each employee must receive basic written information about interacting with participants who have Alzheimer's disease or dementia-related disorders~~.

~~(b) In addition to the information provided under paragraph (a), newly hired home health agency personnel who will be providing direct care to patients must complete 2 hours of training in Alzheimer's disease and dementia-related disorders within 9 months after beginning employment with the agency. This training must include, but is not limited to, an overview of dementia, a demonstration of basic skills in communicating with persons who have dementia, the management of problem behaviors, information about promoting the client's independence in activities of daily living, and instruction in skills for working with families and caregivers.~~

~~(c) For certified nursing assistants, the required 2 hours of training shall be part of the total hours of training~~

~~required annually.~~

~~(d) For a health care practitioner as defined in s. 456.001, continuing education hours taken as required by that practitioner's licensing board shall be counted toward the total of 2 hours.~~

~~(e) For an employee who is a licensed health care practitioner as defined in s. 456.001, training that is sanctioned by that practitioner's licensing board shall be considered to be approved by the Department of Elderly Affairs.~~

~~(f) The Department of Elderly Affairs, or its designee, must approve the required training. The department must consider for approval training offered in a variety of formats. The department shall keep a list of current providers who are approved to provide the 2-hour training. The department shall adopt rules to establish standards for the employees who are subject to this training, for the trainers, and for the training required in this section.~~

~~(g) Upon completing the training listed in this section, the employee shall be issued a certificate that states that the training mandated under this section has been received. The certificate shall be dated and signed by the training provider. The certificate is evidence of completion of this training, and the employee is not required to repeat this training if the employee changes employment to a different home health agency.~~

(2)~~(h)~~ A licensed home health agency whose unduplicated census during the most recent calendar year was composed ~~comprised~~ of at least 90 percent of individuals aged 21 years or younger at the date of admission is exempt from the training requirements in this section.

(3) ~~(2)~~ An agency licensed under this part which claims that it provides special care for persons who have Alzheimer's disease or other related disorders must disclose in its advertisements or in a separate document those services that distinguish the care as being especially applicable to, or suitable for, such persons. The agency must give a copy of all such advertisements or a copy of the document to each person who requests information about the agency and must maintain a copy of all such advertisements and documents in its records. The Agency for Health Care Administration shall examine all such advertisements and documents in the agency's records as part of the license renewal procedure.

Section 5. Subsection (1) of section 400.6045, Florida Statutes, is amended to read:

400.6045 Patients with Alzheimer's disease or other related disorders; staff training requirements; certain disclosures.—

(1) A hospice licensed under this part must provide ~~the following~~ staff training as required in s. 430.5025~~:~~

~~(a) Upon beginning employment with the agency, each employee must receive basic written information about interacting with persons who have Alzheimer's disease or dementia-related disorders~~.

~~(b) In addition to the information provided under paragraph (a), employees who are expected to, or whose responsibilities require them to, have direct contact with participants who have Alzheimer's disease or dementia-related disorders must complete initial training of at least 1 hour within the first 3 months after beginning employment. The training must include an overview of dementias and must provide instruction in basic skills for communicating with persons who have dementia.~~

~~(c) In addition to the requirements of paragraphs (a) and (b), an employee who will be providing direct care to a participant who has Alzheimer's disease or a dementia-related disorder must complete an additional 3 hours of training within 9 months after beginning employment. This training must include, but is not limited to, the management of problem behaviors, information about promoting the patient's independence in activities of daily living, and instruction in skills for working with families and caregivers.~~

~~(d) For certified nursing assistants, the required 4 hours of training shall be part of the total hours of training required annually.~~

~~(e) For a health care practitioner as defined in s. 456.001, continuing education hours taken as required by that practitioner's licensing board shall be counted toward the total of 4 hours.~~

~~(f) For an employee who is a licensed health care practitioner as defined in s. 456.001, training that is sanctioned by that practitioner's licensing board shall be considered to be approved by the Department of Elderly Affairs.~~

~~(g) The Department of Elderly Affairs or its designee must approve the required 1-hour and 3-hour training provided to employees or direct caregivers under this section. The department must consider for approval training offered in a variety of formats. The department shall keep a list of current providers who are approved to provide the 1-hour and 3-hour training. The department shall adopt rules to establish standards for the employees who are subject to this training,~~

~~for the trainers, and for the training required in this section.~~

~~(h) Upon completing any training described in this section, the employee or direct caregiver shall be issued a certificate that includes the name of the training provider, the topic covered, and the date and signature of the training provider. The certificate is evidence of completion of training in the identified topic, and the employee or direct caregiver is not required to repeat training in that topic if the employee or direct caregiver changes employment to a different hospice or to a home health agency, assisted living facility, nursing home, or adult day care center.~~

Section 6. Subsections (2) through (8) of section 429.178, Florida Statutes, are amended to read:

429.178 Special care for persons with Alzheimer's disease or other related disorders.—

(2)~~(a)~~ An individual who is employed by a facility that provides special care for residents who have Alzheimer's disease or other related disorders~~, and who has regular contact with such residents,~~ must complete the ~~up to 4 hours of initial dementia-specific~~ training as required in s. 430.5025 ~~developed or approved by the department. The training must be completed within 3 months after beginning employment and satisfy the core training requirements of s. 429.52(3)(g)~~.

~~(b) A direct caregiver who is employed by a facility that provides special care for residents who have Alzheimer's disease or other related disorders and provides direct care to such residents must complete the required initial training and 4 additional hours of training developed or approved by the department. The training must be completed within 9 months after beginning employment and satisfy the core training requirements of s. 429.52(3)(g).~~

~~(c) An individual who is employed by a facility that provides special care for residents with Alzheimer's disease or other related disorders, but who only has incidental contact with such residents, must be given, at a minimum, general information on interacting with individuals with Alzheimer's disease or other related disorders, within 3 months after beginning employment.~~

~~(3) In addition to the training required under subsection (2), a direct caregiver must participate in a minimum of 4 contact hours of continuing education each calendar year. The continuing education must include one or more topics included in the dementia-specific training developed or approved by the department, in which the caregiver has not received previous training.~~

~~(4) Upon completing any training listed in subsection (2), the employee or direct caregiver shall be issued a certificate that includes the name of the training provider, the topic covered, and the date and signature of the training provider. The certificate is evidence of completion of training in the identified topic, and the employee or direct caregiver is not required to repeat training in that topic if the employee or direct caregiver changes employment to a different facility. The employee or direct caregiver must comply with other applicable continuing education requirements.~~

~~(5) The department, or its designee, shall approve the initial and continuing education courses and providers.~~

~~(6) The department shall keep a current list of providers~~

~~who are approved to provide initial and continuing education for staff of facilities that provide special care for persons with Alzheimer's disease or other related disorders.~~

(3) ~~(7)~~ Any facility more than 90 percent of whose residents receive monthly optional supplementation payments is not required to pay for the training and education programs required under this section. A facility that has one or more such residents must ~~shall~~ pay a reduced fee that is proportional to the percentage of such residents in the facility. A facility that does not have any residents who receive monthly optional supplementation payments must pay a reasonable fee, as established by the department, for such training and education programs.

(4) ~~(8)~~ The department shall adopt rules to establish standards for trainers and training and to implement this section.

Section 7. Subsection (1) of section 429.52, Florida Statutes, is amended to read:

429.52 Staff training and educational requirements.—

(1) Each new assisted living facility employee who has not previously completed core training must attend a preservice orientation provided by the facility before interacting with residents. The preservice orientation must be at least 2 hours in duration and cover topics that help the employee provide responsible care and respond to the needs of facility residents. Upon completion, the employee and the administrator of the facility must sign a statement that the employee completed the required preservice orientation. The facility must keep the signed statement in the employee's personnel record. Each

assisted living facility shall provide staff training as required in s. 430.5025.

Section 8. Subsection (1) of section 429.917, Florida Statutes, is amended to read:

429.917 Patients with Alzheimer's disease or other related disorders; staff training requirements; certain disclosures.—

(1) An adult day care center licensed under this part must provide ~~the following~~ staff training as required in s. 430.5025~~:~~

~~(a) Upon beginning employment with the facility, each employee must receive basic written information about interacting with participants who have Alzheimer's disease or dementia-related disorders~~.

~~(b) In addition to the information provided under paragraph (a), newly hired adult day care center personnel who are expected to, or whose responsibilities require them to, have direct contact with participants who have Alzheimer's disease or dementia-related disorders must complete initial training of at least 1 hour within the first 3 months after beginning employment. The training must include an overview of dementias and must provide instruction in basic skills for communicating with persons who have dementia.~~

~~(c) In addition to the requirements of paragraphs (a) and (b), an employee who will be providing direct care to a participant who has Alzheimer's disease or a dementia-related disorder must complete an additional 3 hours of training within 9 months after beginning employment. This training must include, but is not limited to, the management of problem behaviors, information about promoting the participant's independence in activities of daily living, and instruction in skills for~~

~~working with families and caregivers.~~

~~(d) For certified nursing assistants, the required 4 hours of training shall be part of the total hours of training required annually.~~

~~(e) For a health care practitioner as defined in s. 456.001, continuing education hours taken as required by that practitioner's licensing board shall be counted toward the total of 4 hours.~~

~~(f) For an employee who is a licensed health care practitioner as defined in s. 456.001, training that is sanctioned by that practitioner's licensing board shall be considered to be approved by the Department of Elderly Affairs.~~

~~(g) The Department of Elderly Affairs or its designee must approve the 1-hour and 3-hour training provided to employees and direct caregivers under this section. The department must consider for approval training offered in a variety of formats. The department shall keep a list of current providers who are approved to provide the 1-hour and 3-hour training. The department shall adopt rules to establish standards for the employees who are subject to this training, for the trainers, and for the training required in this section.~~

~~(h) Upon completing any training described in this section, the employee or direct caregiver shall be issued a certificate that includes the name of the training provider, the topic covered, and the date and signature of the training provider. The certificate is evidence of completion of training in the identified topic, and the employee or direct caregiver is not required to repeat training in that topic if the employee or direct caregiver changes employment to a different adult day~~

~~care center or to an assisted living facility, nursing home, home health agency, or hospice. The direct caregiver must comply with other applicable continuing education requirements.~~

~~(i) An employee who is hired on or after July 1, 2004, must complete the training required by this section.~~

Section 9. This act shall take effect July 1, 2021.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR AUDREY GIBSON
6th District

COMMITTEES:
Judiciary, *Vice Chair*
Appropriations
Appropriations Subcommittee on Education
Appropriations Subcommittee on Transportation, Tourism, and Economic Development
Military and Veterans Affairs, Space, and Domestic Security
Rules

JOINT COMMITTEE:
Joint Legislative Budget Commission

February 4, 2021

Senator Manny Diaz Jr., Chair
Committee on Health Policy
530 Knott Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

Chair Diaz:

I respectfully request that SB 634, be placed on the next committee agenda.

SB 634, would enhance the existing training for staff in Florida's long-term care communities, assisted living facilities, nursing homes, home health agencies, adult day care and Hospice facilities. The bill seeks to consolidate and streamline training across the spectrum of those working with the Alzheimer's and dementia population, to follow the most up to date information and techniques in caring for those suffering from the diseases.

Thank you for your kind and consideration.

Sincerely,

Audrey Gibson
State Senator
District 6

101 East Union Street, Suite 104, Jacksonville, Florida 32202 (904) 359-2553
410 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5006

2021 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Department of Elder Affairs

BILL INFORMATION	
BILL NUMBER:	SB 634
BILL TITLE:	Dementia-related Staff Training-2021
BILL SPONSOR:	Sen. Gibson
EFFECTIVE DATE:	July 1, 2021

COMMITTEES OF REFERENCE
1) Health Policy
2) Children, Families, and Elder Affairs
3) Appropriations
4) NA
5) NA

CURRENT COMMITTEE
Health Policy

SIMILAR BILLS	
BILL NUMBER:	NA
SPONSOR:	NA

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

IDENTICAL BILLS	
BILL NUMBER:	HB 309
SPONSOR:	Rep. Byrd

Is this bill part of an agency package?
No

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	2/11/2021
LEAD AGENCY ANALYST:	Derek Miller, Legislative Analyst
ADDITIONAL ANALYST(S):	Alexa Hansli, Director of Livable Florida
LEGAL ANALYST:	Richard Tritschler, General Counsel
FISCAL ANALYST:	Sonya Smith, Budget Director

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

This bill establishes the "Florida Alzheimer's Disease and Dementia Training Act"; requiring certain entities, as a condition of licensure, to provide specified dementia-related training for new employees within a specified timeframe; requiring annual dementia-related training for certain employees; providing that such additional training counts toward a certified nursing assistant's total annual training; authorizing certain health care practitioners to count certain continuing education hours toward the dementia-related training requirements. This bill creates a new section of Statute defining Alzheimer's Disease and Related Dementias (ADRD) Training for staff in facilities who provide care for persons with Dementia. (Creating a single training requirement to replace requirements as currently defined in sections 400.1755, 400.4785, 400.6045, 429.52, 429.178, and 429.917, Florida Statutes.)

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

The Department of Elder Affairs (DOEA), through Rule 58A-5.0194, Florida Administrative Code (F.A.C.), "Alzheimer's Disease or Related Disorders Training Provider and Curriculum Approval" has authority for administering the existing ADRD and currently does so through a contract with the University of South Florida (USF) [Contract XQ092, effective July 1, 2020, and AHCA Agreement AA412, effective July 21, 2020, between Department of Elder Affairs, USF Board of Trustees, and the Agency for Health Care Administration (Agency)].

For Contract XQ092, USF, through its Training Academy on Aging, reviews and approves ADRD Training Providers and Training Curriculum Programs for the DOEA's ADRD Training Providing and Curriculum Approval Program. The mission of the ADRD training program is to improve the care of individuals with ADRD who receive services from nursing homes, assisted living facilities, home health agencies, adult day care centers, and hospice care facilities. The ADRD training program is designed to ensure that agency/facility staff members who have regular contact with or provide direct care to, persons with ADRD receive the appropriate ADRD-related training.

Rule 58A-5.0194, F.A.C., "Alzheimer's Disease or Related Disorders Training Provider and Curriculum Approval" is related to the following.

- Applicants seeking approval as ADRD training providers
- Applicants seeking approval of ADRD curricula
- Approved ADRD training providers must maintain records of each course taught for three years following each training presentation that includes specific information
- Upon successful completion of training, the trainee must be issued a certificate by the approved training provider
- Right to attend and monitor ADRD training courses, review records and course materials approved under this rule and revoke approval in certain circumstances
- Maintain a list of approved ADRD training providers and curricula

2. EFFECT OF THE BILL:

This bill creates section 430.5025, F.S., increasing the existing training for staff in Florida's long-term care groups, including:

- Assisted Living Facilities;
- Nursing Homes;
- Home Health Agencies;
- Adult Day Care Centers and;
- Hospices.

Long-term care licensees must provide to their employees, within 30 days after their employment begins, 1 hour of dementia-related training, which must include methods for interacting with persons with Alzheimer's disease or a related disorder and for identifying warning signs of dementia. Additionally, all employees who are direct care workers, within their first 3 months after their employment begins must receive at least 3 hours of training if the direct care workers are expected to, or their responsibilities require them to, have direct contact with clients, patients, or residents with Alzheimer's disease or a related disorder or with populations that are at a greater risk for Alzheimer's disease or a related disorder. Each calendar year afterward, the licensee must require all of its direct care workers to receive at least 4 hours of continuing education, approved by the Department of Elder Affairs (DOEA).

This bill allows DOEA to develop an evidence-based curriculum for the training requirements and review the curriculum at least every 4 years to make any necessary changes based on current research and best practices. The department is

encouraged to consult with a nationally recognized organization that has expertise in the care of individuals with Alzheimer's disease or a related disorder to develop the curriculum. This bill also requires DOEA to develop a process for registering training providers and maintain a list of those providers approved to provide training. Under this bill, a training provider must have at least 2 years of experience related to Alzheimer's disease or related disorders, gerontology, health care, or a related field. Additionally, for each training topic required, DOEA or its designee will develop an assessment that measures an individual's understanding of the topic and indicate a minimum required score to pass the assessment.

Under this bill, if an employee or a direct care worker completes training and passes the related assessment, the training provider must issue the employee or direct care worker a certificate that includes the training provider's name and unique identifier, the topic covered in the training, the date of completion, and the signature of the training provider. An employee or direct care worker is not required to repeat training in that topic if he or she changes employment to a different licensee, but he or she must comply with any applicable continuing education requirements under section 430.5025, F.S. Additionally, the bill requires DOEA to adopt rules to carry out section 430.5025, F.S.

Lastly, the bill amends sections 400.1755, 400.4785, 400.6045, 429.178, 429.52, and 429.917, F.S., to conform to changes made by the bill.

This bill shall take effect on July 1, 2021.

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

If yes, explain:	The bill requires DOEA to adopt rules to establish standards for trainers and training to implement section 430.5025, F.S.
Is the change consistent with the agency's core mission?	Y☒ N☐
Rule(s) impacted (provide references to F.A.C., etc.):	Rule 58A-5.0194

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

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

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y☐ N☒

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

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

Board:	NA
Board Purpose:	NA
Who Appoints:	NA

Changes:	NA
Bill Section Number(s):	NA

FISCAL ANALYSIS

1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT? Y☐ N☒

Revenues:	NA
Expenditures:	NA
Does the legislation increase local taxes or fees? If yes, explain.	No
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	NA

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

Revenues:	NA
Expenditures:	NA
Does the legislation contain a State Government appropriation?	No
If yes, was this appropriated last year?	No

3. DOES THE BILL HAVE A FISCAL IMPACT TO THE PRIVATE SECTOR? Y☒ N☐

Revenues:	NA
Expenditures:	Unknown
Other:	NA

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

If yes, explain impact.	NA
Bill Section Number:	NA

TECHNOLOGY IMPACT

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

If yes, describe the anticipated impact to the agency including any fiscal impact.	No

FEDERAL IMPACT

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

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

ADDITIONAL COMMENTS

LEGAL - GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	

YOU MUST PRINT AND DELIVER THIS FORM TO THE ASSIGNED TESTIMONY ROOM

THE FLORIDA SENATE

APPEARANCE RECORD

03/10/21
Meeting Date

634
Bill Number (if applicable)

375452
Amendment Barcode (if applicable)

Topic Support for Amendment to SB 634

Name Jon Conley

Job Title Director of State Affairs

Address 3311 Dartmouth Drive
Street

Phone (850) 566-7478

Tallahassee FL 32317
City *State* *Zip*

Email jbconley@alz.org

Speaking: ☑ For ☐ Against ☑ Information

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

Representing Alzheimer's Association

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

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THE FLORIDA SENATE

APPEARANCE RECORD

3/10/2021
Meeting Date

634
Bill Number (if applicable)

Topic Dementia-related Staff Training

Amendment Barcode (if applicable)

Name Derek Miller

Job Title Legislative Affairs

Address 4040 Esplanade Way
Street

Phone 850-414-2130

Tallahassee FL 32399
City *State* *Zip*

Email millerd@elderaffairs.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing FL Department of Elder Affairs

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

YOU MUST PRINT AND DELIVER THIS FORM TO THE ASSIGNED TESTIMONY ROOM

THE FLORIDA SENATE

APPEARANCE RECORD

3/10/21
Meeting Date

634
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Assisted Living Facilities Concerns

Name Jason Hand

Job Title Vice President of Public Policy

Address 2292 Wednesday Street
Street

Tallahassee FL 32308
City *State* *Zip*

Phone 850-443-0024

Email jhand@floridaseniorliving.org

Speaking: ☐ For ☑ Against ☐ Information

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

Representing Florida Senior Living Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 1064
INTRODUCER:	Senator Brodeur
SUBJECT:	Hospital, Hospital System, or Provider Organization Transactions
DATE:	March 9, 2021
REVISED:	

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

I. Summary:

SB 1064 creates s. 542.275, F.S., to require hospitals, hospital systems, and other specified provider organizations to provide a written report to the Office of the Attorney General (AG) concurrently with its report to the federal government when required to report under the Hart-Scott-Rodino Antitrust Improvements Act[1] (Act) or at least 90 days prior to a transaction that will result in a material change, as defined by the bill, if not required to report by the Act. The bill specifies what information must be included in the written report and authorizes the AG to request additional information or to issue a civil investigative demand under s. 542.28, F.S.

The bill requires the AG to provide a biennial report, beginning on Jan. 1, 2022, to the Legislature regarding its review of transactions under the provisions of the bill and provides for up to a $500,000 civil penalty for organizations who fail to report when required by the bill.

The bill also creates two unnumbered sections of Florida law to:

- Specify that the AG may engage consultants, experts, accountants, economists, analysts, and other assistants to aid in any review conducted under the bill. The reasonable expenses related to such services must be paid by the parties to the transaction under review; and
- To allow the Department of Legal Affairs (DLA) to hire 12 full-time equivalent (FTE) positions with the associated salary rate of 629,382 and to appropriate $1,221,249 in recurring and $47,472 in nonrecurring funds from general revenue for the purpose of implementing the bill.

The bill provides an effective date of July 1, 2021.

[1] 15 U.S.C. s. 18a(a)

II. Present Situation:

Federal Antitrust Laws

Congress passed the first antitrust law, the Sherman Act, in 1980 as a "comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade." In 1914, Congress passed two additional antitrust laws: the Federal Trade Commission Act, which created the FTC, and the Clayton Act. With some revisions, these are the three core federal antitrust laws still in effect today.[2]

The Sherman Act

The Sherman Act outlaws "every contract, combination, or conspiracy in restraint of trade," and any "monopolization, attempted monopolization, or conspiracy or combination to monopolize." The Sherman Act does not prohibit every restraint of trade, only those that are unreasonable. For instance an agreement between two individuals to form a partnership may restrain trade, but may not do so unreasonably, and thus may be lawful under the antitrust laws. On the other hand, certain acts are considered so harmful to competition that they are almost always illegal. These include plain arrangements among competing individuals or businesses to fix prices, divide markets, or rig bids. These acts are "per se" violations of the Sherman Act; in other words, no defense or justification is allowed.[3]

The penalties for violating the Sherman Act can be severe. Although most enforcement actions are civil, the Sherman Act is also a criminal law, and individuals and businesses that violate it may be prosecuted by the U.S. Department of Justice (DOJ). Criminal prosecutions are typically limited to intentional and clear violations, such as when competitors fix prices or rig bids. The Sherman Act imposes criminal penalties of up to $100 million for a corporation and $1 million for an individual, along with up to 10 years in prison. Under federal law, the maximum fine may be increased to twice the amount the conspirators gained from the illegal acts or twice the money lost by the victims of the crime, if either of those amounts is over $100 million.[4]

The Federal Trade Commission Act

The Federal Trade Commission Act bans "unfair methods of competition" and "unfair or deceptive acts or practices." The Supreme Court has said that all violations of the Sherman Act also violate the FTC Act. Thus, although the Federal Trade Commission (FTC) does not technically enforce the Sherman Act, it can bring cases under the FTC Act against the same kinds of activities that violate the Sherman Act. The FTC Act also reaches other practices that harm competition but that may not fit neatly into categories of conduct formally prohibited by the Sherman Act. Only the FTC brings cases under the FTC Act.[5]

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[2] *The Antitrust Laws*, Federal Trade Commission, *available at* https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws, (last visited on Feb. 25, 2021).
[3] Id.
[4] Id.
[5] Id.

The Clayton Act

The Clayton Act addresses specific practices that the Sherman Act does not clearly prohibit, such as mergers and interlocking directorates (the same person making business decisions for competing companies). Section 7 of the Clayton Act prohibits mergers and acquisitions where the effect "may be substantially to lessen competition, or to tend to create a monopoly." As amended by the Robinson-Patman Act of 1936, the Clayton Act also bans certain discriminatory prices, services, and allowances in dealings between merchants. The Clayton Act was amended again in 1976 by the Hart-Scott-Rodino Antitrust Improvements Act to require companies planning large mergers or acquisitions to notify the government of their plans in advance. The Clayton Act also authorizes private parties to sue for triple damages when they have been harmed by conduct that violates either the Sherman or Clayton Act and to obtain a court order prohibiting the anticompetitive practice in the future.[6]

The Hart-Scott-Rodino Antitrust Improvement Act

The Act, which was passed in 1976 and became effective in 1978 upon final passage of implementing rules, requires that parties to certain mergers or acquisitions must notify the Federal Trade Commission (FTC) and the federal Department of Justice (DOJ) before consummating the proposed acquisition.[7] The parties to the transaction must wait a specific period of time, usually 30 days, to allow the enforcement agencies to review the proposed transaction.[8] If, during the review, either the FTC or the DOJ determine that further inquiry is necessary, the agency may request additional information or documents from the parties, which extends the waiting period, usually by an additional 30 days.[9] Additionally, if the reviewing agency believes that the proposed transaction may violate antitrust laws, it may seek an injunction from federal district court to prohibit the consummation of the transaction.[10]

Whether a particular acquisition is subject to these requirements depends on the value of the acquisition and the size of the parties, as measured by their sales and assets. Small acquisitions, acquisitions involving small parties, and other classes of acquisitions that are less likely to raise antitrust concerns are excluded from the Act's coverage.[11] As a general matter, the Act and the rules require both acquiring and acquired persons to file notifications under the Act if all of the following conditions are met:

- As a result of the transaction, the acquiring person will hold an aggregate amount of voting securities, non-controlling interests (NCI), and/or assets of the acquired person valued in excess of $200 million (as adjusted) , regardless of the sales or assets of the acquiring and acquired persons; or
- As a result of the transaction, the acquiring person will hold an aggregate amount of voting securities, NCI, and/or assets of the acquired person valued in excess of $50 million (as adjusted) but less than $200 million; and

[6] *Supra* note 2.
[7] *What is the Premerger Notification Program: An Overview*, FTC Premerger Notification Office, revised March 2009, p. 1 *available at* https://www.ftc.gov/sites/default/files/attachments/premerger-introductory-guides/guide1.pdf, (last visited February 25, 2021).
[8] Id.
[9] Id.
[10] Id.
[11] Id.

- One person has sales or assets of at least $100 million (as adjusted); and
- The other person has sales or assets of at least $10 million (as adjusted).

Florida Antitrust Statutes

The Florida Antitrust Act of 1980

Florida law also provides protections against anticompetitive practices. Chapter 542, F.S., short-titled the Florida Antitrust Act of 1980, has a stated purpose to complement the body of federal law prohibiting restraints of trade or commerce in order to foster effective competition.[12] The chapter outlaws "every contract, combination, or conspiracy in restraint of trade or commerce" in the state[13] and any person from monopolizing or attempting or conspiring to monopolize any part of trade.[14]

The chapter specifies that its provisions be liberally construed to accomplish its beneficial purpose[15] but exempts any activity or conduct otherwise exempt under Florida statutory or common law, exempt under federal antitrust laws,[16] and the chapter provides the contracts in restraint of trade are valid[17] as well as certain specified acts which may restrain trade.[18] The chapter provides both criminal and civil penalties for violating its provisions[19] and allows suits for damages to be instigated by injured parties.[20] The chapter also provides enforcement authority to the AG[21] and allows the AG and the state attorneys to serve civil investigative demands in furtherance of its enforcement authority.[22]

The Health Care Community Antitrust Guidance Act

Specific to health care, s. 408.18, F.S., allows any member of the health care community[23] to request a review of proposed business activity by the AG and request in writing that the AG issue an antitrust no-action letter. The AG may seek whatever documentation, data, or other material it deems necessary to conduct its review, and the parties are under an affirmative obligation to make a full, true, and accurate disclosure with respect to the activities for which the antitrust no-action letter is requested. The AG has 90 days to complete its review and, at the completion of the review, the AG may issue the no-action letter, decline to issue any type of letter, or take another position or action as it considers appropriate.

[12] Section 542.16, F.S.
[13] Section 542.18, F.S.
[14] Section 542.19, F.S.
[15] *Supra.* note 12.
[16] Section 542.20, F.S.
[17] Section 542.33, F.S.
[18] Section 542.335, F.S.
[19] Section 542.21, F.S.
[20] Section 542.22, F.S.
[21] Section 542.27, F.S.
[22] Section 542.28, F.S.
[23] Defined as all licensed health care providers, insurers, networks, purchasers, and other participants in the health care system. *See* s. 408.18(3)(a), F.S.

III. Effect of Proposed Changes:

SB 1064 creates s. 542.275, F.S., to require hospitals, hospital systems, and other provider organizations conducting business in Florida to notify the AG concurrently when required to provide a notice to the Federal Government under the Hart-Scott-Rodino Antitrust Improvements Act, or at least 90 days before the effective date of any transaction that would result in a material change, as defined in the bill, that is not required to be reported under the Act. The bill defines the following terms:

- "Acquisition" means an agreement, arrangement, or activity that results in a hospital, hospital system, or provider organization, directly or indirectly, obtaining control of another hospital, hospital system, or provider organization, including, but not limited to, the acquisition of voting securities and non-corporate interests, such as assets, capital stock, membership interests, or equity interests.
- "Contracting affiliation" means a relationship between two or more entities wherein the entities have the ability to negotiate jointly with payors over rates for health care services, or one entity negotiates on behalf of the other entity with payors over rates for professional medical services in the primary service area in which the entities operate. The term does not include arrangements among entities under common ownership.
- "Health care provider" means a physician licensed under chapters 458, 459, 460, or 461, F.S., or a person licensed under ch. 463, F.S., or a dentist licensed under ch. 466, F.S.
- "Hospital" has the same meaning as provided in s. 395.002, F.S.
- "Hospital system" means:
  - A corporation that owns one or more hospitals and any entity affiliated with such corporation through ownership or control; or
  - A hospital and any entity affiliated with such hospital through ownership.
- "Material change" means a merger, acquisition, or contracting affiliation that generates a combined revenue of $50 million or more between two or more entities of the following types:
  - Hospitals;
  - Hospital systems; or
  - Provider organizations.
- "Payor" means any entity or person that negotiates or assumes financial responsibility for a defined set of benefits from a health insurance plan or health insurance program. The term includes, but is not limited to, federal, state, and local governmental entities or agencies; affiliates; health insurance companies; health maintenance organizations; insurers; nonprofit religious organizations; persons; preferred provider organizations; prepaid limited health service organizations; and third-party administrators.
- "Primary service area" means the geographic area measured by the fewest number of zip codes from which the hospital, hospital system, or provider organization draws at least 75 percent of its patients.
- "Provider organization" means a corporation, a partnership, a business trust, an association, or an organized group of persons, whether incorporated or not, which is in the business of health care services and represents four or more health care providers in contracting with payors for the payment of health care services. The term includes, but is not limited to, physician organizations, physician-hospital organizations, independent practice associations, provider networks, and accountable care organizations.

The notice to the AG must:

- Include the names of the parties and their current business addresses.
- Include a description of the proposed relationship among the parties to the proposed transaction.
- Include a description of the health care services at each location at which services are currently provided and at any locations at which health care services will be provided.
- Identify the primary service area to be served by each location.
- Identify any information deemed by the filing organization to be a trade secret, as defined in s. 688.002, F.S., or exempt from public records laws pursuant to any other statutory exemption.

A hospital, hospital system, or provider organization that is a party to a material change may also voluntarily provide additional information to the AG. A hospital, hospital system, or provider organization that fails to comply with the section is subject to a civil penalty of not more than $500,000 which will be deposited into the Legal Affairs Revolving Trust Fund under s. 16.53(1), F.S. Beginning on January 1, 2022, the AG must submit a biennial report to the Legislature regarding its review of transactions under this section.

The bill also creates two new unnumbered sections of Florida law.

Section 2 of the bill authorizes the AG to engage the services of consultants, experts, accountants, economists, analysts, and other assistants as necessary to conduct its review under Section 1 of the bill. The bill specifies that reasonable expenses related to such services must be paid by the parties to the transaction.

Section 3 of the bill authorizes, for the 2021-2022 fiscal year, the DLA to hire 12 FTE at a salary rate of 629,382 and appropriates $1,221,249 in recurring and $47,472 in nonrecurring funds to the DLA for the purposes of implementing section 1 of the bill.

The bill provides an effective date of July 1, 2021.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

Article VII, Section 19 of the State Constitution requires a new state tax or fee that is imposed or authorized by the Legislature to be "contained in a separate bill that contains no other subject."

Section 2 of SB 1064 authorizes the AG to "engage the services of consultants, experts, accountants, economists, analysts, and other assistants" to aid in reviews authorized by the bill and requires the reasonable expenses for such experts to be paid by the parties to the transaction under review.

The bill's requirement for the parties to the transaction to pay such expenses may constitute the imposition or authorization of a new fee by the Legislature and therefore may require a separate fee bill and a two-thirds vote of the Legislature pursuant to the State Constitution.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 1064 may have an indeterminate negative fiscal impact on hospitals, hospital systems, and provider organizations if transactions between such entities are delayed or halted due to the review AG's review required by the bill. Additionally, such entities may see an indeterminate negative fiscal impact from Section 2 of the bill which requires the parties to a transaction under review to pay the reasonable expenses for the services of consultants, experts, accountants, economists, analysts, and other assistants hired by the AG to aid in its review.

C. Government Sector Impact:

SB 1064 appropriates $1,221,249 in recurring and $47,472 in nonrecurring funds to the DLA from the General Revenue Fund to hire 12 FTE and implement the provisions of section 1 of the bill.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 542.275 of the Florida Statutes.

This bill creates two unnumbered sections of Florida law.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Brodeur

9-00987-21 20211064__

A bill to be entitled

An act relating to hospital, hospital system, or provider organization transactions; creating s. 542.275, F.S.; defining terms; requiring certain entities to submit written notice of a specified filing to the Office of the Attorney General relating to certain hospital, hospital system, or provider organization mergers, acquisitions, and other transactions within a specified timeframe; requiring that such entities submit written notice of a material change to the office within a specified timeframe; providing requirements for such notice; authorizing the office to request additional information or issue a civil investigative demand; requiring the office to submit a biennial report to the Legislature beginning on a specified date; providing a civil penalty; requiring that the penalty be deposited into the Legal Affairs Revolving Trust Fund; authorizing the office to engage the services of certain persons to fulfill its duties; authorizing positions and providing appropriations; providing an effective date.

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

Section 1. Section 542.275, Florida Statutes, is created to read:

542.275 Hospital, hospital system, or provider organization mergers, acquisitions, and other transactions; notice; reporting; penalty.—

9-00987-21 20211064__

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

(a) "Acquisition" means an agreement, arrangement, or activity that results in a hospital, hospital system, or provider organization, directly or indirectly, obtaining control of another hospital, hospital system, or provider organization, including, but not limited to, the acquisition of voting securities and noncorporate interests, such as assets, capital stock, membership interests, or equity interests.

(b) "Contracting affiliation" means a relationship between two or more entities wherein the entities have the ability to negotiate jointly with payors over rates for health care services, or one entity negotiates on behalf of the other entity with payors over rates for professional medical services in the primary service area in which the entities operate. The term does not include arrangements among entities under common ownership.

(c) "Health care provider" means a physician licensed under chapter 458, chapter 459, chapter 460, or chapter 461 or a person licensed under chapter 463 or a dentist licensed under chapter 466.

(d) "Hospital" has the same meaning as provided in s. 395.002.

(e) "Hospital system" means:

1. A corporation that owns one or more hospitals and any entity affiliated with such corporation through ownership or control; or

2. A hospital and any entity affiliated with such hospital through ownership.

(f) "Material change" means a merger, acquisition, or

contracting affiliation that generates a combined revenue of $50 million or more between two or more entities of the following types:

1. Hospitals;

2. Hospital systems; or

3. Provider organizations.

(g) "Payor" means any entity or person that negotiates or assumes financial responsibility for a defined set of benefits from a health insurance plan or health insurance program. The term includes, but is not limited to, federal, state, and local governmental entities or agencies; affiliates; health insurance companies; health maintenance organizations; insurers; nonprofit religious organizations; persons; preferred provider organizations; prepaid limited health service organizations; and third-party administrators.

(h) "Primary service area" means the geographic area measured by the fewest number of zip codes from which the hospital, hospital system, or provider organization draws at least 75 percent of its patients.

(i) "Provider organization" means a corporation, a partnership, a business trust, an association, or an organized group of persons, whether incorporated or not, which is in the business of health care services and represents four or more health care providers in contracting with payors for the payment of health care services. The term includes, but is not limited to, physician organizations, physician-hospital organizations, independent practice associations, provider networks, and accountable care organizations.

(2)(a) Any hospital, hospital system, or provider

organization conducting business in this state which is required to file the Notification and Report Form for Certain Mergers and Acquisitions pursuant to the Hart-Scott-Rodino Antitrust Improvements Act, 15 U.S.C. s. 18a(a), shall provide written notice of such filing to the Office of the Attorney General at the same time that notice is filed with the Federal Government.

(b) Except when notice is required pursuant to paragraph (a), at least 90 days before the effective date of any transaction that would result in a material change, the parties to the transaction shall submit written notice to the Office of the Attorney General of such material change. Such written notice must identify all acquisitions that occurred during the 5 years preceding the date of the notice.

(c) The written notice required under paragraphs (a) and (b) must include all of the following:

1. The names of the parties and their current business addresses.

2. A description of the proposed relationship among the parties to the proposed transaction.

3. A description of the health care services at each location at which services are currently provided and at any locations at which health care services will be provided.

4. The primary service area to be served by each location.

(d) Any written notice required under this subsection must identify any information that the hospital, hospital system, or provider organization deems a trade secret, as defined in s. 688.002, or exempt from public records laws pursuant to any other statutory exemption.

(e) Upon receipt of any written notice submitted pursuant

to this subsection, the Office of the Attorney General may request additional information or issue a civil investigative demand under s. 542.28.

(f) A hospital, hospital system, or provider organization who is a party to a material change may voluntarily provide additional information to the office.

(3) Beginning January 1, 2022, the Office of the Attorney General shall submit a biennial report to the President of the Senate and the Speaker of the House of Representatives regarding its review of transactions under this section.

(4) A hospital, hospital system, or provider organization that fails to comply with this section is subject to a civil penalty of not more than $500,000, which shall be deposited into the Legal Affairs Revolving Trust Fund created under s. 16.53(1).

Section 2. In any review authorized under this act, the Office of the Attorney General may engage the services of consultants, experts, accountants, economists, analysts, and other assistants. When the review of a transaction is completed, the reasonable expenses related to such services shall be paid by the parties to the transaction.

Section 3. For the 2021-2022 fiscal year, 12 full-time equivalent positions with associated salary rate of 629,382 are authorized and the sums of $1,221,249 in recurring funds and $47,472 in nonrecurring funds from the General Revenue Fund are appropriated to the Department of Legal Affairs for the purpose of implementing s. 542.275, Florida Statutes.

Section 4. This act shall take effect July 1, 2021.

The Florida Senate

Committee Agenda Request

To: Senator Manny Diaz, Jr., Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: February 10, 2021

I respectfully request that **Senate Bill 1064**, relating to Hospital, Hospital System, or Provider Organization Transactions, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Jason Brodeur

Senator Jason Brodeur
Florida Senate, District 9

File signed original with committee office

S-009 (03/2004)

YOU MUST PRINT AND DELIVER THIS FORM TO THE ASSIGNED TESTIMONY ROOM

Health Q 10:30

THE FLORIDA SENATE

APPEARANCE RECORD

3/10/21
Meeting Date

1064
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Hospital, Hospital System, or Provider Organization Transactions

Name Brewster Bevis

Job Title Senior Vice President

Address 513 N Adams St
Street

Phone 224-7173

Tallahassee FL 32301
City *State* *Zip*

Email bbevis@aif.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Associated Industries of Florida

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

YOU MUST PRINT AND DELIVER THIS FORM TO THE ASSIGNED TESTIMONY ROOM

THE FLORIDA SENATE

APPEARANCE RECORD

03/10/2021
Meeting Date

1064
Bill Number (if applicable)

Topic _____
Amendment Barcode (if applicable)

Name Michael Williams

Job Title Senior Vice President of Federal Affairs & General Counsel

Address _____ Phone _____
Street

_____ Email michaelw@fha.org
City *State* *Zip*

Speaking: ☐ For ☑ Against ☐ Information

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

Representing Florida Hospital Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/10/21
Meeting Date

1064
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Niland

Job Title _____

Address 4427 Herrchel St
Street

Jacksonville, FL 32210
City *State* *Zip*

Phone 904-283-3051

Email nlandlaw@aol.com

Speaking: ☐ For ☑ Against ☐ Information

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

Representing Florida Society of Gastroenterology

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/10/21
Meeting Date

SB 1064
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Jeff Scott

Job Title _____

Address 1430 Piedmont Dr. E.
Street

Tallchassee FL 32308
City *State* *Zip*

Phone 850 224-6496

Email jscott@flmedical.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Medical Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

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THE FLORIDA SENATE

APPEARANCE RECORD

03/10/2021
Meeting Date

1064
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Hospital, Hospital Systems, or Provider Transactions

Name Jason Rodriguez

Job Title State Government Relations Manager

Address 2985 Drew Street
Street

Phone 7275191885

Clearwater FL 33759
City *State* *Zip*

Email jason.rodriguez@baycare.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing BayCare Health System

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

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THE FLORIDA SENATE

APPEARANCE RECORD

03/10/2021
Meeting Date

1064
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Hospital, Hospital Systems, or Provider Transactions

Name Keri Eisenbeis

Job Title Vice President, Government & Community Relations

Address 2985 Drew Street
Street

Phone 7275191884

Clearwater FL 33759
City *State* *Zip*

Email keri.eisenbeis@baycare.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing BayCare Health System

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 240
INTRODUCER:	Health Policy Committee and Senator Book
SUBJECT:	Donor Human Milk Bank Services
DATE:	March 10, 2021
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 240 requires the Department of Health (DOH) to adopt rules and establish minimum standards for the regulation of donor human milk banks which must address the operations of the bank and procedures for donating, distributing, and testing donor human milk and its derivatives. The bill requires a donor human milk bank operating in this state to comply with the DOH standards.

The bill provides an effective date of July 1, 2021.

II. Present Situation:

Donor Human Breast Milk

According to the federal Centers for Disease Control and Prevention (CDC), breast milk is the best source of nutrition for most infants.[1] Ideally, an infant should be fed his or her own mother's breast milk because nutritional components within the mother's breast milk change to meet the infant's needs as he or she ages.[2] Mothers of infants born prematurely are sometimes unable to produce milk because their bodies aren't ready, they too are sick, or they're affected by the stress

[1] Centers for Disease Control and Prevention, *Frequently Asked Questions* (FAQ) (May 28, 2020) *available at* https://www.cdc.gov/breastfeeding/faq/index.htm (last visited Mar. 4, 2021).
[2] *Id.*

of having their premature infant in intensive care.[3] Breast milk donated by nursing mothers provides an option for infants who are unable to receive adequate nutrition from their mother's own milk or from commercial infant formulas. Very few illnesses are transmitted via breast milk, even in cases where someone else's breast milk is given to another child.[4]

The American Academy of Pediatrics (AAP) notes that human donor breast milk can be effective for high-risk and very low birthweight infants if the child's mother is unable to provide enough milk.[5] Additionally, the World Health Organization (WHO) indicates that human donor breast milk can prevent some digestive disorders but specifies that any donor milk must come from safe facilities and is not recommended for sick infants or those weighing less than 1000 grams.[6,7] In the absence of a mother's milk, the WHO notes that standard formula is also an acceptable alternative.[8]

Currently, the federal Food and Drug Administration (FDA) considers human donor breast milk a "food" source rather than a medical product. The FDA does not have established guidelines or standards for human donor breast milk or milk banks, although it does recommend consulting with a health care provider before feeding it to an infant.[9] Additionally, the FDA recommends that the caregiver only feed an infant milk from a source that has screened its donors and has taken precautions to ensure milk safety, such as a milk bank.[10]

The Human Milk Banking Association of North America (HMBANA)

Founded in 1985, the Human Milk Banking Association of North America (HMBANA) serves as the professional organization that accredits nonprofit milk banks in the United States and Canada.[11] The HMBANA is funded by membership fees from its 31 member nonprofit milk banks, foundation funds, and individual donors.[12] There is one HMBANA-accredited location in Florida – the Mother's Milk Bank of Florida located in Orlando.[13] The Mother's Milk Bank of Florida supplies pasteurized donor human milk to 38 of the 68[14] neonatal intensive care units

[3] Naseem S. Miller, *Bill aims to get Medicaid coverage for donor breast milk: 'Something like this makes smart policy'*, Orlando Sentinel (Mar. 15, 2019) *available at* https://www.orlandosentinel.com/health/os-ne-mothers-milk-bank-bill-20190315-story.html (last visited Mar. 2, 2021).
[4] *Supra* note 1.
[5] American Academy of Pediatrics Committee on Nutrition, Section on Breastfeeding and Committee on Fetus and Newborn, Policy Statement, *Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States* (Jan. 2017) *available at* https://pediatrics.aappublications.org/content/pediatrics/139/1/e20163440.full.pdf (last visited Mar. 4, 2021).
[6] Agency for Health Care Administration, *Senate Bill 240 Analysis* (Dec. 28, 2020) (on file with Senate Committee on Health Policy).
[7]World Health Organization, *Recommendations for the Feeding of low-birth-weight infants in low- and middle-income countries, available at* https://www.who.int/elena/titles/full_recommendations/feeding_lbw/en/ (last visited Mar. 4, 2021).
[8] *Id.*
[9] U.S. Food and Drug Administration, *Use of Donor Human Milk* (Mar. 22, 2018) *available at* https://www.fda.gov/science-research/pediatrics/use-donor-human-milk (last visited Mar. 2, 2021).
[10] *Id.*
[11] Human Milk Banking Association of North America, *About Us, available at* https://www.hmbana.org/about-us/ (last visited Mar. 2, 2021).
[12] *Id.*
[13] Human Milk Banking Association of North America, *Find a Milk Bank, available at* https://www.hmbana.org/find-a-milk-bank/ (last visited Mar. 2, 2021).
[14] *Supra* note 3.

(NICUs) in Florida, as well as to medically fragile babies at home who have been prescribed human donor breast milk.[15]

Donor human breast milk, which costs approximately $4 an ounce and can add up to over $1,000 per month per infant, is not covered by Florida Medicaid or by most private insurers.[16] Through donations and fundraisers, the Mother's Milk Bank of Florida provides grants to low-income families to make donor human breast milk more affordable.[17]

HMBANA Safety Guidelines[18]

The HMBANA reports that its member milk banks follow guidelines that were developed by the HMBANA in consultation with the CDC and the FDA. The FDA reports that it has not been involved in establishing these voluntary guidelines.[19] According to the AHCA, no federal or state regulations are in place to oversee the Mother's Milk Bank of Florida.[20]

Under the HMBANA's guidelines, before milk is collected, each donor is strictly screened for medical and lifestyle risk factors and serum is screened for HIV, HTLV, syphilis, and Hepatitis B and C.[21] After the milk is collected, it is mixed and pooled so that each pool includes human milk from three to five donors. This is done to ensure an even distribution of nutritional components. Bottles are filled with the pooled milk and then the milk is pasteurized to eliminate potentially harmful bacteria while retaining the majority of the milk's beneficial nutrients. Milk samples are taken during the pasteurization process and cultured to check for bacterial growth. Any contaminated milk is discarded. No milk is dispensed after pasteurization until a culture is found to be negative for bacteriological growth. After pasteurization, the milk is frozen and shipped to hospitals and outpatient families.

III. Effect of Proposed Changes:

Section 1 of the bill creates s. 383.017, F.S., relating to donor human milk banks. The bill provides that it is the intent of the Legislature to protect the health, safety, and welfare of human milk donors and recipients of human milk donation and to encourage the use of donor human milk and donor human milk derivatives.

The bill defines a "donor human milk bank" as any entity or organization operating within this state which collects, processes, stores, tests, or distributes donor human milk or donor human milk derivatives.

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[15] Mothers' Milk Bank of Florida, *Covid-19 Update*, *available at* https://milkbankofflorida.org/covid-19-update/ (last visited Mar. 2, 2021).
[16] *Supra* note 3.
[17] *Id*.
[18] Human Milk Banking Association of North America, *Milk Processing and Safety*, *available at* https://www.hmbana.org/our-work/milk-processing-safety.html (last visited Mar. 2, 2021).
[19] *Supra* note 9.
[20] *Supra* note 6.
[21] Human Milk Banking Association of North America, *Milk Banking and COVID-19* (Apr. 2, 2020) *available at* https://www.hmbana.org/file_download/inline/a04ca2a1-b32a-4c2e-9375-44b37270cfbd (last visited Mar. 2, 2021).

The bill requires the DOH to establish minimum standards for the regulation of donor human milk banks which must address:

- The operation of a donor human milk bank that facilitates the donation, processing, and distribution of donor human milk and donor human milk derivatives;
- Procedures for donation and distribution of donor human milk and donor human milk derivatives; and
- Testing of donor human milk and donor human milk derivatives before donation, processing, and distribution to ensure the absence of adulterants and other contaminants as determined by the DOH.

The bill requires a donor human milk bank operating in this state to comply with the DOH standards.

The bill requires the DOH to adopt rules to implement s. 383.017, F.S., as created by the bill.

Section 2 of the bill provides an effective date of July 1, 2021.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The bill may pose a minor fiscal and operational impact on the DOH as it adopts rules and establishes minimum standards for donor human milk banks. The fiscal impact may be absorbed within existing DOH resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill requires a donor human milk bank operating in this state to comply with the DOH's minimum standards for donor human milk banks, but the DOH will not license such entities under the bill and is not given authority to enforce compliance.

VIII. Statutes Affected:

This bill creates section 383.017 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on March 10, 2021:
The CS replaces the Medicaid reimbursement authorizations and requirements in the underlying bill and instead requires:

- The DOH to adopt rules and establish minimum standards for the regulation of donor human milk banks which must address the operations of the bank and procedures for donating, distributing, and testing donor human milk and its derivatives.
- A donor human milk bank operating in this state to comply with the DOH standards.

B. Amendments:

None.

172844

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/10/2021	.	
	.	
	.	
	.	

The Committee on Health Policy (Book) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Section 383.017, Florida Statutes, is created to read:

383.017 Donor human milk banks.—

(1) It is the intent of the Legislature to protect the health, safety, and welfare of human milk donors and recipients of human milk donation and to encourage the use of donor human milk and donor human milk derivatives.

172844

(2) As used in this section, the term "donor human milk bank" means any entity or organization operating within this state which collects, processes, stores, tests, or distributes donor human milk or donor human milk derivatives.

(3) The Department of Health shall establish minimum standards for the regulation of donor human milk banks which must address the following:

(a) The operation of a donor human milk bank that facilitates the donation, processing, and distribution of donor human milk and donor human milk derivatives;

(b) Procedures for donation and distribution of donor human milk and donor human milk derivatives; and

(c) Testing of donor human milk and donor human milk derivatives before donation, processing, and distribution to ensure the absence of adulterants and other contaminants as determined by the department.

(4) A donor human milk bank operating in this state shall comply with the standards established by the department pursuant to this section.

(5) The department shall adopt rules to implement this section.

Section 2. This act shall take effect July 1, 2021.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to donor human milk bank services;

172844

creating s. 383.017, F.S.; providing legislative intent; defining the term "donor human milk bank"; requiring the Department of Health to establish certain standards for the regulation of donor human milk banks; requiring donor human milk banks to comply with certain standards; requiring the Department of Health to adopt rules; providing an effective date.

By Senator Book

32-00432-21 2021240__

A bill to be entitled

An act relating to donor human milk bank services; amending s. 409.906, F.S.; authorizing the Agency for Health Care Administration to pay for donor human milk bank services as an optional Medicaid service if certain conditions are met; specifying coverage requirements; amending s. 409.908, F.S.; adding donor human milk bank services to the list of Medicaid services authorized for reimbursement on a fee-for-service basis; amending s. 409.973, F.S.; adding donor human milk bank services to the list of minimum benefits required to be covered by Medicaid managed care plans; providing an effective date.

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

Section 1. Subsection (28) is added to section 409.906, Florida Statutes, to read:

409.906 Optional Medicaid services.—Subject to specific appropriations, the agency may make payments for services which are optional to the state under Title XIX of the Social Security Act and are furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any optional service that is provided shall be provided only when medically necessary and in accordance with state and federal law. Optional services rendered by providers in mobile units to Medicaid recipients may be restricted or prohibited by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees,

32-00432-21 2021240__

reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216. If necessary to safeguard the state's systems of providing services to elderly and disabled persons and subject to the notice and review provisions of s. 216.177, the Governor may direct the Agency for Health Care Administration to amend the Medicaid state plan to delete the optional Medicaid service known as "Intermediate Care Facilities for the Developmentally Disabled." Optional services may include:

(28) DONOR HUMAN MILK BANK SERVICES.—The agency may pay for the cost of donor human milk, for home and inpatient use, for which a licensed physician or nurse practitioner has issued an order for an infant who is medically or physically unable to receive maternal breast milk or breastfeed or whose mother is medically or physically unable to produce maternal breast milk or breastfeed. Such infant must have a documented birth weight of 1,500 grams or less; have a congenital or acquired intestinal condition and be at high risk for developing a feeding intolerance, necrotizing enterocolitis, or an infection; or otherwise require nourishment by breast milk. The donor human milk must be procured from a nonprofit milk bank certified by the Human Milk Banking Association of North America (HMBANA). Coverage for donor human milk may not be less than the reasonable cost of such milk procured from an HMBANA-certified milk bank, plus reasonable processing and handling fees.

Section 2. Present paragraphs (f) through (t) of subsection (3) of section 409.908, Florida Statutes, are redesignated as

paragraphs (g) through (u), respectively, and a new paragraph (f) is added to that subsection, to read:

409.908 Reimbursement of Medicaid providers.—Subject to specific appropriations, the agency shall reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in the rules of the agency and in policy manuals and handbooks incorporated by reference therein. These methodologies may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding pursuant to s. 287.057, and other mechanisms the agency considers efficient and effective for purchasing services or goods on behalf of recipients. If a provider is reimbursed based on cost reporting and submits a cost report late and that cost report would have been used to set a lower reimbursement rate for a rate semester, then the provider's rate for that semester shall be retroactively calculated using the new cost report, and full payment at the recalculated rate shall be effected retroactively. Medicare-granted extensions for filing cost reports, if applicable, shall also apply to Medicaid cost reports. Payment for Medicaid compensable services made on behalf of Medicaid eligible persons is subject to the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216. Further, nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act, provided the

adjustment is consistent with legislative intent.

(3) Subject to any limitations or directions provided for in the General Appropriations Act, the following Medicaid services and goods may be reimbursed on a fee-for-service basis. For each allowable service or goods furnished in accordance with Medicaid rules, policy manuals, handbooks, and state and federal law, the payment shall be the amount billed by the provider, the provider's usual and customary charge, or the maximum allowable fee established by the agency, whichever amount is less, with the exception of those services or goods for which the agency makes payment using a methodology based on capitation rates, average costs, or negotiated fees.

(f) Donor human milk bank services.

Section 3. Present paragraphs (e) through (bb) of subsection (1) of section 409.973, Florida Statutes, are redesignated as paragraphs (f) through (cc), respectively, and a new paragraph (e) is added to that subsection, to read:

409.973 Benefits.—

(1) MINIMUM BENEFITS.—Managed care plans shall cover, at a minimum, the following services:

(e) Donor human milk bank services.

Section 4. This act shall take effect July 1, 2021.

SENATOR LAUREN BOOK
32nd District

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Children, Families, and Elder Affairs, *Chair*
Regulated Industries, *Vice Chair*
Appropriations
Appropriations Subcommittee on Health and Human Services
Health Policy
Rules

SELECT COMMITTEE:
Select Committee on Pandemic Preparedness and Response

JOINT COMMITTEE:
Joint Legislative Budget Commission

January 4, 2021

Chair Manny Diaz
Committee on Health Policy
530 Knott Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

Chair Diaz:

I respectfully request that **SB 240—Donor Human Milk Bank Services** be placed on the agenda for the next Committee on Health Policy meeting.

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

Thank you,

Lauren Book

Senator Lauren Book
Senate District 32

ENTERED
1-4-21

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

REPLY TO:
❒ 967 Nob Hill Road, Plantation, Florida 33324 (954) 424-6674
❒ 412 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5032

Senate's Website: *www.flsenate.gov*

WILTON SIMPSON
President of the Senate

AARON BEAN
President Pro Tempore

2021 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

BILL INFORMATION	
BILL NUMBER:	SB 240
BILL TITLE:	Donor Human Milk Bank Services
BILL SPONSOR:	Senator Book
EFFECTIVE DATE:	July 1, 2021

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

CURRENT COMMITTEE

SIMILAR BILLS	
BILL NUMBER:	
SPONSOR:	

PREVIOUS LEGISLATION	
BILL NUMBER:	SB 42
SPONSOR:	Senator Book
YEAR:	2020
LAST ACTION:	Died in Health Policy, never put on agenda or heard

IDENTICAL BILLS	
BILL NUMBER:	
SPONSOR:	

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

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	December 28, 2020
LEAD AGENCY ANALYST:	
ADDITIONAL ANALYST(S):	
LEGAL ANALYST:	
FISCAL ANALYST:	Ana Rivas

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

Senate Bill (SB) 240 (Donor Human Milk Bank Services) amends sections 409.906, 409.908 and 409.973, Florida Statutes (F.S.), authorizing Florida Medicaid to pay for donor human milk bank services as an optional covered service in the fee-for-service delivery system and requiring health plans participating in the Statewide Medicaid Managed Care (SMMC) program to cover donor human milk bank services. Within s. 409.906, F.S., the bill stipulates health conditions for which human donor milk services would be medically necessary as well as criteria that milk banks must meet to qualify as Medicaid providers. In addition, the bill specifies that Medicaid's reimbursement rates for donor human milk cannot be less than the milk bank's cost to procure it plus reasonable processing and handling fees.

SB 240 poses operational and fiscal impacts to Florida Medicaid. By federal law, Medicaid states can only cover services that are medically necessary. In order to cover human donor breast milk, the provider must meet all elements of Florida Medicaid's medical necessity criteria, which includes that no equally effective and more conservative or cost effective treatment is available to meet the recipient's medical needs. This would require the provider to demonstrate that the infant cannot tolerate or has medical contra-indications for commercial formula available through programs like WIC or prescription formulas already covered under Florida Medicaid (to the extent these options are more cost effective).

The changes in this bill would require the Agency to update its rules, fee schedules, and contracts with the SMMC health plans. These actions are part of the Agency's routine business practices and can be accomplished using existing resources. Because this is not currently a covered service under the Florida Medicaid program, there will be a fiscal impact. Lastly, milk banks would need to enroll as a Durable Medical Equipment provider under Florida Medicaid, which requires a minimum $50,000 surety bond payment as specified in section 409.912, F.S. In order to be reimbursed for donor human milk provided to infants enrolled in SMMC health plans, milk banks would need to contract SMMC plans.

The changes in the bill will have a fiscal impact on Florida Medicaid, but the extent of the fiscal impact is indeterminate based on the specific criteria outlined in the bill. Strictly focusing on the number of infants with a very low birth weight of 1,500 grams or less in a NICU, the estimated impact in SFY 2021-22 would be $29,867,890 with $11,570,821 being the General Revenue impact.

The bill has an effective date of July 1, 2021.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

The Agency for Health Care Administration (Agency) is the single state agency responsible for the administration of the Florida Medicaid program, authorized under Title XIX of the Social Security Act (SSA). This authority includes establishing and maintaining a Medicaid state plan approved by the Centers for Medicare and Medicaid Services (CMS) and maintaining any Medicaid waivers needed to operate the Florida Medicaid program as directed by the Florida Legislature.

A Medicaid state plan is an agreement between a state and the federal government describing how that state administers its Medicaid programs; it establishes groups of individuals covered under the Medicaid program, services that are provided, payment methodologies, and other administrative and organizational requirements. State Medicaid programs may request a formal waiver of the requirements codified in the SSA. Federal waivers give state flexibility not afforded through the Medicaid state plan.

In Florida, the majority of Medicaid recipients receive their services through a managed care plan contracted with the Agency under the Statewide Medicaid Managed Care (SMMC) program. The SMMC program has three components: the integrated Managed Medical Assistance (MMA) program and Long-Term Care (LTC) program, and the Dental program. Florida's SMMC program benefits are authorized through federal waivers and are specifically delineated by the Florida Legislature in sections 409.973 and 409.98, F.S.

Medical Necessity Requirements

Florida Medicaid covers services that are medically necessary, as defined in its Medicaid state plan and codified in Rule 59G-1.010, Florida Administrative Code. As part of its routine work, the Agency reviews new health services, products, and supplies for potential coverage under Florida Medicaid and bases its determinations on whether a service meets medical necessity criteria. This includes ensuring that the service is consistent with generally accepted professional medical standards and is not experimental or investigational.

Under federal law, Medicaid states must have a process in place to pay for services that are medically necessary but are not covered for recipients under the age of 21. This is often referred to as the federal Early and Periodic Screening, Diagnosis and Treatment (EPSDT) guidelines (see Title 42 Code of Federal Regulations Section 441.5). Health plans participating in the SMMC program must also adhere to EPSDT guidelines.

Human Donor Breast Milk

Donated by nursing mothers, human donor breast milk provides an option for infants who are unable to receive adequate nutrition from their mother's own milk or commercially prepared infant formulas. Because it is a biological product, milk banks must screen donors and pasteurize the milk prior to dispensing to mothers and infants.

The American Academy of Pediatrics (AAP) notes that human donor breast milk can be effective for high-risk and very low birth weight infants if the child's mother is unable to provide enough milk. Additionally, the World Health Organization (WHO) indicates that human donor breast milk can prevent some digestive disorders but specifies that any donor milk must come from safe facilities and is not recommended for sick infants or those weighing less than 1.0 kg. In the absence of a mother's milk, the WHO notes that standard formula is also an acceptable alternative. The Centers for Disease Control and Prevention (CDC) and AAP state that using the mother's breast milk is optimal, but when it is not available, a human donor is an option as well as standard infant formula is also a viable choice.

Currently, the U.S. Food and Drug Administration (FDA) considers human donor breast milk a "food" source, rather than a medical product. The FDA does not have any established guidelines or standards for human donor breast milk or milk banks, although it does recommend consulting with a health care provider before deciding to use it to feed an infant. Additionally, the FDA recommends that the caregiver only use milk from a source that has screened its donors and has taken precautions to ensure milk safety. The FDA and AAP further advise avoiding milk from internet-based sharing sites and using milk banks instead.

Serving as the professional organization for U.S. milk banks, the Human Milk Banking Association of North America (HMBANA) is the current source for regulations for milk banks. HMBANA's guidelines are voluntary and do not have to adhere to the FDA's standards. All individuals that donate to an HMBANA milk bank must undergo screening that includes an interview and testing for infectious disease and possible contaminants. Following collection, the milk banks pasteurize the milk to eliminate harmful bacteria or other infecting organisms.

HMBANA lists Mothers' Milk Bank of Florida as the only milk bank in Florida, and it requires a prescription for human donor breast milk. Mothers' Milk Bank of Florida states it uses the HMBANA's established guidelines for milk safety with advisement from the CDC, FDA, and blood and tissue industries. However, no federal or state regulations are in place to oversee the facility.

Coverage of Nutritional Supplements for Infants

Florida Medicaid covers prescription enteral and parenteral nutritional formulas under the Durable Medical Equipment and Supplies benefit, when medically necessary. This service is covered for recipients diagnosed with conditions such as metabolic disorders or who are unable to accept nutrition orally. In addition, if an infant needs formula during an inpatient hospital stay, it would be covered as part of the all-inclusive payment to the hospital (e.g., through a Diagnosis Related Grouper payment [DRG]), just as any food or medicine needed would be covered for child and adult patients.

The Women, Infants, and Children (WIC) program is a federally funded program that provides nutritional support for women and children. Administered by the Florida Department of Health, WIC provides food assistance such as milk and infant and toddler formulas. If a child is not able to consume a contract formula, WIC can make exceptions with appropriate medical documentation. A variety of contract formulas available through WIC include: Enfamil, Enfagrow, Gerber Good Start Soy 1, and Gerber Good Start Soy 3. WIC does not provide human donor breast milk to program participants.

In July 2017, New York Medicaid began covering pasteurized human donor breast milk, in both its fee-for-service and managed care delivery systems. New York's enacting legislation is similar to the requirements specified in this bill, except that services are only provided during an inpatient hospital stay (most likely for infants still in the Neonatal Intensive Care Unit). California Medicaid has been covering human donor breast milk since 1998, but only allows it when the mother is unable to utilize her own milk supply and the infant cannot tolerate or has medical contra-indications to the use of any formula, including enteral formula.

Florida Medicaid does not reimburse separately for human donor breast milk or formulas covered through WIC. If an infant needed human donor breast milk outside of the hospital setting, a request for it would need to be made through the EPSDT coverage process. The Agency is not aware of any such requests being made for infants in fee-for-service or Medicaid managed care.

2. EFFECT OF THE BILL:

Senate Bill (SB) 240 (Donor Human Milk Bank Services) amends sections 409.906, 409.908, and 409.973 Florida Statutes (F.S.), authorizing Florida Medicaid to pay for donor human milk bank services as an optional service for home and inpatient hospital use. Within s. 409.906, F.S., the bill stipulates the health conditions for which donor human milk services would be medically necessary, including:

- requiring a prescription for the product, AND
- the infant must be unable to receive maternal breast milk or breastfeed or the mother must be unable to produce maternal breast milk or breastfeed, AND
- the infant must have one of the following conditions:
    - have a birth weight of 1,500 grams or less
    - have a congenital or acquired intestinal condition and be at high risk for developing a feeding intolerance, necrotizing enterocolitis, or an infection
    - otherwise require nourishment by breast milk.

The language in the bill is more expansive than what is currently covered by other state Medicaid programs such as New York or California. For example, in New York the services are only provided during an inpatient hospital stay (most likely for infants still in the Neonatal Intensive Care Unit).

The bill establishes criteria that milk banks must meet to qualify as Medicaid providers.

The bill specifies that Medicaid's reimbursement rates for donor human milk cannot be less than the milk bank's cost to procure it plus reasonable processing and handling fees. To ensure this requirement is met for infants who need human donor milk in the hospital, it must be reimbursed separately from, and in addition to, the all-inclusive hospital payment.

In section 409.908, F.S., the bill adds donor human milk to the list of services which the Agency may cover under the Florida Medicaid. The bill also amends section 409.973, F.S. to require health plans participating in the Statewide Medicaid Managed Care (SMMC) program to cover donor human milk bank services.

SB 240 poses operational and fiscal impacts to Florida Medicaid. By federal law, Medicaid states can only cover services that are medically necessary. In Florida, in order for a service to be medically necessary, it must:

- Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain

- Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs
- Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational
- Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide
- Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider

In order to cover human donor breast milk, the provider must demonstrate that all elements specified above are met, including that no equally effective and more conservative or cost effective treatment is available to meet the infant's medical needs (e.g., formula available through programs like WIC). The likely outcome is that human donor milk services authorized would more align with California's coverage policy, which requires that the mother is unable to utilize her own milk supply and the infant cannot tolerate or has medical contra-indications to the use of any commercial or prescription formula.

With few exceptions, most enteral formula providers are enrolled in Florida Medicaid as a Durable Medical Equipment and Medical Supplies provider. To add human donor breast milk as a covered service, the Agency will need to update administrative rules, specifically the Durable Medical Equipment and Medical Supplies (DME) Coverage Policy and fee schedule, and update the Florida Medicaid Management Information System to pay claims for these services. These actions are part of the Agency's routine business practices and can be accomplished using existing resources. However, milk banks would need to enroll as DME providers under Florida Medicaid, which requires a minimum $50,000 surety bond payment as specified in section 409.912, F.S. In order to be reimbursed for donor human milk provided to infants enrolled in SMMC health plans, milk banks would need to contract SMMC plans.

The fiscal impact analysis is unable to account for all possible costs, as it is unknown how many infants would meet the criteria specified in the bill and Medicaid's medical necessity criteria. The fiscal impact therefore focuses on a percent of infants with a very low birth weight of 1,500 grams or less in a NICU. In SFY 2019-20 there were 2,494 infants with a very low birth weight of 1,500 grams or less in a NICU covered by Medicaid. The analysis assumes that 47.60% of these infants will receive donor milk for the first 6 months of life. The 47.60% is based on the count for breastfed babies in Florida who are not breast feeding at 6 months according to information from the Centers for Disease Control and Prevention.

Based on these assumptions about very low birth weight infants, the estimated fiscal impact in SFY 2021-22 is $29,867,890 with $11,570,821 being the General Revenue impact. The estimated impact in SFY 2022-23 is $29,867,890 with $11,657,438 being the General Revenue impact.

The bill specifies other requirements for infants to meet in order to receive donor milk, but there is no accurate way to determine the number of infants that may qualify, so the fiscal impact on these infants is indeterminate. These infants may be eligible to receive donor milk for up to 12 months, but this fiscal impact is also indeterminate. Some of the fiscal impact may be offset if the infant was going to be discharged on a medical supplemental formula that is covered by Medicaid, but instead is going to use the human donor breast milk. However, this impact is indeterminate.

The changes in the bill will have an operational impact to the agency, but these changes can be completed using current resources.

The bill takes effect on July 1, 2021.

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

If yes, explain:	Existing rules will need to be amended to comply with the bill.
Is the change consistent with the agency's core mission?	Y __X_ N ___

Rule(s) impacted (provide references to F.A.C., etc.):	Rule 59G-4.035, F.A.C.

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

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

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

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

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

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

FISCAL ANALYSIS

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

Revenues:	None
Expenditures:	Unknown
Does the legislation increase local taxes or fees? If yes, explain.	No
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	N/A

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

Revenues:	Unknown
Expenditures:	The fiscal impact analysis is unable to account for all possible costs, as it is unknown how many infants would meet the criteria specified in the bill and Medicaid's medical necessity criteria. The fiscal impact therefore focuses on infants with a very low birth weight of 1,500 grams or less. In

	SFY 2019-20 there were 2,494 such infants covered by Medicaid. The analysis assumes that 47.60% of these infants will receive donor milk for the first 6 months of life. The 47.60% is based on the count for breastfed babies in Florida who are not breast feeding at 6 months according to information from the Centers for Disease Control and Prevention. Based on these assumptions about very low birth weight infants, the estimated fiscal impact in SFY 2021-22 is $29,867,890 with $11,570,821 being the General Revenue impact. The estimated impact in SFY 2022-23 is $29,867,890 with $11,657,438 being the General Revenue impact. The bill specifies other requirements for infants to meet in order to receive donor milk, but there is no accurate way to determine the number of infants that may qualify, so the fiscal impact on these infants is indeterminate. These infants may be eligible to receive donor milk for up to 12 months, but this fiscal impact is also indeterminate. Some of the fiscal impact may be offset if the infant was going to be discharged on a medical supplement formula that is covered by Medicaid, but instead is going to use the human donor breast milk. However, the impact is indeterminate.
Does the legislation contain a State Government appropriation?	No
If yes, was this appropriated last year?	N/A

Estimated 6 month total in Ounces	6,874
Estimated rate per ounce	$ 3.66
Estimated Total 6 month Cost	$ 25,159
NICU infants that were very low birth weight (<1500 grams)	2,494
Average Breastfed Infant % for Florida for 1st 6 months	**52.40%**
Average Donor Milk Infant % for Florida for 1st 6 months	47.60%
Total Estimated cost for first 6 months of life of Human Donor Milk	$29,867,890

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

Revenues:	N/A
Expenditures:	N/A
Other:	N/A

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

If yes, explain impact.	N/A
Bill Section Number:	N/A

FISCAL IMPACT:	Year 1 (FY 2021-22)	Year 2 (FY 2022-23)	Year 3 (FY 2023-24)

1. **Non-Recurring Impact:**

Expenditures:	
Total Non-Recurring Expenditures	$ -

2. **Recurring Impact:**

Special Categories/Contracted Services			
102673 Prepaid Health Plans	$ 29,867,890	$ 29,867,890	$ 29,867,890
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
Total Special Categories/Contracted Services	**$ 29,867,890**	**$ 29,867,890**	**$ 29,867,890**
Total Recurring Expenditures	**$ 29,867,890**	**$ 29,867,890**	**$ 29,867,890**

3. **Total Revenues and Expenditures:**

Sub-Total Recurring Revenues	$ -	$ -	$ -
Total Revenues	**$ -**	**$ -**	**$ -**
Sub-Total Non-Recurring Expenditures	$ -	$ -	$ -
Sub-Total Recurring Expenditures	29,867,890	29,867,890	29,867,890
Total Expenditures	**$ 29,867,890**	**$ 29,867,890**	**$ 29,867,890**
Net Impact (Total Revenues minus Total Expenditures)	**$ (29,867,890)**	**$ (29,867,890)**	**$ (29,867,890)**

4. **Net Impact (By Fund)**

General Revenue Fund (1000)	$ (11,570,821)	$ (11,657,438)	$ (11,403,560)
Medical Care Trust Fund (2474)	(18,297,069)	(18,210,453)	(18,464,330)
-	-	-	-
-	-	-	-
Net Impact (By Fund)	**$ (29,867,890)**	**$ (29,867,890)**	**$ (29,867,890)**

TECHNOLOGY IMPACT

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

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

FEDERAL IMPACT

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

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

ADDITIONAL COMMENTS

LEGAL – GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	

Health Policy

THE FLORIDA SENATE

APPEARANCE RECORD

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

3-10-21
Meeting Date

240
Bill Number (if applicable)

Topic Human Milk Banks

Amendment Barcode (if applicable)

Name Barbara DeVane

Job Title

Address 625 E. Brevard St
Street

Phone 251-4280

City *State* *Zip*

Email barbaradevane1@yahoo.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing FL NOW

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Subcommittee on Health and Human Services, *Chair*
Appropriations, *Vice Chair*
Environment and Natural Resources
Health Policy
Rules

JOINT COMMITTEE:
Joint Legislative Budget Commission

SENATOR AARON BEAN
President Pro Tempore
4th District

March 9, 2021

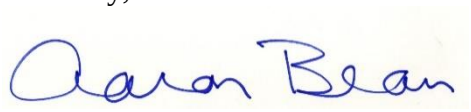
Senator Manny Diaz
Chair, Health Policy
306 Senate Building
404 South Monroe Street
Tallahassee, Florida 32399

Dear Senator Diaz:

I am writing to request approval to be excused from the Health Policy meeting scheduled for Wednesday, March 10, 2021, due to testing positive for COVID -19.

I appreciate your consideration in this matter.

Sincerely,



Aaron Bean
Senator | 4th District

REPLY TO:
❒ Duval Station, 13453 North Main Street, Suite 301, Jacksonville, Florida 32218 (904) 757-5039 FAX: (888) 263-1578
❒ 404 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5004 FAX: (850) 410-4805

Senate's Website: *www.flsenate.gov*

WILTON SIMPSON
President of the Senate

AARON BEAN
President Pro Tempore

CourtSmart Tag Report

Room: KB 412 **Case No.:** - **Type:**
Caption: Senate Health Policy Committee **Judge:**

Started: 3/10/2021 10:34:06 AM
Ends: 3/10/2021 12:09:10 PM Length: 01:35:05

10:34:06 AM Meeting called to order by Chair Diaz
10:34:14 AM Chair turned over to Senator Brodeur
10:34:22 AM Roll call by CAA Lynn Wells
10:34:33 AM Quorum present
10:34:37 AM Comments from Chair Brodeur
10:35:24 AM Introduction of Tab 1, SB 876 by Chair Brodeur
10:36:06 AM Speaker Lauren Whritenove, Luxohica in support
10:36:30 AM Speaker Chris Nuland, Florida Society of Plastic Surgeons waives in opposition
10:36:42 AM Speaker Sarah Wellik, Florida Society of Ophthalmology in opposition
10:39:29 AM Speaker Dr. Andrew Bowman, Florida Society of Ophthalmology in opposition
10:41:54 AM Speaker Bruce May, Florida Society of Ophthalmology in opposition
10:44:06 AM Speaker Dr. Douglas Murphy, Florida Medical Association in opposition
10:46:50 AM Speaker Dr. Darby Miller, waives in opposition
10:48:15 AM Comments from Chair Brodeur
10:48:27 AM Question from Senator Book
10:48:39 AM Response from Senator Diaz
10:48:54 AM Senator Garcia in debate
10:50:07 AM Senator Jones in debate
10:51:19 AM Senator Farmer in debate
10:52:25 AM Senator Book in debate
10:52:59 AM Senator Albritton in debate
10:53:46 AM Senator Cruz in debate
10:54:30 AM Chair Brodeur in debate
10:54:45 AM Senator Diaz in closure
10:55:14 AM Roll call by CAA
10:56:16 AM SB 876 reported favorably
10:56:43 AM Chair passed back to Senator Diaz
10:56:51 AM Introduction of Tab 7, SB 1064 by Chair Diaz
10:57:28 AM Explanation of SB 1064, Hospital, Hospital System, or Provider Organization Transactions by Senator Brodeur
10:58:23 AM Comments from Chair Diaz
10:58:35 AM Jeff Scott, Florida Medical Association in opposition
10:58:45 AM Speaker Michael Williams, Florida Hospital Association in opposition
11:01:09 AM Brewster Bevis, Associated Industries of Florida
11:01:17 AM Speaker Chris Nuland, Florida Society of Gastroenterology in opposition
11:02:22 AM Comments from Chair Diaz
11:02:39 AM Senator Farmer in debate
11:03:40 AM SB 1064 temporarily postponed
11:03:54 AM Introduction of Tab 2, SB 262 by Chair Diaz
11:04:15 AM Explanation of SB 262, Dispensing Medicinal Drugs by Senator Harrell
11:06:07 AM Comments from Chair Diaz
11:06:18 AM Clay Meenan, Florida Hospital Association waives in support
11:06:22 AM Phillip Suderman, Americans for Prosperity waives in support
11:06:27 AM Steve Winn, Florida Osteopathic Medical Association waives in support
11:06:53 AM Senator Harrell in closure
11:07:05 AM Roll call by CAA
11:07:10 AM SB 262 reported favorably
11:07:27 AM Introduction of Tab 3, SB 990 by Chair Diaz
11:07:42 AM Explanation of SB 990, Occupational Therapy by Senator Bradley
11:08:14 AM Introduction of Amendment Barcode 373056 by Chair Diaz
11:08:27 AM Explanation of Amendment by Senator Bradley
11:09:26 AM Comments from Chair Diaz

11:09:41 AM Amendment adopted
11:09:53 AM Question from Senator Farmer
11:10:01 AM Response from Senator Bradley
11:10:55 AM Speaker Anita Berry, Florida Occupational Therapy Association in support
11:11:24 AM Senator Bradley in closure
11:11:28 AM Roll call by CAA
11:11:32 AM CS/SB 990 reported favorably
11:11:46 AM Introduction of Tab 5, SB 1084 by Chair Diaz
11:12:08 AM Explanation of SB 1084, Volunteer Ambulance Services by Senator Pizzo
11:13:29 AM Comments from Chair Diaz
11:13:40 AM Introduction of Late-filed Amendment Barcode 446228
11:13:49 AM Explanation of Late-filed Amendment by Senator Pizzo
11:14:22 AM Comments from Chair Diaz
11:14:27 AM Closure waived
11:14:30 AM Amendment adopted
11:14:37 AM Comments from Chair Diaz
11:14:46 AM Speaker Chief Ray Colburn, Florida Fire Chiefs' Association in opposition
11:15:40 AM Speaker Schneur Oirechman, Hatzalah in support
11:20:04 AM Speaker Nicole Fumarda, Hatzalah in support
11:21:09 AM Comments from Chair Diaz
11:21:16 AM Senator Book in debate
11:21:51 AM Senator Farmer in debate
11:23:04 AM Senator Pizzo in closure
11:23:16 AM Roll call by CAA
11:24:15 AM CS/SB 1084 reported favorably
11:24:38 AM Introduction of Tab 8, SB 240 by Chair Diaz
11:24:52 AM Comments from Chair Book
11:25:04 AM Introduction of Amendment Barcode 172844 by Chair Diaz
11:25:11 AM Explanation of Amendment by Senator Book
11:26:40 AM Comments from Chair Diaz
11:27:06 AM Amendment adopted
11:27:12 AM Comments from Chair Diaz
11:27:18 AM Barbara DeVane, FL NOW waives in support
11:27:34 AM Comments from Chair Diaz
11:27:39 AM Closure waived
11:27:41 AM Roll call by CAA
11:27:45 AM CS/SB 240 reported favorably
11:28:01 AM Introduction of Tab 6, SB 634 by Chair Diaz
11:28:24 AM Explanation of SB 634, Dementia-related Staff Training by Senator Farmer
11:29:18 AM Introduction of Amendment Barcode 375452 by Chair Diaz
11:29:37 AM Explanation of Amendment by Senator Farmer
11:29:51 AM Comments from Chair Diaz
11:30:11 AM Speaker Jon Conley, Alzheimer's Association in support
11:30:54 AM Comments from Chair Diaz
11:31:11 AM Amendment adopted
11:31:15 AM Comments from Chair Diaz
11:31:27 AM Question from Senator Jones
11:31:34 AM Response from Senator Farmer
11:31:49 AM Derek Miller, Florida Department of Elder Affairs in support
11:31:56 AM Speaker Jason Hand, Florida Senior Living Association in opposition
11:32:46 AM Speaker Jon Conley, Alzheimer's Association in support
11:34:37 AM Comments from Chair Diaz
11:34:51 AM Senator Farmer in closure
11:34:57 AM Roll call by CAA
11:35:19 AM CS/SB 634 reported favorably
11:35:36 AM Recording Paused
11:35:36 AM Recording Resumed
11:35:38 AM Introduction of Tab 4, SB 1140 by Chair Diaz
11:36:38 AM Explanation of SB 1140, Unlawful Use of DNA by Senator Rodrigues
11:38:33 AM Comments from Chair Diaz
11:38:37 AM Question from Senator Jones
11:38:45 AM Response from Senator Rodrigues

11:40:25 AM Follow-up question from Senator Jones
11:40:30 AM Response from Senator Rodrigues
11:41:21 AM Question from Senator Jones
11:41:39 AM Response from Senator Rodrigues
11:41:48 AM Speaker Alli Liby-Schoonover, Ancestry.com and 23andMe in support
11:43:02 AM Comments from Chair Diaz
11:43:09 AM Closure waived
11:43:13 AM Roll call by CAA
11:43:17 AM SB 1140 reported favorably
11:43:39 AM Senator Baxley would like to be shown voting in the affirmative on SB 876, SB 262, CS/SB 990, CS/SB 240, CS/S 1084 and CS/SB 634
11:44:18 AM Comments from Chair Diaz - Motion adopted
11:44:37 AM Recording Paused
12:06:29 PM Recording Resumed
12:06:34 PM Comments from Chair Diaz
12:07:06 PM Senator Brodeur in closure on SB 1064
12:07:27 PM Roll call by CAA
12:07:44 PM SB 1064 reported favorably
12:08:07 PM Comments from Chair Diaz
12:08:14 PM Senator Brodeur would like to be shown voting in the affirmative on SB 262, CS/SB 990, CS/SB 240, CS/SB 1084. CS/SB 634 and SB 1140
12:08:39 PM Comments from Chair Diaz - Motion adopted
12:08:54 PM Senator Jones moves to adjourn
12:08:59 PM Meeting adjourned