

Professions and Public Health Subcommittee

Thursday, April 1, 2021
9:00 AM – 12:00 PM
Webster Hall (212 Knott)

Meeting Packet

Chris Sprowls
Speaker

Will Robinson
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Professions & Public Health Subcommittee

Start Date and Time: Thursday, April 01, 2021 09:00 am

End Date and Time: Thursday, April 01, 2021 12:00 pm

Location: Webster Hall (212 Knott)

Duration: 3.00 hrs

Consideration of the following bill(s):

HB 721 Prohibited Acts by Health Care Practitioners by Massullo
HB 949 Communicable and Infectious Diseases by Fetterhoff, Omphroy
HB 1045 Delegation of the Administration of Prescription Medications by Snyder
HB 1233 Genetic Counseling Patient Protection Act by Silvers
HB 1235 Fees by Silvers
HB 1345 Pharmaceutical Products Containing Cannabis by Persons-Mulicka, Learned

Consideration of the following proposed committee substitute(s):

PCS for HB 361 -- Consent for Pelvic Examinations
PCS for HB 463 -- Community Association Pools
PCS for HB 957 -- Hearing Aid Consultations and Sales
PCS for HB 1091 -- Relating to Substance Abuse Prevention

This meeting will be live-streamed on https://thefloridachannel.org/. Persons who wish to attend must register at www.myfloridahouse.gov, and pick up a pass at the Legislative Welcome Center on the 4th Floor of the Capitol beginning one hour before the start of the meeting. Audience seating will be socially distanced and will be available on a first-come, first-served basis. Registration closes three hours before the meeting starts.

NOTICE FINALIZED on 03/30/2021 4:22PM by Osborne.Erin

PCS for HB 361

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for HB 361 Consent for Pelvic Examinations
SPONSOR(S): Professions & Public Health Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Professions & Public Health Subcommittee		Guzzo	McElroy

SUMMARY ANALYSIS

Informed consent is a process in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention. Such information enables a patient to make a competent decision about whether to undergo a procedure or treatment.

Current law defines a pelvic examination as the series of tasks that comprise an examination of the vagina, cervix, uterus, fallopian tubes, ovaries, rectum, or external pelvic tissue or organs using any combination of modalities, which may include, but is not limited to, the health care provider's gloved hand or instrumentation. A health care practitioner must obtain a pelvic examination specific written informed consent from a patient before performing a pelvic examination. A health care practitioner does not have to obtain such consent if the pelvic examination is required by a court order or is immediately necessary to avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function of the patient. Questions have arisen within the medical community as to how to interpret the law's requirements.

PCS for HB 361 revises the definition of pelvic examination to mean a manual examination of the organs of the female reproductive system. The bill also revises the emergency exception to the informed consent requirement allowing a health care practitioner to perform a pelvic examination without the written consent of the patient if the pelvic examination is necessary for the provision of emergency services and care or the patient has an emergency medical condition. These changes address questions raised by the medical community regarding what constitutes a pelvic examination and when informed consent is required.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Informed Consent

Informed consent for medical treatment is fundamental in both ethics and law.[1] Informed consent is a process in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention.[2] A patient must be competent to make a voluntary decision about whether to undergo a procedure. Foregoing the process of consent within medicine can result in violations of both autonomy and basic rights, as well as trust.[3]

The idea of informed consent was established in 1914, in a case in which a patient was operated on without her consent.[4] In determining whether she had a cause of action against the hospital in which the operation was formed, Judge Cardozo opined that "every human being of adult years and sound mind has a right to determine what shall be done to his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable for damages."[5]

Pelvic Examinations

A pelvic examination involves the visual examination of the external genitalia and an internal visual examination of the vaginal walls and cervix using a speculum and palpation of the pelvic organs.[6] Health care practitioners often perform pelvic examinations as a part of the annual well woman visit.[7] A health care practitioner may also perform a pelvic examination to diagnose specific health conditions, such as cancer and bacterial vaginosis.[8]

Benefits of routine pelvic examinations include early detection of treatable gynecologic conditions before symptoms occur and incidental findings such as dermatologic changes and foreign bodies.[9] These examinations also give the health care practitioner an opportunity to establish open communication with the patient to answer specific questions and reassure her of normalcy.[10]

New clinical guidelines have recommended against pelvic examinations on asymptomatic, non-pregnant, adult women.[11] Routine pelvic examination has not been shown to benefit such women in

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[1] American Medical Association, *Informed Consent: Code of Medical Ethics Opinion 2.1.1*, available at https://www.ama-assn.org/delivering-care/ethics/informed-consent (last visited Mar. 30, 2021).
[2] William Gossman, Imani Thornton, John Hipskind, *Informed Consent*, (July 2019), available at https://www.ncbi.nlm.nih.gov/books/NBK430827/ (last visited Mar. 30, 2021).
[3] Phoebe Friesen, *Educational Pelvic Exams on Anesthetized Women: Why Consent Matters (Abstract),* 32 BIOETHICS 298 (June 2018), available at https://onlinelibrary.wiley.com/doi/abs/10.1111/bioe.12441 (last visited Mar. 30, 2021).
[4] *Schloendorff v. Society of N.Y. Hosp.*, 105 N>E. 92, 93 (N.Y. 1914).
[5] Id.
[6] Id. A pelvic examination usually involves an examination of woman's vulva, vagina, uterus, ovaries, and fallopian tubes. It may also include examination of the bladder and the rectum. Melissa Conrad Stoppler, MD, *Pelvic Exam*, MedicineNet, available at https://www.medicinenet.com/pelvic_exam/article.htm#why_is_a_pelvic_exam_performed (last visited Mar. 30, 2021).
[7] Amir Qaseem, et al., *Screening Pelvic Examination in Adult Women: A Clinical Practice Guideline from the American College of Physicians*, 161 Ann Intern Med 67 (2014), available at https://annals.org/aim/fullarticle/1884537/screening-pelvic-examination-adult-women-clinical-practice-guideline-from-american?_ga=2.7498674.1663533724.1580510917-1215329083.1580510917 (last visited Mar. 30, 2021).
[8] Id.
[9] American College of Obstetricians and Gynecologists, Committee on Gynecologic Practice, *ACOG Committee Opinion, Number 754*, 132(4) OBSTETRICS & GYNECOLOGY 174 (Oct. 2018), available at https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/The-Utility-of-and-Indications-for-Routine-Pelvic-Examination?IsMobileSet=false (last visited Mar. 30, 2021).
[10] Id.
[11] *Supra* note 7. This recommendation does not apply to pap smears.

that it rarely detects important disease and does not reduce mortality.[12] Several harms have been identified for the performance of pelvic examinations including fear, anxiety, embarrassment, pain, and discomfort.[13] Other physical harms include urinary tract infections and symptoms such as dysuria and frequent urination.[14]

The American College of Obstetricians and Gynecologists finds that data is currently insufficient to make a recommendation for or against routine pelvic examinations.[15] Therefore, it recommends that pelvic examinations be performed when indicated by medical history or symptoms, such as abnormal bleeding, pelvic pain, or urinary issues.[16]

Florida Requirements for Informed Consent of Pelvic Examinations

Pursuant to Florida statutes, a pelvic examination is the series of tasks that comprise an examination of the vagina, cervix, uterus, fallopian tubes, ovaries, rectum, or external pelvic tissue or organs using any combination of modalities, which may include, but is not limited to the health care provider's gloved hand or instrumentation.[17]

Current law prohibits a health care practitioner from performing a pelvic examination on a patient without express written consent unless an exception applies.[18] A health care practitioner does not have to obtain written consent if the pelvic examination is required by a court order or is immediately necessary to avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function of the patient.[19]

Following the enactment of s. 456.51, F.S., questions arose within the medical community as to how to interpret the law's requirements, and a Petition for Declaratory Statement was filed with the Florida Board of Medicine (BOM), requesting a determination of: [20]

- Whether the definition of pelvic examination applies only to female patients or to males as well;
- Whether performance of surgery on the vagina, cervix, uterus, fallopian tubes, ovaries, rectum, or external pelvic tissue or organs constitutes a pelvic examination;
- Whether a discrete visual examination of the vagina, cervix, uterus, fallopian tubes, ovaries, rectum, or external pelvic tissue or organs constitutes a pelvic examination;
- Whether a pelvic examination requires separate written consents every time a pelvic examination was performed during a course of treatment; and
- Whether a pelvic examination in emergent circumstances required a written consent when the patient or a legal representative were unable to give consent.

[12] American College of Physicians, *American College of Physicians Recommends Against Screening Pelvic Examinations in Adult, Asymptomatic, Average Risk, Non-Pregnant Women*, (July 1, 2014), available at https://www.acponline.org/acp-newsroom/american-college-of-physicians-recommends-against-screening-pelvic-examination-in-adult-asymptomatic (last visited on Mar. 30, 2021).
[13] Id.
[14] Id.
[15] Id.
[16] Id.
[17] S. 456.51(1), F.S.
[18] S. 456.51(2), F.S.
[19] Id.
[20] See Florida Department of Health, Board of Medicine, Final Order NO DOH-20-1553-DS-MQA filed Oct. 9, 2020, *available at* https://s3.amazonaws.com/thenewsserviceofflorida/web/dist/downloads/2020/10/DOH_20-1553_DS_Doug_Murphy__FMA__etc__1_.pdf (last visited Mar. 30, 2021).

The BOM, in its Final Order, answered the above questions regarding what constitutes a pelvic examination under s. 456.51, F.S., as follows: [21]

- A pelvic examination applies only to female patients;
- Surgery on the vagina, cervix, uterus, fallopian tubes, ovaries, rectum, or external pelvic tissue or organs does not constitute a pelvic examination; and
- Discrete visual examination of the vagina, cervix, uterus, fallopian tubes, ovaries, rectum, or external pelvic tissue or organs does not constitute a pelvic examination.

The BOM declined to answer the questions regarding informed consent.

Effect of the Bill

PCS for HB 361 revises the definition of pelvic examination to mean a manual examination of the organs of the female reproductive system. The bill also revises the emergency exception to the informed consent requirement allowing a health care practitioner to perform a pelvic examination without the written consent of the patient if:

- The pelvic examination is necessary for the provision of emergency services and care, as defined in s. 395.002(9), F.S.,[22] or
- The patient has an emergency medical condition, as defined in s. 395.002(8), F.S.[23]

These changes address questions raised by the medical community regarding what constitutes a pelvic examination and when informed consent is required.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 456.51, F.S., relating to consent for pelvic examinations.
Section 2: Provides an effective date of July 1, 2021.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

[21] *Id.*
[22] S. 395.002(9), F.S. Emergency services and care means medical screening, examination, and evaluation by a physician, or, to the extent permitted by applicable law, by other appropriate personnel under the supervision of a physician, to determine if an emergency medical condition exists and, if it does, the care, treatment, or surgery by a physician necessary to relieve or eliminate the emergency medical condition, within the service capability of the facility.
[23] S. 395.002(8), F.S. Emergency medical condition means s medical condition manifesting itself by acute symptoms of sufficient severity, which may include severe pain, such that the absence of immediate medical attention could reasonably be expected to result in any of the following: serious jeopardy to patient health, including a pregnant woman or fetus; serious impairment to bodily functions; serious dysfunction of any bodily organ or part; that there is inadequate time to effect safe transfer to another hospital prior to delivery; that a transfer may pose a threat to the health and safety of the patient or fetus; or that there is evidence of the onset and persistence of uterine contractions or rupture of the membranes.

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No rule-making authority is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to consent for pelvic examinations; amending s. 456.51, F.S.; revising the definition of the term "pelvic examination"; revising the circumstances under which a pelvic examination may be performed without written consent; providing an effective date.

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

Section 1. Section 456.51, Florida Statutes, is amended to read:

456.51 Consent for pelvic examinations.—

(1) As used in this section, the term "pelvic examination" means a manual ~~the series of tasks that comprise an~~ examination of the ~~vagina, cervix, uterus, fallopian tubes, ovaries, rectum, or external pelvic tissue or~~ organs of the female reproductive system ~~using any combination of modalities, which may include, but need not be limited to, the health care provider's gloved hand or instrumentation~~.

(2) A health care practitioner, a medical student, or any other student receiving training as a health care practitioner may not perform a pelvic examination on a patient without the written consent of the patient or the patient's legal representative executed specific to, and expressly identifying,

the pelvic examination, unless:

(a) A court orders performance of the pelvic examination for the collection of evidence; or

(b) The pelvic examination is ~~immediately~~ necessary for the provision of emergency services and care, as defined in section 395.002(9), or the patient has an emergency medical condition, as defined in section 395.002(8) ~~to avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function of the patient~~.

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

PCS for HB 463

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for HB 463 Community Association Pools
SPONSOR(S): Professions & Public Health Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Professions & Public Health Subcommittee		Woodruff	McElroy

SUMMARY ANALYSIS

A homeowners' association (HOA) is an association of residential property owners in which voting membership is made up of parcel owners, membership is a mandatory condition of parcel ownership, and which is authorized to impose assessments that, if unpaid, may become a lien on the parcel.

The Department of Health (DOH) is responsible for the oversight and regulation of water quality and safety of public swimming pools in Florida. In order to operate or continue to operate a public swimming pool, a valid operating permit from DOH must be obtained. DOH may, at any reasonable time, enter any and all parts of a public swimming pool to examine and investigate the pool's sanitary and safety conditions. County health departments are responsible for the routine surveillance of water quality in all public swimming pools. Pools that are used by condominiums or cooperatives with 32 units or less and which are not being operated as public lodging establishes are exempt from DOH's public pools requirements, except for maintaining water quality standards. HOA pools are not exempt from DOH regulation even where the HOA has 32 homes or less.

HB 463 specifies that HOAs and other property associations with 32 units or less and which are not operated as pubic lodging establishments are exempt from supervision under ch. 514, F.S., except for supervision necessary to ensure water quality and under ss. 514.0315, 514.05, and 514.06, F.S.

There is an insignificant, negative fiscal impact on DOH. There is no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Homeowners' Associations

The Florida Division of Condominiums, Timeshares and Mobile Homes (Division), within the Department of Business and Professional Regulation, provides consumer protection for Florida residents living in regulated communities through education, complaint resolution, mediation and arbitration, and developer disclosure. The Division has regulatory authority over Homeowners' Associations (limited to arbitration of election and recall disputes).

A homeowners' association (HOA) is an association of residential property owners in which voting membership is made up of parcel owners, membership is a mandatory condition of parcel ownership, and which is authorized to impose assessments that, if unpaid, may become a lien on the parcel.[1] Only HOAs whose covenants and restrictions include mandatory assessments are regulated by ch. 720, F.S. Like a condominium or cooperative, an HOA is administered by an elected board of directors. The powers and duties of an HOA include the powers and duties provided in ch. 720, F.S., and in the association's governing documents, which include the recorded covenants and restrictions, together with the bylaws, articles of incorporation, and duly adopted amendments to those documents. Current law sets procedures and minimum requirements for HOA operation and provides for a mandatory binding arbitration program, administered by the Division for certain election and recall disputes, but no state agency has direct oversight of HOAs.

HOA Swimming Pools

The Department of Health (DOH) is responsible for the oversight and regulation of water quality and safety of public swimming pools[2] in Florida under ch. 514, F.S. In order to operate or continue to operate a public swimming pool, a valid operating permit from DOH must be obtained. If DOH determines that the public swimming pool is, or may reasonably be expected, to be operated in compliance with state laws and rules, DOH will issue a permit. However, if it is determined that the pool is not in compliance with state laws and rules, the application for a permit will be denied. DOH is authorized to establish a schedule of fees for plan approval and permitting.[3] Operating permits must be renewed annually and may be transferred from one name or owner to another.[4]

The Virginia Graeme Baker federal Pool and Spa Safety Act of 2007[5] implemented by the Consumer Product Safety Commission, and duplicated in s. 514.0315, F.S., requires all public swimming pools to assure compliance for anti-entrapment safety features to prevent drowning and entrapment injuries.

DOH may, at any reasonable time, enter any and all parts of a public swimming pool to examine and investigate the pool's sanitary and safety conditions.[6] County health departments are responsible for the routine surveillance of water quality in all public swimming pools.[7]

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[1] S. 720.301(9), F.S.

[2] S. 514.011(2) defines "public swimming pool" or "public pool" to include a watertight structure of concrete, masonry, or other approved materials which is located either indoors or outdoors, used for bathing or swimming by humans, and filled with a filtered and disinfected water supply, together with buildings, appurtenances, and equipment used in connection therewith. A public swimming pool or public pool means a conventional pool, spa-type pool, wading pool, special purpose pool, or water recreation attraction, to which admission may be gained with or without payment of a fee and includes, but is not limited to, pools operated by or serving camps, churches, cities, counties, day care centers, group home facilities for eight or more clients, health spas, institutions, parks, state agencies, schools, subdivisions, or the cooperative living-type projects of five or more living units, such as apartments, boardinghouses, hotels, mobile home parks, motels, recreational vehicle parks, and townhouses.

[3] S. 514.033, F.S.

[4] Ss. 514.031(2) and (3), F.S.

[5] 15 U.S.C. §8003

Pools that are used by condominiums or cooperatives with 32 units or less and which are not being operated as public lodging establishments are exempt from DOH's public pools requirements, except for maintaining water quality standards.[8] HOA pools are not exempt from DOH regulation, even where the HOA has 32 homes or less.

DOH estimates that 200 public swimming pools would be effected if HOA pools were exempt from DOH regulation.[9]

Effect of Proposed Changes

HB 463 specifies that HOAs and other property associations which have no more than 32 units or parcels and which are not operated as pubic lodging establishments are exempt from supervision under ch. 514, F.S., except for:

- Supervision necessary to ensure water quality.
- Section 514.0315, F.S., related to required safety features for public swimming pools and spas.
- Section 514.05, F.S., related to denial, suspension, or revocation of permit; administrative fines.
- Section 514.06, F.S., related to injunction to restrain violations.

B. SECTION DIRECTORY:

Section 1: Amending s. 514.0115, F.S., related to exemptions from supervision or regulation; venues.
Section 2: Amending s. 553.77, F.S., related to specific powers of the commission.
Section 3: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH estimates it could lose a total of $50,000 in annual operating permits if the 200 HOA public swimming pools are exempt from DOH regulation.[10]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

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[6] S. 514.04, F.S.
[7] S. 514.025, F.S.
[8] S. 514.0115(2), F.S.
[9] Email from Gary Landry, Florida Department of Health, re: data request, (Mar. 30, 2021)(on file with Professions & Public Health Subcommittee staff).
[10] *Id*.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill does not require rulemaking to implement the bill's provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to community association pools; amending s. 514.0015, F.S.; exempting certain homeowners' association pools from supervision by the Department of Health; amending s. 553.77, F.S.; conforming cross references; providing an effective date.

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

Section 1. Subsections (3) through (7) of section 514.0114, Florida Statutes, are renumbered as subsections (4) through (8), respectively, and a new subsection (3) is added to that section to read:

514.0115 Exemptions from supervision or regulation; variances.—

(3) Pools serving homeowners' associations and other property associations which have no more than 32 units or parcels and which are not operated as public lodging establishments are exempt from supervision under this chapter, except for supervision necessary to ensure water quality and compliance with s. 514.0315, and under ss. 514.05 and 514.06.

Section 2. Subsection (7) of section 553.77, Florida Statutes, is amended to read:

(7) Building officials shall recognize and enforce

variance orders issued by the Department of Health under s. 514.0115(8) ~~pursuant to s. 514.0115(7)~~, including any conditions attached to the granting of the variance.

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

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

HB 721

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 721 Prohibited Acts by Health Care Practitioners
SPONSOR(S): Massullo
TIED BILLS: **IDEN./SIM. BILLS:** SB 1142

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Professions & Public Health Subcommittee		Morris	McElroy
2) Health & Human Services Committee			

SUMMARY ANALYSIS

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners. The MQA works in conjunction with 22 boards and four councils to license and regulate seven types of health care facilities and more than 40 health care professions, including allopathic physicians, osteopathic physicians, and dentists.

An unlicensed individual may be subject to administrative action or criminal penalties if the individual states or otherwise implies that he or she is a licensed medical professional. This may include the use of certain terms or titles that the public generally associates with a specific medical profession. DOH does not license a physician's specialty or sub-specialty based upon board certification, but does limit who can hold themselves out as board-certified specialists.

HB 721 prohibits health care practitioners from making misleading, deceptive, or fraudulent representations regarding a health care practitioner's specialty designation. The bill prohibits a health care practitioner from using the title "anesthesiologist" unless the health care practitioner is licensed as an allopathic physician under chapter 458, F.S., an osteopathic physician under chapter 459, F.S., or a dentist under chapter 466, F.S. The bill also prohibits a health care practitioner from using the title "dermatologist" unless the health care practitioner is licensed as an allopathic physician under chapter 458, F.S., or an osteopathic physician under chapter 459, F.S.

The bill requires DOH, rather than the boards, to enforce the bill's provisions. The bill requires DOH to issue an emergency order to cease and desist to a health care practitioner who violates the bill's provisions. DOH must issue an order imposing a citation and daily fine, reprimand or letter of concern, or suspension of license, if the health care practitioner does not immediately correct the violation upon receipt of the emergency cease and desist order.

The bill has an indeterminate, negative fiscal impact on DOH, which current resources are adequate to absorb.

The bill has no fiscal impact on local governments.

The bill takes effect upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Licensure and Regulation of Physicians

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners.[1] The MQA works in conjunction with 22 boards and four councils to license and regulate seven types of health care facilities and more than 40 health care professions, including Medical Doctors (allopathic physicians) and Doctors of Osteopathic Medicine (osteopathic physicians).[2] Each profession is regulated by an individual practice act and by ch. 456, F.S., which provides general regulatory and licensure authority for the MQA. MQA is statutorily responsible for the following boards and professions established within the division:[3]

- The Board of Acupuncture, created under ch. 457, F.S.;
- The Board of Medicine, created under ch. 458, F.S.;
- The Board of Osteopathic Medicine, created under ch. 459, F.S.;
- The Board of Chiropractic Medicine, created under ch. 460, F.S.;
- The Board of Podiatric Medicine, created under ch. 461, F.S.;
- Naturopathy, as provided under ch. 462, F.S.;
- The Board of Optometry, created under ch. 463, F.S.;
- The Board of Nursing, created under part I of ch. 464, F.S.;
- Nursing assistants, as provided under part II of ch. 464, F.S.;
- The Board of Pharmacy, created under ch. 465, F.S.;
- The Board of Dentistry, created under ch. 466, F.S.;
- Midwifery, as provided under ch. 467, F.S.;
- The Board of Speech-Language Pathology and Audiology, created under part I of ch. 468, F.S.;
- The Board of Nursing Home Administrators, created under part II of ch. 468, F.S.;
- The Board of Occupational Therapy, created under part III of ch. 468, F.S.;
- Respiratory therapy, as provided under part V of ch. 468, F.S.;
- Dietetics and nutrition practice, as provided under part X of ch. 468, F.S.;
- The Board of Athletic Training, created under part XIII of ch. 468, F.S.;
- The Board of Orthotists and Prosthetists, created under part XIV of ch. 468, F.S.;
- Electrolysis, as provided under ch. 478, F.S.;
- The Board of Massage Therapy, created under ch. 480, F.S.;
- The Board of Clinical Laboratory Personnel, created under part III of ch. 483, F.S.;
- Medical physicists, as provided under part IV of ch. 483, F.S.;
- The Board of Opticianry, created under part I of ch. 484, F.S.;
- The Board of Hearing Aid Specialists, created under part II of ch. 484, F.S.;
- The Board of Physical Therapy Practice, created under ch. 486, F.S.;
- The Board of Psychology, created under ch. 490, F.S.;
- School psychologists, as provided under ch. 490, F.S.;
- The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, created under ch. 491, F.S.; and

[1] Pursuant to s. 456.001(4), F.S., health care practitioners are defined to include acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists, midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, counselors, and psychotherapists, among others.
[2] Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2019-2020*, p. 5, http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/2019-2020-annual-report.pdf (last visited March 15, 2021).
[3] S. 456.001(4), F.S; Id.

- Emergency medical technicians and paramedics, as provided under part III of ch. 401, F.S.

Allopathic Physician Licensure

Chapter 458, F.S., provides for the licensure and regulation of the practice of medicine by the Florida Board of Medicine (allopathic board) in conjunction with DOH. The chapter imposes requirements for licensure examination and licensure by endorsement.

Allopathic Licensure Requirements

An individual seeking to be licensed by examination as an allopathic physician must, among other things:

- Complete 2 years of post-secondary education which includes, at a minimum, courses in fields such as anatomy, biology, and chemistry prior to entering medical school;
- Meet one of the following medical education and postgraduate training requirements:
    - Graduate from an allopathic medical school recognized and approved by an accrediting agency recognized by the U.S. Office of Education or recognized by an appropriate governmental body of a U.S. territorial jurisdiction, and have completed at least one year of approved residency training;
    - Graduate from an allopathic foreign medical school registered with the World Health Organization and certified pursuant to statute as meeting the standards required to accredit U.S. medical schools, and have completed at least one year of approved residency training; or
    - Graduate from an allopathic foreign medical school that has not been certified pursuant to statute; have an active, valid certificate issued by the Educational Commission for Foreign Medical Graduates (ECFMG),[4] have passed that commission's examination; and have completed an approved residency or fellowship of at least 2 years in one specialty area; and
- Obtain a passing score on:
    - The United States Medical Licensing Examination (USMLE);
    - A combination of the USMLE, the examination of the Federation of State Medical Boards of the United States, Inc. (FLEX), or the examination of the National Board of Medical Examiners up to the year 2000; or
    - The Special Purpose Examination of the Federation of State Medical Boards of the United States (SPEX), if the applicant was licensed on the basis of a state board examination, is currently licensed in at least one other jurisdiction of the United States or Canada, and has practiced for a period of at least 10 years. [5]

An individual who holds an active license to practice medicine in another jurisdiction may seek licensure by endorsement to practice medicine in Florida.[6] The applicant must meet the same requirements for licensure by examination. To qualify for licensure by endorsement, the applicant must also submit evidence of the licensed active practice of medicine in another jurisdiction for at least 2 of the preceding 4 years, or evidence of successful completion of either a board-approved postgraduate training program within 2 years preceding filing of an application or a board-approved clinical competency examination within the year preceding the filing of an application for licensure.

Osteopathic Physician Licensure

[4] A graduate of a foreign medical school does not need to present an ECFMG certification or pass its exam if the graduate received his or bachelor's degree from an accredited U.S. college or university, studied at a medical school recognized by the World Health Organization, and has completed all but the internship or social service requirements, has passed parts I and II of the National Board Medical Examiners licensing examination or the ECFMG equivalent examination. Section 458.311, F.S.
[5] Section 458.311(1), F.S.
[6] Section 458.313, F.S.

Chapter 459, F.S., provides for the licensure and regulation of the practice of medicine by the Florida Board of Osteopathic Medicine (osteopathic board) in conjunction with DOH. The chapter imposes requirements for licensure by examination and licensure by endorsement.

Osteopathic Licensure Requirements

An individual seeking to be licensed as an osteopathic physician must, among other things:[7]

- Graduate from a medical college recognized and approved by the American Osteopathic Association;
- Successfully complete a resident internship of at least 12 months in a hospital approved by the Board of Trustees of the American Osteopathic Association or any other internship approved by the osteopathic board; and
- Obtain a passing score, as established by rule of the osteopathic board, on the examination conducted by the National Board of Osteopathic Medical Examiners or other examination approved by the osteopathic board, no more than five years prior to applying for licensure.[8]

If an applicant for a license to practice osteopathic medicine is licensed in another state, the applicant must have actively practiced osteopathic medicine within the two years prior to applying for licensure in this state.

Dentist Licensure

The Board of Dentistry, in conjunction with DOH, regulates dental practice in Florida, including dentists, dental hygienists, and dental assistants under the Dental Practice Act.[9] A dentist is licensed to examine, diagnose, treat, and care for conditions within the human oral cavity and its adjacent tissues and structures.[10]

Dental Licensure Requirements

Any person wishing to practice dentistry in this state must apply to DOH and meet specified requirements. To qualify to take the Florida dental licensure examination, an applicant must be 18 years of age or older, be a graduate of a dental school accredited by the American Dental Association or be a student in the final year of a program at an accredited institution, and have successfully completed the NBDE dental examination.

Section 466.006, F.S., requires dentistry licensure applicants to sit for and pass the following licensure examinations:

- The National Board of Dental Examiners dental examiner (NBDE);
- A written examination on Florida laws and rules regulating the practice of dentistry; and
- A practical examination, which is the American Dental Licensing Examination developed by the American Board of Dental Examiners, Inc., and graded by a Florida-licensed dentist employed by DOH for such purpose.[11]

Board Certification and Florida Licensure

DOH does not license physicians by specialty or subspecialty; however, current law limits which physicians may hold themselves out as board-certified specialists. An allopathic physician may not hold himself or herself out as a board-certified specialist unless he or she has received formal recognition as a specialist from a specialty board of the American Board of Medical Specialties (ABMS) or other

[7] Section 459.0055(1), F.S.
[8] However, if an applicant has been actively licensed in another state, the initial licensure in the other state must have occurred no more than five years after the applicant obtained the passing score on the licensure examination.
[9] Section 466.004, F.S.
[10] Section 466.003(3), F.S.
[11] A passing score is valid for 365 days after the date the official examination results are published. A passing score on an examination obtained in another jurisdiction must be completed on or after October 1, 2011.

recognizing agency[12] approved by the allopathic board.[13] Additionally, an allopathic physician may not hold himself or herself out as a board-certified specialist in dermatology unless the recognizing agency, whether authorized in statute or by rule, is triennially reviewed and reauthorized by the allopathic board.[14] Similarly, an osteopathic physician may not hold himself or herself out as a board-certified specialist unless he or she has successfully completed the requirements for certification by the American Osteopathic Association (AOA) or the Accreditation Council on Graduate Medical Education (ACGME) and is certified as a specialist by a certifying agency[15] approved by the board.[16]

A dentist may not hold himself or herself out as a specialist, or advertise membership in or specialty recognition by an accrediting organization, unless the dentist has completed a specialty education program approved by the American Dental Association and the Commission on Dental Accreditation and the dentist is:[17]

- Eligible for examination by a national specialty board recognized by the American Dental Association; or
- Is a diplomate of a national specialty board recognized by the American Dental Association.

If a dentist announces or advertises a specialty practice for which there is not an approved accrediting organization, the dentist must clearly state that the specialty is not recognized or that the accrediting organization has not been approved by the American Dental Association or the Florida Board of Dentistry in capital letters.[18]

Cease and Desist

Florida law prohibits an individual from practicing a regulated health care profession without a license. An individual must meet minimum education and training requirements to become licensed and practice a health care profession.[19] An unlicensed individual providing healthcare services is subject to administrative and criminal penalties. Among other actions, DOH may issue a cease and desist letter to such a person and impose, by citation, an administrative penalty of up to $5,000 per offense.[20]

DOH is not authorized to issue a cease and desist letter to licensed health care practitioners for:

- Making misleading, deceptive, or fraudulent representations related to his or her licensed profession or specialty designation;
- Using the title “anesthesiologist” if not licensed as an allopathic physician under chapter 458, F.S., osteopathic physician under chapter 459, F.S., or dentist under chapter 466, F.S.; and
- Using the title “dermatologist” if not licensed as an allopathic physician under chapter 458, F.S., or an osteopathic physician under chapter 459, F.S.

DOH may also seek a civil penalty of up to $5,000 for each offense through the circuit court, in addition to or in lieu of the administrative penalty.[21] An individual practicing, attempting to practice or offering to practice, a health care profession without an active, valid Florida license is subject to criminal penalties, in addition to any administrative and civil penalties incurred by the unlicensed individual.[22]

[12] The allopathic board has approved the specialty boards of the ABMS as recognizing agencies. Rule 64B8-11.001(1)(f), F.A.C.
[13] Section 458.3312, F.S.
[14] Id.
[15] The osteopathic board has approved the specialty boards of the ABMS and AOA as recognizing agencies. Rule 64B15-14.001(h), F.A.C.
[16] Section 459.0152, F.S.
[17] Section 466.0282, F.S. A dentist may also hold himself or herself out as a specialist if the dentist has continuously held himself or herself out as a specialist since December 31, 1964, in a specialty recognized by the American Dental Association.
[18] Section 466.0282(3), F.S.
[19] Section 456.065(1), F.S.
[20] Section 456.065, F.S. Each day that the unlicensed practice continues after issuance of a notice to cease and desist constitutes a separate offense.
[21] Section 456.065(2)(c), F.S.
[22] Section 456.065(2)(d), F.S.

Discipline of Health Care Practitioners

Section 456.072, F.S., authorizes a regulatory board or DOH, if there is no board, to discipline a health care practitioner's licensure for a number of offenses, including but not limited to:

- Making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession; or
- Failing to identify through writing or orally to a patient the type of license under which the practitioner is practicing.

Making misleading, deceptive, or fraudulent representations related to a licensee's specialty designation or failing to identify such specialty designation to a patient is not ground for discipline under current law.

If the board or DOH finds that a licensee committed a violation, the board or DOH may:[23]

- Refuse to certify, or to certify with restrictions, an application for a license;
- Suspend or permanently revoke a license;
- Place a restriction on the licensee's practice or license;
- Impose an administrative fine not to exceed $10,000 for each count or separate offense; if the violation is for fraud or making a false representation, a fine of $10,000 must be imposed for each count or separate offense;
- Issue a reprimand or letter of concern;
- Place the licensee on probation;
- Require a corrective action plan;
- Refund fees billed and collected from the patient or third party on behalf of the patient; or
- Require the licensee to undergo remedial education.

Investigations

DOH, on behalf of the professional boards, investigates any complaint that is filed against a health care practitioner if the complaint is in writing, signed by the complainant, and legally sufficient.[24] A complaint is legally sufficient if it contains allegations of ultimate facts that, if true, show that a regulated practitioner has violated ch. 456, F.S., his or her practice act, or a rule of his or her board or the DOH.[25]

The Consumer Services Unit within MQA receives the complaints and refers them to the closest Investigative Services Unit (ISU) office.[26] The ISU investigates complaints against health care practitioners.[27] Complaints that present an immediate threat to public safety are given priority; however, all complaints are investigated as timely as possible. When the complaint is assigned to an investigator, the complainant will be contacted and given the opportunity to provide additional information. A thorough investigation will be conducted. The steps taken in the investigation are determined by the specifics of the allegations, but generally include the following:[28]

- Obtaining medical records, documents, and evidence;
- Locating and interviewing the complainant, the patient, the subject, and any witnesses; and
- Drafting and serving subpoenas for necessary information.

[23] Section 456.073(1), F.S.
[24] Section 456.073(1), F.S.
[25] Id.
[26] Department of Health, *Consumer Services*, http://www.floridahealth.gov/licensing-and-regulation/enforcement/admin-complaint-process/consumer-services.html (last visited March 26, 2021).
[27] Department of Health, *Investigative Services,* http://www.floridahealth.gov/licensing-and-regulation/enforcement/admin-complaint-process/isu.html (last visited March 26, 2021).
[28] Id.

The ISU includes a staff of professional investigators and senior pharmacists who conduct interviews, collect documents and evidence, prepare investigative reports for the Prosecution Services Unit (PSU), and serve subpoenas and official orders for the DOH.[29]

The PSU is responsible for providing legal services to the DOH in the regulation of all health care boards and councils.[30] The PSU will review the investigative file and report from ISU and recommend a course of action to the State Surgeon General (when an immediate threat to the health, safety, and welfare of the people of Florida exists), the appropriate board's probable cause panel, or the DOH, if there is no board, which may include:[31]

- Having the file reviewed by an expert;
- Issuing a closing order;
- Filing an administrative complaint; or
- Issuing an emergency order (emergency restriction order or emergency suspension order).

If the ISU investigative file received by PSU does not pose an immediate threat to the health, safety, and welfare of the people of Florida, then the PSU attorneys review the file and determine, first, whether expert review is required and, then, whether to recommend to the board's probable cause panel a closing order, an administrative complaint, or a letter of guidance.[32]

Final DOH action, including all of the above, as well as cases where the subject has failed to respond to an AC, are presented before the applicable board, or DOH if there is no board. The subject may be required to appear. The complainant is notified of the date and location of the hearing and may attend. If the subject is entitled to, and does, appeal the final decision, PSU defends the final order before the appropriate appellate court.[33]

If the ISU investigative file received by the PSU presents evidence of an immediate threat to the health, safety, and welfare of the people of Florida, then PSU will present the file to the State Surgeon General and recommend one of two types of emergency orders – emergency suspension order (ESO) or emergency restriction order (ERO) – which are exclusively issued by the State Surgeon General against licensees who pose such a threat to the people of Florida.[34]

Whether the State Surgeon General issues an ERO or an ESO depends on the level of danger the licensee presents because the DOH is permitted to use only the "least restrictive means" to stop the danger.[35] The distinction between the two orders is:[36]

- ESOs – Licensees are deemed to be a threat to the public at large; or
- EROs – Licensees are considered a threat to a segment of the population.

The emergency order process is carried out without a hearing, restricting someone's right to work, and when the order is served on the licensee, it must contain a notice to the licensee of his or her right to an immediate appeal of the emergency order.[37] An ESO or ERO is not considered final agency action, and the DOH must file an AC on the underlying facts supporting the ESO or ERO within 20 days of its

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[29] Id.
[30] Department of Health, *Prosecution Services,* http://www.floridahealth.gov/licensing-and-regulation/enforcement/admin-complaint-process/psu.html (last visited March 26, 2021).
[31] Id.
[32] Section 456.073(2), F.S. The DOH may recommend a letter of guidance in lieu of finding probable cause if the subject has not previously been issued a letter of guidance for a related offense.
[33] *Supra* note 27.
[34] Section 456.073(8) and 120.60(6), F.S.
[35] Section 120.60(6)(b), F.S.
[36] Department of Health, Licensing and Regulation, Enforcement, Administrative Complaint Process, Prosecution Services, *A Quick Guide to the MQA Disciplinary Process Discretionary Emergency Orders – 3 Things to Know,* http://www.floridahealth.gov/licensing-and-regulation/enforcement/admin-complaint-process/_documents/a-quick-guide-to-the-mqa-disciplinary-process-discrtionary-emergency-orders.pdf (last visited Mar. 26, 2021).
[37] *See* Rule 28-106.501(3), F.A.C., and ss. 120.569(2)(n) or 120.60(6), F.S.

issuance.[38] The appeal of the emergency order and the normal disciplinary process under the AC, and regular prosecution can run simultaneously.[39]

Mandatory EROs and ESOs

Section 456.074, F.S., directs that in certain cases, the DOH must issue an ESO or ERO to certain licensed practitioners under certain circumstances. The State Surgeon General must issue an ESO to certain practitioners if they have plead guilty to, been convicted of, found guilty of, or have entered a plea of nolo contendere to, regardless of adjudication, Medicare fraud, Medicaid fraud, health care fraud, or reproductive battery.[40] Such practitioners include:[41]

- Allopathic physician, physician assistants, anesthesiologist assistants, medical assistants;
- Osteopathic physician, physician assistants, and anesthesiologist assistants;
- Chiropractic physician and physician assistants;
- Podiatric physicians;
- Naturopathic physicians;
- Optometrists - licensed and certified;
- Autonomous advanced practice registered nurses, advanced practice registered nurses, registered nurses, licensed practical nurses and certified nursing assistants;
- Pharmacists and pharmacy technicians;
- Dentists, dental hygienist and dental laboratories; and
- Opticians.

DOH may issue an ESO or ERO if the Board of Medicine (BOM) or Board of Osteopathic Medicine (BOOM) has previously found one of its physicians has committed medical malpractice,[42] gross medical malpractice, or repeated medical malpractice,[43] and the probable cause panel again finds probable of cause for another malpractice violation. In such cases, the State Surgeon General must review the matter to determine if an ESO or ERO is warranted.[44]

DOH may issue an ESO or ERO if any practitioner governed by ch. 456, F.S., tests positive for any drug on any government or private sector pre-employment or employer-ordered confirmed drug test[45] when the practitioner does not have a lawful prescription and legitimate medical reason for using such drug.[46]

The DOH must issue an ESO if it receives information that a massage therapist, a person with an ownership interest in the establishment, or a massage corporate establishment corporation whose owners, officers, or individual are directly involved in the management of the establishment, has been convicted of, found guilty of, or has entered a guilty or *nolo contendere* plea to, regardless of adjudication, a felony under any of the following crimes anywhere:[47]

- Prostitution;[48]

[38] Rule 28-106.501(3), F.A.C.
[39] Section 120.60(6)(c), F.S.
[40] Section 456.073(1), F.S.
[41] Id.
[42] Section 456.50(1)(g), F.S., "Medical malpractice" means the failure to practice medicine in accordance with the level of care, skill, and treatment recognized in law related to health care licensure.
[43] Id. "Repeated medical malpractice" is medical malpractice, and any similar wrongful act, neglect, or default committed in another state or country which, if committed in this state, would have been considered medical malpractice, and will be considered medical malpractice, if the standard of care and burden of proof applied in the other state or country equaled or exceeded that used in this state.
[44] Section 456.074(2), F.S.
[45] *See* s. 112.0445, F.S.
[46] Section 456.074(3), F.S. The practitioner must be given 48 hours from the time of notification of the confirmed test results to produce a lawful prescription for the drug before an emergency order is issued.
[47] 456.074(4), F.S.
[48] Section 796.07(1)(a), F.S., "Prostitution" means the giving or receiving of the body for sexual activity for hire, but excludes sexual activity between spouses. Prostitution that took place at massage establishment is reclassified to the next higher degree. *See* s. 796.07(2)(a), F.S., which is reclassified under s. 796.07(7), F.S.

- Kidnapping;[49]
- False imprisonment;[50]
- Luring or enticing a child;[51]
- Human trafficking;[52]
- Human smuggling;[53]
- Sexual battery;[54]
- Female genital mutilation;[55]
- Procuring a person under 18 for prostitution;[56]
- Selling or buying of minors into prostitution;[57]
- Forcing, compelling, or coercing another to become a prostitute;[58]
- Deriving support from the proceeds of prostitution;[59]
- Prohibiting prostitution and related acts;[60]
- Lewd or lascivious offenses committed upon or in the presence of persons under 16;[61]
- Lewd or lascivious offenses committed upon or in the presence of an elderly or disabled person;[62]
- Sexual performance by a child;[63]
- Protection of minors;[64]
- Computer pornography;[65]
- Transmission of material harmful to minors, to a minor by electronic device or equipment;[66] and
- Selling or buying of minors.[67]

DOH must issue an ESO if a BOM or BOOM probable cause panel determines that the following constitutes a violation of the practice act and there exists an immediate danger to the public:[68]

- The registered surgery office where office surgery liposuction, or Level II or Level III office surgeries are being performed, or the physician practicing in the office, are not in compliance with the standards of practice for office surgery set by statute and board rule;[69] or
- The physician is practicing beyond the scope of his or her education, training, and experience and is performing procedures the licensee knows, or has reason to know, that he or she is not competent to perform.[70]

Due Process Under Chapter 120, F.S.

Chapter 120, F.S., known as the Administrative Procedure Act, (APA), provides uniform procedures for the exercise of specified authority. Section 120.60, F.S., pertains to licensing and provides for due process for persons seeking government-issued licensure or who have been granted such licensure. Under the APA, no revocation, suspension, annulment, or withdrawal of any license is lawful unless,

[49] Section 787.01, F.S.
[50] Section 787.02, F.S.
[51] Section 787.025, F.S.
[52] Section 787.06, F.S.
[53] Section 787.07, F.S.
[54] Section 794.011, F.S.
[55] Section 794.08, F.S.
[56] Former s. 796.03, F.S.
[57] Former s. 796.035, F.S.
[58] Section 796.04, F.S.
[59] Section 796.05, F.S.
[60] Section 796.07(4)(a)3., F.S., relating to a felony of the third degree for a third or subsequent violation of s. 796.07, F.S.
[61] Section 800.04, F.S.
[62] Section 825.1025(2)(b), F.S.
[63] Section 827.071, F.S.
[64] Section 847.0133, F.S.
[65] Section 847.0135, F.S.
[66] Section 847.0138, F.S.
[67] Section 847.0145, F.S.
[68] Section 456.074(5), F.S.
[69] Rules 64B-9.009 and 64B15-14.007, F.A.C.
[70] Sections 458.331(1)(v) and 459.015(1)(z), F.S.

prior to the entry of a final order, the governmental agency has served, by personal service or certified mail, an administrative complaint which affords reasonable notice to the licensee of facts or conduct which warrant the intended action and unless the licensee has been given an adequate opportunity to request a hearing under ss. 120.569 and 120.57, F.S.[71]

When personal service cannot be made and the certified mail notice is returned undelivered, the agency must cause a short, plain notice to the licensee to be published once each week for four consecutive weeks in a newspaper published in the county of the licensee's last known address as it appears on the records of the agency, or, if no newspaper is published in that county, the notice may be published in a newspaper of general circulation in that county.[72]

The APA provides a process for cases in which a governmental agency finds that immediate serious danger to the public health, safety, or welfare requires emergency suspension, restriction, or limitation of a license.[73] In such cases, the agency may take such action by any procedure that is fair under the circumstances if:[74]

- The procedure provides at least the same procedural protection as is given by other statutes, the State Constitution, or the U.S. Constitution;
- The agency takes only that action necessary to protect the public interest under the emergency procedure; and
- The agency states in writing at the time of, or prior to, its action the specific facts and reasons for finding an immediate danger to the public health, safety, or welfare and its reasons for concluding that the procedure used is fair under the circumstances. The agency's findings of immediate danger, necessity, and procedural fairness are judicially reviewable. Summary suspension, restriction, or limitation may be ordered, but a suspension or revocation proceeding pursuant to ss. 120.569 and 120.57, F.S., must also be promptly instituted and acted upon.

Effect of the Bill

HB 721 prohibits health care practitioners from making misleading, deceptive, or fraudulent representations regarding a health care practitioner's specialty designation. The bill prohibits a health care practitioner from using the title "anesthesiologist" unless the health care practitioner is licensed as an allopathic physician under chapter 458, F.S., an osteopathic physician under chapter 459, F.S., or a dentist under chapter 466, F.S. The bill also prohibits a health care practitioner from using the title "dermatologist" unless the health care practitioner is licensed as an allopathic physician under chapter 458, F.S., an osteopathic physician under chapter 459, F.S.

The bill requires DOH, rather than the boards, to enforce the bill's provisions. The bill requires DOH to issue an emergency order to cease and desist to a health care practitioner who violates the bill's provisions. DOH must send the emergency order to the health care practitioner's email address and by certified mail to the practitioner's physical address, and to any other address at which the practitioner may be reached. DOH must issue an order imposing a citation and daily fine, reprimand or letter of concern, or suspension of license, if the health care practitioner does not immediately correct the violation upon receipt of the emergency cease and desist order.

The bill takes effect upon becoming law.

B. SECTION DIRECTORY:

Section 1 Amends s. 456.072, F.S., relating to grounds for discipline; penalties; enforcement.
Section 2 Provides an effective date of upon becoming law.

[71] Section 120.60(5), F.S.
[72] Id.
[73] Section 120.60(6), F.S.
[74] Id.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH may experience a recurring increase in workload associated with additional complaints, investigations, and prosecutions resulting from the bill. The extent to which such complaints, investigations, and prosecutions may materialize is unknown; therefore, the fiscal impact is indeterminate.[75]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care practitioners in violation of the restrictions in this bill may be subject to disciplinary actions and fines.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

No applicable. The bill does not appear to affect county of municipal governments.

2. Other:

The bill's requirement for DOH to enter an order imposing penalties if a person does not immediately comply with an emergency cease and desist order, in a manner that differs from procedures that provide due process under current law, may subject those provisions of the bill to challenge as a violation of the licensee's due process rights under the Florida Constitution and the United States Constitution.

B. RULE-MAKING AUTHORITY:

Current law provides sufficient rulemaking authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

DOH advises that while the bill focuses on a practitioner's misuse of a specialty designation as grounds for discipline, the term "specialty designation" is not defined in the bill or in existing statute and is not a term used in the ordinary course of health care practitioner regulation. Absent a definition or guidelines about what constitutes a misrepresentation, the bill's new grounds for discipline are so vague as to be

[75] Department of Health, Agency Analysis of 2021 House Bill 721 (March 20, 2021).

unenforceable, according to DOH. While some physicians hold board certifications in their specialty areas from the American Board of Medical Specialties or the American Osteopathic Association, not all specialists hold or maintain such credentials. Health care providers who participate in Medicare typically have a specialty designation under which they bill for payment. It is unclear to DOH what credentials a practitioner must hold to use a "specialty designation" under the bill and when the use of such designation would be considered misleading or fraudulent.[76]

DOH also advises that, because the bill requires the department, not the applicable regulatory board, to impose discipline for violations of ss. 456.072(1)(a) and (t), F.S., the bill will require the creation of a new disciplinary process. DOH will need to create a unique procedure and tracking system for these specific charges. For all other disciplinary grounds, it is the board that issued the license that takes disciplinary action against that license. The bill would authorize DOH to suspend a practitioner's license without the involvement or input of the board that issued the license, which could be interpreted to conflict with current law regarding practitioner discipline.[77]

DOH further advises that, under the bill's requirement for DOH to issue an emergency order to cease and desist, the procedures for issuing such an order are unclear. Currently, when DOH issues an emergency order, it must show that allowing the practitioner to continue to practice would constitute an immediate serious danger to the health, safety, or welfare of the citizens of Florida and that nothing short of the emergency action would protect citizens from that danger, as required under s. 120.60(6), F.S. It is unclear to DOH how these requirements would be met under the circumstances specified in the bill.[78]

DOH further advises that the bill's requirement for the department to enter an order imposing penalties if a person does not immediately comply with an emergency cease and desist order may conflict with s. 456.073(5), F.S., which provides that a formal hearing must be held before an administrative law judge in disciplinary matters if there are material issues of disputed fact. This portion of the bill may also conflict with s. 120.60(5), F.S., which provides that no revocation, suspension, annulment, or withdrawal of any license is lawful unless, prior to the entry of the order, the governmental agency has served, by personal service or certified mail, an administrative complaint which affords reasonable notice to the licensee of facts or conduct which warrant the intended action and the licensee has been given an adequate opportunity to request a proceeding pursuant to ss. 120.569 and 120.57, F.S.[79]

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[76] Id.

[77] Id. Sections 456.073(1) and (2), F.S., provide that the DOH investigates complaints and violations of the grounds for discipline and provides the completed investigative report to the probable cause panel of the appropriate regulatory board. The statute provides for the report to be sent to the department only when there is no board for the profession in question. Section 456.073(4), F.S., provides that the determination of the existence of probable cause is made by the probable cause panel and that the DOH determines probable cause only if there is no board. And, s. 456.073(6), F.S., provides that the appropriate board issues the final order in each health care professional disciplinary case, unless there is no board, in which case the DOH would issue the final order.

[78] *Supra*, note 75.

[79] Id.

A bill to be entitled

An act relating to prohibited acts by health care practitioners; amending s. 456.072, F.S.; prohibiting specified acts by health care practitioners relating to specialty designations; authorizing the Department of Health to enforce compliance with the act; authorizing the department to take specified disciplinary action against health care practitioners in violation of the act; specifying applicable administrative penalties; providing an effective date.

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

Section 1. Paragraphs (a) and (t) of subsection (1) and subsection (2) of section 456.072, Florida Statutes, are amended to read:

456.072 Grounds for discipline; penalties; enforcement.—

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(a) Making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession or specialty designation. The term "anesthesiologist" may be used only if the practitioner is licensed as a physician under chapter 458 or chapter 459 or as a dentist under chapter

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

466, and the term "dermatologist" may be used only if the practitioner is licensed as a physician under chapter 458 or chapter 459.

(t) Failing to identify through written notice, which may include the wearing of a name tag, or orally to a patient the type of license or specialty designation under which the practitioner is practicing. Any advertisement for health care services naming the practitioner must identify the type of license the practitioner holds. This paragraph does not apply to a practitioner while the practitioner is providing services in a facility licensed under chapter 394, chapter 395, chapter 400, or chapter 429. The department shall enforce this paragraph ~~Each board, or the department where there is no board, is authorized by rule to determine how its practitioners may comply with this disclosure requirement~~.

(2)(a) When the board, or the department when there is no board, finds any person guilty of the grounds set forth in subsection (1) or of any grounds set forth in the applicable practice act, including conduct constituting a substantial violation of subsection (1) or a violation of the applicable practice act which occurred before ~~prior to~~ obtaining a license, it may enter an order imposing one or more of the following penalties:

1.~~(a)~~ Refusal to certify, or to certify with restrictions, an application for a license.

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2. ~~(b)~~ Suspension or permanent revocation of a license.

3. ~~(c)~~ Restriction of practice or license, including, but not limited to, restricting the licensee from practicing in certain settings, restricting the licensee to work only under designated conditions or in certain settings, restricting the licensee from performing or providing designated clinical and administrative services, restricting the licensee from practicing more than a designated number of hours, or any other restriction found to be necessary for the protection of the public health, safety, and welfare.

4. ~~(d)~~ Imposition of an administrative fine not to exceed $10,000 for each count or separate offense. If the violation is for fraud or making a false or fraudulent representation, the board, or the department if there is no board, must impose a fine of $10,000 per count or offense.

5. ~~(e)~~ Issuance of a reprimand or letter of concern.

6. ~~(f)~~ Placement of the licensee on probation for a period of time and subject to such conditions as the board, or the department when there is no board, may specify. Those conditions may include, but are not limited to, requiring the licensee to undergo treatment, attend continuing education courses, submit to be reexamined, work under the supervision of another licensee, or satisfy any terms which are reasonably tailored to the violations found.

7. ~~(g)~~ Corrective action.

8.~~(h)~~ Imposition of an administrative fine in accordance with s. 381.0261 for violations regarding patient rights.

9.~~(i)~~ Refund of fees billed and collected from the patient or a third party on behalf of the patient.

10.~~(j)~~ Requirement that the practitioner undergo remedial education.

In determining what action is appropriate, the board, or department when there is no board, must first consider what sanctions are necessary to protect the public or to compensate the patient. Only after those sanctions have been imposed may the disciplining authority consider and include in the order requirements designed to rehabilitate the practitioner. All costs associated with compliance with orders issued under this subsection are the obligation of the practitioner.

(b)1. When the department finds that a person has violated paragraph (1)(a), the department must issue an emergency order to the person to cease and desist the use of the name or title, or any other words, letters, abbreviations, or insignia indicating that he or she may practice under the specialty designation. The department must send the emergency cease and desist order to the person by certified mail and e-mail to the person's physical address and e-mail address of record on file with the department and to any other mailing address or e-mail address through which the department believes the person may be

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

reached.

2. If the person does not cease and desist his or her actions in violation of paragraph (1)(a) immediately upon receipt of the emergency cease and desist order, the department must enter an order imposing any of the following penalties, or a combination thereof, until the person complies with the cease and desist order:

a. A citation and a daily fine.

b. A reprimand or a letter of concern.

c. Suspension of license.

Section 2. This act shall take effect upon becoming a law.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION

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

Committee/Subcommittee hearing bill: Professions & Public Health Subcommittee

Representative Smith, C. offered the following:

Amendment (with directory amendment)

Between lines 40 and 41, insert:

(rr) Knowingly using the name or title "anesthetist" unless that person is a certified registered nurse anesthetist under s. 464.012.

Remove line 92 and insert:

paragraph (1)(a) or paragraph (1)(rr), the department must issue an emergency order

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D I R E C T O R Y A M E N D M E N T

Remove line 15 and insert:

subsection (2) of section 456.072, Florida Statutes, are amended, and paragraph (rr) is added to subsection (1) of that section,

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 949 Communicable and Infectious Diseases
SPONSOR(S): Fetterhoff and Omphroy
TIED BILLS: **IDEN./SIM. BILLS:** HB 963, SB 1314, SB 1422

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Government Operations Subcommittee	14 Y, 0 N	Villa	Smith
2) Professions & Public Health Subcommittee		Guzzo	McElroy
3) Appropriations Committee			
4) State Affairs Committee			

SUMMARY ANALYSIS

Any person employed full time by the state or a political subdivision as a firefighter, paramedic, emergency medical technician, law enforcement officer, or correctional officer who suffers a condition caused by hepatitis, meningococcal meningitis, or tuberculosis that results in total or partial disability or death is presumed to have a disability suffered in-the-line-of-duty and is therefore entitled to certain higher benefits. This presumption can be defeated by competent evidence to the contrary.

The bill adds an “infectious disease” to the list of diseases that, if suffered by an emergency rescue or public safety worker, is presumed to have been suffered in-the-line-of-duty. The bill defines “infectious disease” to mean any condition or impairment of health caused by a disease that has been declared a public health emergency by the State Health Officer.

In order to be entitled to the presumption, the bill requires the emergency rescue or public safety worker to submit a written declaration under penalty of perjury verifying that, to the best of his or her knowledge, he or she contracted the infectious disease during a public health emergency and was not exposed to any person known to have the infectious disease outside the scope of his or her employment.

The bill specifies that the vaccine or immunization that an emergency rescue or public safety worker may be required by their employer to receive in order to enjoy the presumption must be approved by the United States Food and Drug Administration.

The bill requires an emergency rescue or public safety worker to file an incident or accident report with his or her employer for each instance of known or suspected occupational exposure to an infectious disease.

The bill may have a fiscal impact on the state and local governments. *See* Fiscal Comments section.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Workers' Compensation Insurance

Under ch. 440, F.S., which relates to workers' compensation, an employer must pay compensation or furnish benefits if an employee suffers an accidental compensable injury or death arising out of work performed in the course and scope of employment.[1] The injury, its occupational cause, and any resulting disability must be established to a reasonable degree of medical certainty, and the accidental compensable injury must be the major contributing cause of any resulting injury.[2]

Compensation for permanent total disability is equal to 66 2/3 percent of the employee's average weekly wages payable to the employee during the continuance of the total disability.[3] In addition, an employee will generally receive an annual supplemental income benefit equal to 3 percent per year of the compensation payment, multiplied by the number of calendar years since the date of the injury, until age 62.[4]

Compensation for temporary total disability is equal to 66 2/3 percent of the employee's average weekly wages payable to the employee during the continuance of the total disability, but payment may not exceed 104 weeks. At the earlier of the 104th week or the employee reaching maximum medical improvement, the temporary disability payment will cease and the injured employee's permanent impairment will be determined.[5]

Where the disability or death of an employee results from an "occupational disease," it will be treated as an injury by accident.[6] The employee or his or her survivors will be entitled to compensation. "Occupational disease" is defined to mean "only a disease for which there are epidemiological studies showing that exposure to the specific substance involved, at the levels to which the employee was exposed, may cause the precise disease sustained by the employee."[7]

An accidental compensable injury must be the major contributing cause of any resulting injury, meaning that the cause must be more than 50 percent responsible for the injury as compared to all other causes combined, as demonstrated by medical evidence only. For an injury or disease involving an occupational disease or repetitive exposure, both causation and sufficient exposure to support causation must be proven by clear and convincing evidence.[8]

Florida Retirement System

The Florida Retirement System (FRS) was established in 1970 when the Legislature consolidated the Teachers' Retirement System, the State and County Officers and Employees' Retirement System, and the Highway Patrol Pension Fund. In 1972, the Judicial Retirement System was consolidated into the FRS, and in 2007, the Institute of Food and Agricultural Sciences Supplemental Retirement Program was consolidated into the FRS as a closed group.[9]

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[1] Section 440.09(1), F.S.
[2] *Id.*
[3] Section 440.15(1)(a), F.S.
[4] Section 440.15(1)(f), F.S.
[5] Section 440.15(2)(a), F.S.
[6] Section 440.151(1)(a), F.S.
[7] Section 440.151(2), F.S.
[8] Section 440.09(1), F.S.
[9] *Florida Retirement System Pension Plan and Other State Administered Systems Comprehensive Annual Financial Report Fiscal Year 2019-2020,* at 35. A copy of the report can be found at: https://www.dms.myflorida.com/workforce_operations/retirement/publications/annual_reports.

The Florida Retirement System Act[10] governs the FRS, which is a multi-employer, contributory plan that provides retirement income benefits to 644,338 active members,[11] 432,258 annuitants, 15,512 disabled retirees, and 33,593 active participates of the Deferred Retirement Option Program.[12] It is the primary retirement plan for employees of state and county government agencies, district school boards, community colleges, and universities. Municipalities, independent special districts, metropolitan planning districts, and public charter schools may elect to participate in the FRS. Such election is irrevocable.[13] The FRS also serves as the retirement plan for participating employees of the 177 cities and 149 special districts that have elected to join the system.[14]

Membership in the FRS is compulsory for all full-time and part-time employees working in regularly established positions for covered employers.

The FRS is managed by the Department of Management Services and the State Board of Administration.

Class Structure
The membership of the FRS is divided into five membership classes. The five membership classes include:

- Regular Class[15] has 557,754 members;
- Special Risk Class[16] has 76,343 members;
- Special Risk Administrative Support Class[17] has 108 members;
- Elected Officers' Class[18] has 2,153 members; and
- Senior Management Service Class[19] has 7,980 members.[20]

Each class is funded separately based upon the costs attributable to the members of that class.

Plan Options
Members of the FRS have two primary plan options available for participation:

- The investment plan, which is a defined contribution plan; and
- The pension plan, which is a defined benefit plan.

Regardless of whether the member elects to participate in the pension plan or the investment plan, the member must contribute three percent of the member's salary.[21]

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[10] *See* ch. 121, F.S.
[11] As of June 30, 2020, the FRS pension plan, which is a defined benefit plan, had 479,043 members, and the investment plan, which is a defined contribution plan, had 165,295 members.
[12] *Annual Report, supra* note 1, at 160.
[13] *See* s. 121.051(2), F.S.
[14] *Annual Report, supra* note 1, at 195.
[15] Regular Class members are those members who do not qualify for membership in the other classes within the FRS. Section 121.021(12), F.S.
[16] Special Risk Class members include law enforcement officers, firefighters, correctional officers, probation officers, paramedics, and emergency medical technicians, among others. Section 121.0515, F.S.
[17] Special Risk Administrative Support Class members are former members of the Special Risk Class who are transferred or reassigned to an administrative support position in certain circumstances. Section 121.0515(8), F.S.
[18] Membership in the Elected Officers' Class is comprised of those participants who hold specified elective offices in either state or local government. Section 121.052, F.S.
[19] Senior Management Service Class members generally are high level executive and legal staff or as specifically provided in law. Section 121.055, F.S.
[20] All figures from *Annual Report, supra* note 3, at 161.
[21] Prior to 1975, members of the FRS were required to make employee contributions of either 4 percent for Regular Class employees or 6 percent for Special Risk Class members. Employees were again required to contribute to the system after July 1, 2011.

Certain members, as specified by law, may, in lieu of FRS participation, participate in optional retirement plans, which include the Senior Management Service Optional Annuity Program, State Community College System Optional Retirement Program, and the State University System Optional Retirement Program.

Special Risk Class
The Special Risk Class of the FRS consists of state and local government employees who meet the criteria for special risk membership. The class covers persons employed in law enforcement, firefighting, criminal detention, and emergency and forensic medical care who meet the statutory criteria.[22]

When originally establishing the Special Risk Class of membership in the FRS, the Legislature recognized that persons employed in certain categories of positions:

> are required as one of the essential functions of their positions to perform work that is physically demanding or arduous, or work that requires extraordinary agility and mental acuity, and that such persons, because of diminishing physical and mental faculties, may find that they are not able, without risk to the health and safety of themselves, the public, or their coworkers, to continue performing such duties and thus enjoy the full career and retirement benefits enjoyed by persons employed in other membership classes and that, if they find it necessary, due to the physical and mental limitations of their age, to retire at an earlier age and usually with less service, they will suffer an economic deprivation therefrom.[23]

Compared to the Regular Class members, a person who is a member in the Special Risk Class earns a higher annual service accrual rate, may retire at an earlier age, and is eligible to receive higher disability and death benefits. As a result, the contribution rates to fund the normal cost of the special risk benefits are higher than the contribution rates to fund the normal cost of the Regular Class benefits. Similarly, the contribution rates to fund the unfunded liabilities of the Special Risk Class are higher than those contribution rates for the Regular Class.

Disability Retirement Benefits for Special Risk Members of the FRS
There are two types of disability retirement available under the FRS: regular disability retirement and in-the-line-of-duty disability retirement. To qualify for either type of disability retirement, members must be totally and permanently disabled to the extent that they are unable to work.[24] An employee who is physically or mentally unable to continue performing in his or her present occupation, but is able to perform another type of work, will not qualify for disability benefits.[25]

To be eligible for regular disability retirement under the FRS, a member must complete eight years of creditable service.[26] Under the FRS Pension Plan, the minimum benefit under regular disability retirement, regardless of class, is 25 percent of the employee's average final compensation.[27] In contrast, in-the-line-of-duty disability benefits are available to members on their first day of employment. There is no vesting period. Special Risk Class members receive a minimum in-the-line-of-duty disability benefit of 65 percent of their average final compensation.[28] Members in all other classes are eligible to receive a minimum in-the-line-of-duty disability benefit of 42 percent of their average final compensation.[29]

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[22] *See* s. 121.0515, F.S.
[23] Section 121.0515(1), F.S.
[24] Section 121.091(4), F.S.
[25] Florida Retirement System Employer Handbook, Disability Retirement, ch. 10, available at https://www.rol.frs.state.fl.us/forms/EH_ch10.pdf.
[26] Sections 121.091(4)(a) and 121.591(2)(b)2., F.S.
[27] Section 121.091(4)(f), F.S.
[28] *Id.*
[29] *Id.*

Under the FRS Investment Plan, the disability benefits are provided in lieu of the normal retirement benefits (the accumulations of contributions and investment earnings in the member's retirement account).[30] To receive the disability benefits, the member must transfer all of his or her accumulations to the investment plan disability account. The member will then receive a monthly benefit calculated the same as a similarly situated pension plan member.[31]

Death Benefits for Special Risk Members of the FRS
If a member of the FRS is terminated by reason of death prior to becoming vested in the FRS, the member's beneficiary is only entitled to the member's accumulated contributions.[32] Under the pension plan, if the member is vested at the time of his or her death, the member's joint annuitant[33] is entitled to receive the optional form[34] of payment for the annuitant's lifetime.[35] If the designated beneficiary does not qualify as a joint annuitant, the member's beneficiary is only entitled to the return of the member's personal contributions, if any.[36]

The FRS currently provides death benefits for surviving spouses and/or eligible dependents of active members of the pension plan. Death benefits may be paid for an active member of the FRS Pension Plan who dies before retirement due to an injury or illness.[37] If the injury or illness arises out of and in the actual performance of duties required by a member's job, the member's surviving spouse and/or eligible dependent(s) are entitled to in-the-line-of-duty death benefits. These in-the-line-of-duty death benefits are also available to members of the investment plan if the member's beneficiary elects to transfer the accumulations in the member's investment plan account to the pension fund.[38]

If an FRS member who is not in the Special Risk Class dies in the line of duty, the surviving spouse of the member is entitled to receive a monthly benefit equal to one-half of the monthly salary being received by the member at the time of death for the rest of the surviving spouse's lifetime.[39] If there is no surviving spouse or the surviving spouse dies, the member's children under 18 years of age and unmarried may receive the benefits until the youngest child's 18th birthday.[40]

If an FRS member who is in the Special Risk Class dies in the line of duty, the member's surviving spouse and children are eligible to receive a monthly payment equal to the member's total monthly salary at the time of death.[41] These benefits may be extended to the 25th birthday of an unmarried child enrolled as a full time student if there is no surviving spouse or the surviving spouse dies.[42]

Presumptions and Burdens of Proof Relating to in-the-line-of-duty Disability and Death
An FRS member has the burden of proof when claiming in-the-line-of-duty disability or death benefits. The member must show by competent medical evidence that the death or disability occurred in-the-line-of-duty in order to receive the higher benefits. If the employee or the employee's survivors cannot

[30] Section 121.591(2), F.S.
[31] Section 121.591(2)(g), F.S.
[32] For purposes of disbursement of benefits, a member is considered retired as of the date of the death.
[33] A joint annuitant is considered to be the member's spouse, natural or legally adopted child who is either under age 25 or is physically or mentally disabled and incapable of self-support (regardless of age), or any person who is financially dependent upon the member for one-half or more of his or her support and is the member's parent, grandparent, or person for whom the member is the legal guardian. Section 121.021(28), F.S.
[34] Under the pension plan, a member has a choice of payment options. If the member dies prior to retirement, the member's joint annuitant is entitled to select either to receive the member's contributions or a reduced monthly benefit payment for life.
[35] Section 121.091(7)(b)1., F.S.
[36] Section 121.091(7)(b)2., F.S.
[37] Section 121.091(7), F.S.
[38] Section 121.591(4), F.S.
[39] Section 121.091(7)(d)1., F.S.
[40] Section 121.091(7)(d)2. and 3., F.S.
[41] Section 121.091(7)(i), F.S.
[42] *Id.*

meet the burden of proof, the employee or the employee's survivors are entitled only to the lesser benefits available under regular death or disability

An FRS member employed as an emergency rescue or public safety worker[43] who suffers a condition caused by hepatitis, meningococcal meningitis, or tuberculosis that results in total or partial disability or death is presumed to have a disability suffered in-the-line-of-duty and to be entitled to the higher benefits.[44] The presumption can be defeated by competent evidence to the contrary.

In order to be eligible for the presumption, the member, prior to diagnoses, must have undergone test for the disease, which fail to indicate the presence of the infection. A prior negative test is not required, however, in the case of meningococcal meningitis. In addition, the member must sign a written declaration under penalty of perjury verifying he or she has not:

- In the case of a medical condition caused by hepatitis:
    - Been exposed to any person known to have sickness or medical conditions derived from hepatitis, outside the scope of his or her employment;
    - Had a blood transfer, other than a transfusion arising out of an accident or injury happening in connection with his or her employment;
    - Engaged in unsafe sexual practices or other high-risk behavior; or
    - Used intravenous drugs not prescribed by a physician.
- In the case of meningococcal meningitis, in the last 10 days, has not been exposed outside of the scope of his or her employment to any person known to have meningococcal meningitis or known to be an asymptomatic carrier of the disease; and
- In the case of tuberculosis, since the member's last negative tuberculosis skin test, has not been exposed outside of the scope of his or her employment to any person known by the member to have tuberculosis.[45]

If medically indicated in the given circumstances pursuant to the immunization policies established by the Advisory Committee on Immunization Practices of the United States Public Health Service,[46] whenever a medically recognized vaccine or other form of immunization exists for the above mentioned communicable diseases, the emergency rescue or public safety worker may be required by his or her employer to undergo the immunization, unless the member's physician determines in writing that the immunization would pose a significant risk to the member's health.[47] Absent such written declaration, failure or refusal to undergo immunization disqualifies the member from the benefits of the presumption.

An emergency rescue or public safety worker is required to file an incident report with his or her employer for every known or suspected occupational exposure to hepatitis, meningococcal meningitis, or tuberculosis. An employing agency must maintain a record of such exposures, and notify any employee that may have been exposed.[48]

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[43] "Emergency rescue or public safety worker" means any person employed full time by the state or any political subdivision of the state as a firefighter, paramedic, emergency medical technician, law enforcement officer, or correctional officer who, in the course of employment, runs a high risk of occupational exposure to hepatitis, meningococcal meningitis, or tuberculosis and who is not employed elsewhere in a similar capacity. However, the term "emergency rescue or public safety worker" does not include any person employed by a public hospital licensed under chapter 395 or any person employed by a subsidiary thereof. Section 112.181(1)(b), F.S.

[44] Section 112.181(2), F.S.

[45] *Id.*

[46] The Advisory Committee on Immunization Practices comprises medical and public health experts who develop recommendations on the use of vaccines in the civilian population of the United States. The recommendations stand as public health guidance for safe use of vaccines and related biological products. Center for Disease Control and Prevention, *Advisory Committee on Immunization Practices (ACIP)*, https://www.cdc.gov/vaccines/acip/committee/index.html (last visited March 17, 2021).

[47] Section 112.181(3), F.S.

[48] Section 112.181(5), F.S.

Effect of the Bill

The bill adds an "infectious disease" to the list of diseases that, if suffered by an emergency rescue or public safety worker, is presumed to have been suffered in-the-line-of-duty thereby entitling the worker to higher death or disability benefits, unless the contrary can be shown by competent evidence. The bill defines "infectious disease" to mean any condition or impairment of health caused by a disease that has been declared a public health emergency by the State Health Officer.[49]

In order to be entitled to the presumption, the bill requires the emergency rescue or public safety worker to submit a written declaration under penalty of perjury verifying that, to the best of his or her knowledge, he or she contracted the infectious disease during a public health emergency declared by the State Health Officer and was not exposed, outside of the scope of his or her employment, to any person known to have the infectious disease.

The bill specifies that the vaccine or immunization that an emergency rescue or public safety worker may be required by their employer to receive in order to enjoy the presumption must be approved by the United State Food and Drug Administration.

The bill requires an emergency rescue or public safety worker to file an incident or accident report with his or her employer for each instance of known or suspected occupational exposure to an infectious disease.

The bill specifies that similar to meningococcal meningitis, an emergency rescue or public safety worker is not required to undergo test, prior to diagnosis, which fail to indicate the presence of the infection in order to enjoy the presumption.

B. SECTION DIRECTORY:

Section 1 amends s. 112.81, F.S., to add "infectious diseases" to the list of diseases that are presumed to have been suffered in-the-line-of-duty for certain workers.

Section 2 provides an effective date of July 1, 2021.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   See fiscal comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

[49] The State Health Officer is responsible for declaring public health emergencies, issuing public health advisories, and ordering isolation or quarantines. A "public health emergency" means any occurrence, or threat thereof, whether natural or manmade, which results or may result in substantial injury or harm to the public health from infectious disease, chemical agents, nuclear agents, biological toxins, or situations involving mass casualties or natural disasters. Before declaring a public health emergency, the State Health Officer shall, to the extent possible, consult with the Governor and shall notify the Chief of Domestic Security. The declaration of a public health emergency shall continue until the State Health Officer finds that the threat or danger has been dealt with to the extent that the emergency conditions no longer exist and he or she terminates the declaration. However, a declaration of a public health emergency may not continue for longer than 60 days unless the Governor concurs in the renewal of the declaration. Section 381.00315(1)(c), F.S.

1. Revenues:

   None.

2. Expenditures:

   See fiscal comments.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

   None.

D. FISCAL COMMENTS:

   The bill adds a new subset of diseases that are presumed to be suffered in-the-line-of-duty for certain workers, thereby entitling those workers to higher disability and death benefits. Accordingly, more state and local government employees may qualify for enhanced workers' compensation or retirement benefits. The fiscal impact on the state and local governments is unknown at this time.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   The county/municipality mandates provision of Art. VII, s. 18, of the Florida Constitution may apply because this bill creates a new presumption for "infectious disease" that would be applicable to workers' compensation benefits paid to emergency rescue or public safety workers; however, an exemption may apply if the fiscal impact of the bill is insignificant. In addition, an exception may apply because all similarly situated state and local government employers of emergency rescue and public safety workers are required to provide the workers' compensation benefit. However, for this exception to apply, the bill must declare that it fulfills an important state interest.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

   The bill does not confer rulemaking authority nor require rulemaking.

C. DRAFTING ISSUES OR OTHER COMMENTS:

   None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

None.

A bill to be entitled

An act relating to communicable and infectious diseases; amending s. 112.181, F.S.; providing a definition; providing a presumption to specified workers that an impairment of health caused by an infectious disease happened in the line of duty; requiring certain actions in order to be entitled to the presumption; requiring the United States Food and Drug Administration to approve certain vaccines or immunizations; providing an effective date.

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

Section 1. Section 112.181, Florida Statutes, is amended to read:

112.181 Firefighters, paramedics, emergency medical technicians, law enforcement officers, correctional officers; special provisions relative to certain communicable and infectious diseases.—

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

(a) "Body fluids" means blood and body fluids containing visible blood and other body fluids to which universal precautions for prevention of occupational transmission of blood-borne pathogens, as established by the Centers for Disease Control and Prevention, apply. For purposes of potential

transmission of meningococcal meningitis or tuberculosis, the term "body fluids" includes respiratory, salivary, and sinus fluids, including droplets, sputum, and saliva, mucous, and other fluids through which infectious airborne organisms can be transmitted between persons.

(b) "Emergency rescue or public safety worker" means any person employed full time by the state or any political subdivision of the state as a firefighter, paramedic, emergency medical technician, law enforcement officer, or correctional officer who, in the course of employment, runs a high risk of occupational exposure to hepatitis, meningococcal meningitis, ~~or~~ tuberculosis, or an infectious disease and who is not employed elsewhere in a similar capacity. However, the term "emergency rescue or public safety worker" does not include any person employed by a public hospital licensed under chapter 395 or any person employed by a subsidiary thereof.

(c) "Hepatitis" means hepatitis A, hepatitis B, hepatitis non-A, hepatitis non-B, hepatitis C, or any other strain of hepatitis generally recognized by the medical community.

(d) "High risk of occupational exposure" means that risk that is incurred because a person subject to the provisions of this section, in performing the basic duties associated with his or her employment:

1. Provides emergency medical treatment in a non-health-care setting where there is a potential for transfer of body

fluids between persons;

2. At the site of an accident, fire, or other rescue or public safety operation, or in an emergency rescue or public safety vehicle, handles body fluids in or out of containers or works with or otherwise handles needles or other sharp instruments exposed to body fluids;

3. Engages in the pursuit, apprehension, and arrest of law violators or suspected law violators and, in performing such duties, may be exposed to body fluids; or

4. Is responsible for the custody, and physical restraint when necessary, of prisoners or inmates within a prison, jail, or other criminal detention facility, while on work detail outside the facility, or while being transported and, in performing such duties, may be exposed to body fluids.

(e) "Infectious disease" means any condition or impairment of health caused by a disease that has been declared a public health emergency in accordance with s. 381.00315.

(f) ~~(e)~~ "Occupational exposure," in the case of hepatitis, meningococcal meningitis, ~~or~~ tuberculosis, or an infectious disease, means an exposure that occurs during the performance of job duties that may place a worker at risk of infection.

(2) PRESUMPTION; ELIGIBILITY CONDITIONS.—Any emergency rescue or public safety worker who suffers a condition or impairment of health that is caused by hepatitis, meningococcal meningitis, ~~or~~ tuberculosis, or an infectious disease, that

requires medical treatment, and that results in total or partial disability or death is ~~shall be~~ presumed to have a disability suffered in the line of duty, unless the contrary is shown by competent evidence; however, in order to be entitled to the presumption, the emergency rescue or public safety worker must, by written affidavit as provided in s. 92.50, verify by written declaration that, to the best of his or her knowledge and belief:

(a) In the case of a medical condition caused by or derived from hepatitis, he or she has not:

1. Been exposed, through transfer of bodily fluids, to any person known to have sickness or medical conditions derived from hepatitis, outside the scope of his or her employment;

2. Had a transfusion of blood or blood components, other than a transfusion arising out of an accident or injury happening in connection with his or her present employment, or received any blood products for the treatment of a coagulation disorder since last undergoing medical tests for hepatitis, which tests failed to indicate the presence of hepatitis;

3. Engaged in unsafe sexual practices or other high-risk behavior, as identified by the Centers for Disease Control and Prevention or the Surgeon General of the United States, or had sexual relations with a person known to him or her to have engaged in such unsafe sexual practices or other high-risk behavior; or

4. Used intravenous drugs not prescribed by a physician.

(b) In the case of meningococcal meningitis, in the 10 days immediately preceding diagnosis he or she was not exposed, outside the scope of his or her employment, to any person known to have meningococcal meningitis or known to be an asymptomatic carrier of the disease.

(c) In the case of tuberculosis, in the period of time since the worker's last negative tuberculosis skin test, he or she has not been exposed, outside the scope of his or her employment, to any person known ~~by him or her~~ to have tuberculosis.

(d) In the case of an infectious disease, he or she contracted the infectious disease during a public health emergency declared in accordance with s. 381.00315 and was not exposed, outside of the scope of his or her employment, to any person known to have the infectious disease.

(3) IMMUNIZATION.—Whenever any standard, medically recognized vaccine, or other form of immunization or prophylaxis exists for the prevention of a communicable or infectious disease for which a presumption is granted under this section, if medically indicated in the given circumstances under the ~~pursuant to~~ immunization policies established by the Advisory Committee on Immunization Practices of the United States Public Health Service and if the vaccine or immunization has been approved by the United States Food and Drug Administration, an

emergency rescue or public safety worker may be required by his or her employer to undergo the immunization or prophylaxis unless the worker's physician determines in writing that the immunization or other prophylaxis would pose a significant risk to the worker's health. Absent such written declaration, failure or refusal by an emergency rescue or public safety worker to undergo such immunization or prophylaxis disqualifies the worker from the benefits of the presumption.

(4) LIFE AND DISABILITY INSURANCE COVERAGE.—This section does not apply to benefits payable under or granted in a noncompulsory policy of life insurance or disability insurance, unless the insurer and insured have negotiated for such additional benefits to be included in the policy contract. However, the state or any political subdivision of the state may negotiate a policy contract for life and disability insurance which includes accidental death benefits or double indemnity coverage for any condition or impairment of health suffered by an emergency rescue or public safety worker, which condition or impairment is caused by a disease described in this section and results in total or partial disability or death.

(5) RECORD OF EXPOSURES.—The employing agency shall maintain a record of any known or reasonably suspected exposure of an emergency rescue or public safety worker in its employ to the diseases described in this section and shall immediately notify the employee of such exposure. An emergency rescue or

public safety worker shall file an incident or accident report with his or her employer of each instance of known or suspected occupational exposure to hepatitis infection, meningococcal meningitis, ~~or~~ tuberculosis, or an infectious disease.

(6) REQUIRED MEDICAL TESTS; PREEMPLOYMENT PHYSICAL.—In order to be entitled to the presumption provided by this section:

(a) An emergency rescue or public safety worker must, prior to diagnosis, have undergone standard, medically acceptable tests for evidence of the communicable disease for which the presumption is sought, or evidence of medical conditions derived therefrom, which tests fail to indicate the presence of infection. This paragraph does not apply in the case of meningococcal meningitis or an infectious disease.

(b) On or after June 15, 1995, an emergency rescue or public safety worker may be required to undergo a preemployment physical examination that tests for and fails to reveal any evidence of hepatitis or tuberculosis.

(7) DISABILITY RETIREMENT.—This section does not change the basic requirements for determining eligibility for disability retirement benefits under the Florida Retirement System or any pension plan administered by this state or any political subdivision thereof, except to the extent of affecting the determination as to whether a member was disabled in the line of duty or was otherwise disabled.

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

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for HB 957 Hearing Aid Consultations and Sales
SPONSOR(S): Professions & Public Health Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Professions & Public Health Subcommittee		Guzzo	McElroy

SUMMARY ANALYSIS

A person who is not able to hear as well as someone with normal hearing, hearing thresholds of 20 decibels or better in both ears, has hearing loss. In the United States, approximately 15% of adults (37.5 million) report some difficulty hearing and 29 million adults could benefit from hearing aids. In 2019, there were 372,111 people with a hearing disability in Florida.

The Board of Speech-Language Pathology & Audiology within the Department of Health (DOH) is responsible for licensing, monitoring, disciplining and educating audiologists. The practice of audiology includes the application of principles, methods, and procedures for the prevention, identification, evaluation, consultation, habilitation, rehabilitation, instruction, treatment, and research, relative to hearing and the disorders of hearing.

The Board of Hearing Aid Specialists within DOH is responsible for licensing, monitoring, disciplining and educating hearing aid specialists. A licensed hearing aid specialist may practice the dispensing of hearing aids, which includes: conducting and interpreting hearing tests for purposes of selecting suitable hearing aids; making ear molds or ear impressions; providing appropriate counseling; and all acts pertaining to the selling, renting, leasing, pricing, delivery, and warranty of hearing aids.

Audiologists and hearing aid specialists are authorized to conduct and interpret hearing tests and to dispense hearing aids if necessary. Both audiologists and hearing aid specialists are authorized to utilize telehealth to provide audiology services. However, current law prohibits any person from selling or distributing hearing aids through the mail to the ultimate consumer. A violation of the mailing prohibition constitutes a second-degree misdemeanor which is punishable by up to 60 days imprisonment and carries a fine of up to $500. This creates a barrier for audiologists and hearing aid specialists to utilize telehealth to provide audiology services.

PCS for HB 957 repeals sections of law, s. 468.1265, F.S., and s. 484.054, F.S., that prohibit individuals from selling or distributing hearing aids through the mail to the ultimate consumer. This removes a key barrier for audiologists and hearing aid specialists to utilize telehealth to provide audiology services to individuals with hearing loss.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Hearing Loss

A person who is not able to hear as well as someone with normal hearing – hearing thresholds of 20 decibels or better in both ears – is said to have hearing loss.[1] There are four types of hearing loss:[2]

- **Conductive Hearing Loss** – Occurs when something prevents sounds from getting through the outer or middle ear.
- **Sensorineural Hearing Loss** - Occurs when there is a problem in the way the inner ear or hearing nerve works.
- **Mixed Hearing Loss** - Hearing loss that includes both a conductive and a sensorineural hearing loss.
- **Auditory Neuropathy Spectrum Disorder** - Hearing loss that occurs when sound enters the ear normally, but because of damage to the inner ear or the hearing nerve, sound is not organized in a way that the brain can understand.

In the United States, approximately 15% of adults (37.5 million) report some difficulty hearing and 29 million adults could benefit from hearing aids.[3] In 2019, there were 372,111 people with a hearing disability in Florida.[4]

Audiologists

The Board of Speech-Language Pathology & Audiology within the Department of Health (DOH) is responsible for licensing, monitoring, disciplining and educating audiologists.[5] The practice of audiology includes the application of principles, methods, and procedures for the prevention, identification, evaluation, consultation, habilitation, rehabilitation, instruction, treatment, and research, relative to hearing and the disorders of hearing.

In addition to conducting and interpreting hearing tests and dispensing hearing aids a licensed audiologist may also:[6]

- Offer, render, plan, direct, conduct, consult, or supervise certain services to individuals who have or are suspected of having hearing disorders, including:
  - Identification;
  - Evaluation;
  - Treatment;
  - Consultation;
  - Habilitation;

[1] World Health Organization, *Deafness and Hearing Loss,* Mar. 2, 2021, available at https://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss (last visited Mar. 29, 2021). "Disabling hearing loss" refers to hearing loss greater than 35 decibels in the better hearing ear.
[2] Centers for Disease Control and Prevention, *Types of Hearing Loss*, available at https://www.cdc.gov/ncbddd/hearingloss/types.html (last visited on March 30, 2021).
[3] United States Department of Health and Human Services, National Institute of Deafness and Other Communication Disorders, *Quick Statistics About Hearing*, available at https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing (last visited on March 30, 2021). A hearing aid is a small electronic device that goes in or behind an individual's ear to make sounds louder so the person can listen, communicate, and participate more fully in daily activities.
[4] Florida Department of Health – FLHealthCHARTS Community Health Assessment Resource Tool Set, *Census Population Under 18 with Hearing Disability, Census Population 18-64 with Hearing Disability, Hearing Disability 65-74, and Hearing Disability 75+*, available at http://www.flhealthcharts.com/charts/SearchResult.aspx (last visited Mar. 29, 2021).
[5] S. 468.1185, F.S.
[6] S. 468.1125(6)(b), F.S.

    - Rehabilitation;
    - Instruction; and
    - Research.
- Participate in hearing conservation, evaluation of noise environments, and noise control.
- Habilitate and rehabilitate, including, but not limited to, hearing aid evaluation, prescription, preparation, fitting, assistive listening device selection and orientation, auditory training, aural habilitation and rehabilitation, speech conservation, and speechreading;
- Fabricate ear molds;
- Evaluate tinnitus; and
- Provide speech and language screening, limited to a pass/fail determination for identifying individuals with disorders of communication.

Audiologists are required to follow certain minimum procedures and conduct certain tests when fitting a patient for a hearing aid, including:[7]

- Pure tone audiometric testing by air and bone to determine the type and degree of hearing deficiency when indicated;
- Effective masking when indicated; and
- Appropriate testing to determine speech reception thresholds, speech discrimination scores, the most comfortable listening levels, uncomfortable loudness levels, and the selection of the best fitting arrangement for maximum hearing aid benefit when indicated.

All audiometric tests must be conducted in a testing room that has been certified by DOH not to exceed certain sound pressure levels and specified frequencies.[8] An audiologist is required to perform a final fitting for a patient to ensure the physical and operational comfort of the hearing aid when indicated.[9]

Hearing Aid Specialists

The Board of Hearing Aid Specialists within DOH is responsible for licensing, monitoring, disciplining and educating hearing aid specialists. A licensed hearing aid specialist may practice the dispensing of hearing aids, which includes:[10]

- Conducting and interpreting hearing tests for purposes of selecting suitable hearing aids.
- Making ear molds or ear impressions;
- Providing appropriate counseling; and
- All acts pertaining to the selling, renting, leasing, pricing, delivery, and warranty of hearing aids.

Hearing aid specialists are required to follow certain minimum procedures and conduct certain tests when fitting a patient for a hearing aid, including:[11]

- Pure tone audiometric testing by air and bone to determine the type and degree of hearing deficiency;
- Effective masking when indicated; and
- Appropriate testing to determine speech reception thresholds, speech discrimination scores, the most comfortable listening levels, uncomfortable loudness levels, and the selection of the best fitting arrangement for maximum hearing aid benefit.

All audiometric tests must be conducted in a testing room that has been certified by DOH not to exceed certain sound pressure levels and specified frequencies.[12] A hearing aid specialist is required to perform a final fitting for a patient to ensure the physical and operational comfort of the hearing aid.[13]

[7] S. 468.1225(1), F.S.
[8] S. 468.1225(6), F.S.
[9] S. 468.1225(3), F.S.
[10] S. 484.045, F.S.
[11] S. 484.0501(1), F.S.
[12] S. 484.0501(6), F.S.
[13] S. 484.0501(3), F.S.

Telehealth for Audiologists and Hearing Aid Specialists

Florida licensed and Florida registered out-of-state audiologists and hearing aid specialists are authorized to utilize telehealth to provide audiology services.[14] However, current law prohibits any person from selling or distributing hearing aids through the mail to the ultimate consumer.[15] A violation of the mailing prohibition constitutes a second-degree misdemeanor which is punishable by up to 60 days imprisonment and carries a fine of up to $500.[16] This creates a barrier for audiologists and hearing aid specialists to utilize telehealth to provide audiology services.

Effect of the Bill

PCS for HB 957 repeals the sections of law, s. 468.1265, F.S., and s. 484.054, F.S., that prohibit individuals from selling or distributing hearing aids through the mail to the ultimate consumer. This removes a key barrier for audiologists and hearing aid specialists to utilize telehealth to provide audiology services to individuals with hearing loss.

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

B. SECTION DIRECTORY:

Section 1: Repeals ss. 468.1265 and 484.054, F.S.
Section 2: Provides an effective date of July 1, 2021.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

It is possible that allowing audiologists and hearing aid specialists to sell and distribute hearing aids through the mail will result in an indeterminate increase in their sales and revenue.

D. FISCAL COMMENTS:

None.

[14] S. 456.47(1)(b), F.S.
[15] SS. 468.1265, F.S., and 484.054, F.S.
[16] Id., and ss. 775.082(4)(b), F.S., and 775.083(1)(e), F.S.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No rule-making authority is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to hearing aid sales; repealing ss. 468.1265 and 484.054, F.S., relating to the sale or distribution of hearing aids through mail; providing an effective date.

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

Section 1. Sections 468.1265 and 484.054, Florida Statutes, are repealed.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1045 Delegation of the Administration of Prescription Medications
SPONSOR(S): Snyder
TIED BILLS: **IDEN./SIM. BILLS:** SB 1298

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Professions & Public Health Subcommittee		Rahming	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Certified nursing assistants (CNAs) and home-health aides (HHAs) assist older individuals and those with disabilities with daily tasks, such as dressing, bathing, and eating. Under current law, a CNA or HHA may administer oral, transdermal, ophthalmic, otic, rectal, inhaled, enteral, or topical prescription medications to a patient of a home health agency if a registered nurse delegates such tasks and the CAN or HHA:

- Has completed a 6-hour training course approved by the Board of Nursing; and
- Has been found competent to administer medication to a patient in a safe and sanitary manner.

A registered nurse or physician must conduct the training and determine whether the CNA or HHA can competently administer medication, and annually validate such competency. Current law requires the Board of Nursing and the Agency for Health Care Administration (AHCA) to adopt rules, in consultation with each other, on the standards and procedures that a CNA or HHA must follow for medication administration. Such rules must address qualifications for trainers, medication label requirements, documentation and recordkeeping, storage and disposal of medication, instructions for safe medication administration, informed consent, training curriculum, and validation procedures.

A registered nurse is prohibited from delegating the administration of medications listed as Schedule II, Schedule III, or Schedule IV controlled substances.

Under current law, a registered nurse is not authorized to delegate to a CNA or HHA medication administration to a patient of a nurse registry.

A nurse registry is an agency licensed to secure employment for registered nurses, licensed practical nurses, certified nursing assistants, home health aides, homemakers, and companions (caregivers) in a patient's home or with health care facilities or other entities. Caregivers referred for contract to a patient by a nurse registry are independent contractors not employees of the nurse registry. Nurse registries must advise patients that caregivers referred for contract are independent contractors and that the nurse registry is prohibited from monitoring, supervising, managing, or training caregivers.

HB 1045 authorizes a registered nurse to delegate to a CNA or HHA medication administration to a patient of a nurse registry. The bill requires the Board, in consultation with AHCA, to adopt rules on the standards and procedures that a CNA must follow for medication administration to a patient of a nurse registry.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Florida Direct Care Workers

Direct care workers assist older individuals and those with disabilities with daily tasks, such as dressing, bathing, and eating.[1] They work in many different settings, such as private homes, group homes, residential care facilities, assisted living facilities, skilled nursing facilities, and hospitals.[2] Direct care workers account for 70 to 80 percent of all paid hands-on long-term care and personal assistance for the elderly or disabled.[3]

Nursing Assistants or Nursing Aides

Nursing assistants or nursing aides generally work in nursing homes, although some work in assisted living facilities, other community-based settings, or hospitals.[4] The Florida Board of Nursing (Board), within the Department of Health, certifies nursing assistants (CNAs) who must, among other things, hold a high school diploma or equivalent, complete a 120-hour board-approved training program, and pass a nursing assistant competency exam.[5] The Board establishes the general scope of practice for CNAs, who perform services under the general supervision[6] of a registered nurse or licensed practical nurse.[7] A CNA may not work independently and may not perform any tasks that require specialized nursing knowledge, judgment, or skills.[8]

Home Health Aides

Home health aides (HHA) provide essentially the same care and services as nursing assistants, but they assist people in their homes or in community settings under the supervision of a nurse or a physical, speech, occupational, or respiratory therapist.[9] In Florida, HHAs are not licensed or certified. However, the Agency for Health Care Administration (AHCA) licenses home health agencies and establishes training requirements for HHAs employed by home health agencies. A HHA must complete at least 75 hours of training and/or successfully pass a competency evaluation by the home health agency.[10] HHAs who work for a home health agency that is not certified by Medicare or Medicaid or who work for a nurse registry must complete 40 hours of training or pass an AHCA-developed competency examination.[11]

Nurse Delegation of Duties

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[1] Paraprofessional Healthcare Institute, *Understanding the Direct Care Workforce*, available at https://phinational.org/policy-research/key-facts-faq/ (last visited Mar. 28, 2021).
[2] Paraprofessional Healthcare Institute, *Direct Care Workforce 2018 Year in Review*, https://phinational.org/resource/the-direct-care-workforce-year-in-review-2018/ (last visited Mar. 28, 2021), and Paraprofessional Healthcare Institute, *Who Are Direct-Care Workers?* https://phinational.org/wp-content/uploads/legacy/clearinghouse/NCDCW%20Fact%20Sheet-1.pdf (last visited Mar. 28, 2021).
[3] *Id*.
[4] Paraprofessional Healthcare Institute, *Who Are Direct-Care Workers?*, (Feb. 2011), available at https://phinational.org/wp-content/uploads/legacy/clearinghouse/NCDCW%20Fact%20Sheet-1.pdf (last visited Mar. 28, 2021).
[5] S. 464.203, F.S., and r. 64B9-15.006, F.A.C. Eighty hours must be classroom instruction and 40 hours must be clinical instruction, 20 of which must be in long term care clinical instruction in a licensed nursing home. 42 C.F.R. § 483.95 requires 75 hours of training; Florida training requirements exceed the federal minimum training requirements.
[6] Under general supervision, the registered nurse or licensed practical nurse does not need to be present but must be available for consultation and advice, either in person or by a communication device. R. 64B9-15.001(5), F.A.C
[7] R. 64B9-15.002, F.A.C.
[8] *Id.*
[9] *Supra* note 4. If the only service the home health agency provides is physical, speech, or occupational therapy, in addition to home health aide or CNA services, a licensed therapist may provide supervision. R. 59A-8.0095, F.A.C.
[10] Agency for Health Care Administration, *Home Health Aides,* available at https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Lab_HomeServ/HHA/Home_health_aides.shtml (last visited January 20, 2020).
[11] Rules 59A-8.0095(5)

Under current law, a registered nurse is authorized to delegate any task, including medication administration, to a CNA or HHA,[12] if the registered nurse determines that the CNA or HHA is competent to perform the task, the task is delegable under federal law, and the task:[13]

- Is within the nurse's scope of practice;
- Frequently recurs in the routine care of a patient or group of patients;
- Is performed according to an established sequence of steps;
- Involved little or no modification from one patient to another;
- May be performed with a predictable outcome;
- Does not inherently involve ongoing assessment, interpretation, or clinical judgement; and
- Does not endanger a patient's life or well-being.

Medication Administration

Medication administration is to obtain and provide a single dose of a medication to a patient for his or her consumption.[14] Currently, a CNA or HHA may administer oral, transdermal, ophthalmic, otic, rectal, inhaled, enteral, or topical prescription medications to a patient of a home health agency if a registered nurse delegates such tasks to the CNA and the CNA:[15]

- Has completed a 6-hour training course approved by the Board of Nursing; and
- Has been found competent to administer medication to a patient in a safe and sanitary manner.

A registered nurse or physician must conduct the training and determine whether the CNA or HHA can competently administer medication, and annually validate such competency.[16] Current law requires the Board and the AHCA to adopt rules, in consultation with each other, on the standards and procedures that a CNA or HHA must follow for medication administration to a patient of a home health agency.[17] Such rules must address qualifications for trainers, medication label requirements, documentation and recordkeeping, storage and disposal of medication, instructions for safe medication administration, informed consent, training curriculum, and validation procedures.[18]

A registered nurse is prohibited from delegating the administration of medications listed as Schedule II, Schedule III, or Schedule IV controlled substances.[19]

Under current law, a registered nurse is not authorized to delegate to a CNA or HHA medication administration to a patient of a nurse registry. Additionally, the Board and the AHCA are not required to adopt rules on the standards and procedures that a CNA must follow for medication administration to a patient of a nurse registry.

Nurse Registries

A nurse registry is an agency licensed to secure employment for registered nurses, licensed practical nurses, certified nursing assistants, home health aides, homemakers, and companions (caregivers) in a patient's home or with health care facilities or other entities.[20] Nurse registries are governed by part II of chapter 408, F.S.,[21] associated rules in Chapter 59A-35, F.A.C., and the nurse registry rules in Chapter 59A-18, F.A.C. A nurse registry must be licensed by the AHCA to offer contracts in Florida.[22]

[12] Ss. 400.489 and 464.2035, F.S. Home health aide includes those CNAs who work in positions that work as home health aides or equivalent positions.
[13] Ss. 400.489 and 464.0156, F.S.
[14] S. 465.003, F.S.
[15] Ss. 400.489(1) and 464.2035(1), F.S.
[16] *Id*.
[17] Ss. 400.489(3) and 464.2035(3), F.S.
[18] *Id*.
[19] S. 464.0156(1), F.S
[20] S. 400.462(21), F.S.
[21] S. 400.506(2), F.S. A nurse registry is also governed by the provisions in s. 400.506, F.S.
[22] S. 400.506(1), F.S.

A caregiver referred by a nurse registry for contract in a private residences who is not a nurse licensed under part I of chapter 464, such as a CNA or HHA, may only provide patient services or care for which they have been certified or trained to perform under current law or rules of the AHCA or the Department of Business and Professional Regulation.[23] Providing services beyond their authorized scope constitutes the unauthorized practice of medicine or a violation of the Nurse Practice Act and is subject to punishment as provided under current law.

A caregiver referred for contract to a patient by a nurse registry is an independent contractor not an employee of the nurse registry.[24] Nurse registries must advise patients that a caregiver referred for contract is an independent contractor and that the nurse registry is prohibited from monitoring, supervising, managing, or training the caregiver.[25]

Effect of Proposed Bill

HB 1045 authorizes a registered nurse to delegate to a CNA or HHA medication administration to a patient of a nurse registry. The bill requires the Board, in consultation with AHCA, to adopt rules on the standards and procedures that a CNA must follow for medication administration to a patient of a nurse registry.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 464.0156, relating to the delegation of duties.
Section 2: Amends s. 464.2035, relating to the administration of medication.
Section 3: Provides an effective date of July 1, 2021.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

[23] S. 400.506(7).
[24] S. 400.506(6)(d).
[25] S. 400.506(6)(e).

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to delegation of the administration of prescription medications; amending s. 464.0156, F.S.; authorizing a registered nurse to delegate the administration of certain duties for the care of a patient of a nurse registry; amending s. 464.2035, F.S.; authorizing certified nursing assistants to administer certain medication to patients of nurse registries under certain circumstances; conforming a provision to changes made by the act; providing an effective date.

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

Section 1. Subsection (2) of section 464.0156, Florida Statutes, is amended to read:

464.0156 Delegation of duties.—

(2) A registered nurse may delegate to a certified nursing assistant or a home health aide the administration of oral, transdermal, ophthalmic, otic, rectal, inhaled, enteral, or topical prescription medications to a patient of a home health agency or nurse registry~~,~~ if the certified nursing assistant or home health aide meets the requirements of s. 464.2035 or s. 400.489, respectively. A registered nurse may not delegate the administration of any controlled substance listed in Schedule

II, Schedule III, or Schedule IV of s. 893.03 or 21 U.S.C. s. 812.

Section 2. Subsections (1) and (3) of section 464.2035, Florida Statutes, are amended to read:

464.2035 Administration of medication.—

(1) A certified nursing assistant may administer oral, transdermal, ophthalmic, otic, rectal, inhaled, enteral, or topical prescription medication to a patient of a home health agency or nurse registry if the certified nursing assistant has been delegated such task by a registered nurse licensed under part I of this chapter, has satisfactorily completed an initial 6-hour training course approved by the board, and has been found competent to administer medication to a patient in a safe and sanitary manner. The training, determination of competency, and initial and annual validation required under this section must be conducted by a registered nurse licensed under this chapter or a physician licensed under chapter 458 or chapter 459.

(3) The board, in consultation with the Agency for Health Care Administration, shall establish by rule standards and procedures that a certified nursing assistant must follow when administering medication to a patient of a home health agency or nurse registry. Such rules must, at a minimum, address qualification requirements for trainers, requirements for labeling medication, documentation and recordkeeping, the storage and disposal of medication, instructions concerning the

safe administration of medication, informed-consent requirements and records, and the training curriculum and validation procedures.

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

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

COMMITTEE/SUBCOMMITTEE ACTION

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

Committee/Subcommittee hearing bill: Professions & Public Health Subcommittee

Representative Snyder offered the following:

Amendment (with title amendment)

Between lines 14 and 15, insert:

Section 1. Subsection (7) of section 400.506, Florida Statutes, is amended to read:

400.506 Licensure of nurse registries; requirements; penalties.—

(7) A person who is referred by a nurse registry for contract in private residences and who is not a nurse licensed under part I of chapter 464 may perform only those services or care to clients that the person has been certified to perform or trained to perform as required by law or rules of the Agency for Health Care Administration or the Department of Business and

Professional Regulation. Providing services beyond the scope authorized under this subsection constitutes the unauthorized practice of medicine or a violation of the Nurse Practice Act and is punishable as provided under chapter 458, chapter 459, or part I of chapter 464. If a licensed nurse registry authorizes a registered nurse to delegate tasks, including medication administration, to a certified nursing assistant pursuant to chapter 464 or to a home health aide pursuant to s. 400.490, the licensed nurse registry must ensure that such delegation meets the requirements of this chapter and chapter 464 and the rules adopted thereunder.

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

Remove line 3 and insert:

prescription medications; amending s. 400.464, F.S.; requiring a licensed nurse registry that authorizes a registered nurse to delegate tasks to a certified nursing assistant or a home health aide to ensure that certain requirements are met; amending s. 464.0156, F.S.;

PCS for HB 1091

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for HB 1091 Relating to Substance Abuse Prevention
SPONSOR(S): Professions & Public Health Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Professions & Public Health Subcommittee		Woodruff	McElroy

SUMMARY ANALYSIS

An estimated 53 million people worldwide use opioids. An overabundance of opioids in the body can lead to a fatal overdose. An opioid antagonist, such as Narcan, is a drug that blocks the effects of exogenously administered opioids. Opioid antagonists are used in opioid overdoses to counteract life-threatening depression of the central nervous system and respiratory system, allowing an overdose victim to breathe normally. In 2019, Florida reported 5,268 opioid overdose deaths. This was the second highest overdose death rate reported by any state.

Under current law, an authorized health care practitioner may prescribe and dispense an emergency opioid antagonist to a patient or caregiver, and pharmacists may dispense an emergency opioid antagonist pursuant to a prescription or pursuant to a non-patient-specific standing order. A patient or caregiver can store and possess approved emergency opioid antagonists and, in an emergency, when a physician is not immediately available, administer the emergency opioid antagonists to a person believed in good faith to be experiencing an opioid overdose, regardless of whether that person has a prescription for an emergency opioid antagonist. Emergency responders and crime laboratory personnel are authorized to possess, store, and administer emergency opioid antagonists. Current law affords civil liability immunity to anyone who possess, administers, prescribes, dispenses, or stores an approved emergency opioid antagonist.

Current law allows, rather than mandates, emergency medical technicians and paramedics who provide basic and advanced life support services to report controlled substances overdoses to the Department of Health (DOH).

HB 1091 amends s. 381.887, F.S., to reflect that the purpose of the section is for the prescribing, ordering, and dispensing of emergency opioid antagonists. The bill requires DOH to develop and implement a statewide awareness campaign to educate the public on opioid overdoses and the safe disposal of opioids. It allows a pharmacist to order and dispense an emergency opioid antagonist to a patient or caregiver.

The bill expressly authorizes personnel of a law enforcement agency or other agency, including, correctional probation officers and child protective investigators to possess, store, and administer emergency opioid antagonists.

Finally, the bill amends s. 401.253, F.S., to require a basic life support service or advanced life support service that treats and releases, or transports to a medical facility, a person in response to an emergency call for suspected or actual overdose of a controlled substance to report such incidents to DOH.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Opioids

Opioids are psychoactive substances derived from the opium poppy, or their synthetic analogues.[1] They are commonly used as pain relievers to treat acute and chronic pain. An individual experiences pain because of a series of electrical and chemical exchanges among the individual's peripheral nerves, spinal cord, and brain.[2] Opioid receptors occur naturally and are distributed widely throughout the central nervous system and in peripheral sensory and autonomic nerves. [3] When an individual experiences pain, the body releases hormones, such as endorphins, which bind with targeted opioid receptors.[4] This disrupts the transmission of pain signals through the central nervous system and reduces the perception of pain.[5] Opioids function in the same way by binding to specific opioid receptors in the brain, spinal cord and gastrointestinal tract, thereby reducing the perception of pain.[6]

Opioids include prescription medications used to treat pain, as well as illegal drugs. Opioids include[7]:

- Buprenorphine (Subutex, Suboxone)
- Codeine
- Fentanyl (Duragesic, Fentora)
- Heroin
- Hydrocodone (Vicodin, Lortab, Norco)
- Hydromorphone (Dilaudid, Exalgo)
- Meperidine
- Methadone
- Morphine
- Oxycodone (OxyContin, Percodan, Percocet)
- Oxymorphone
- Tramadol
- U-47700

It is estimated that 53 million people worldwide use opioids.[8] Opioids are commonly abused, with an estimated 35.6 million people worldwide suffering from drug use dependence.[9] Opioids can create a euphoric feeling because they affect the regions of the brain involved with pleasure and reward, which can lead to abuse.[10] Continued use of these drugs can lead to the development of tolerance and

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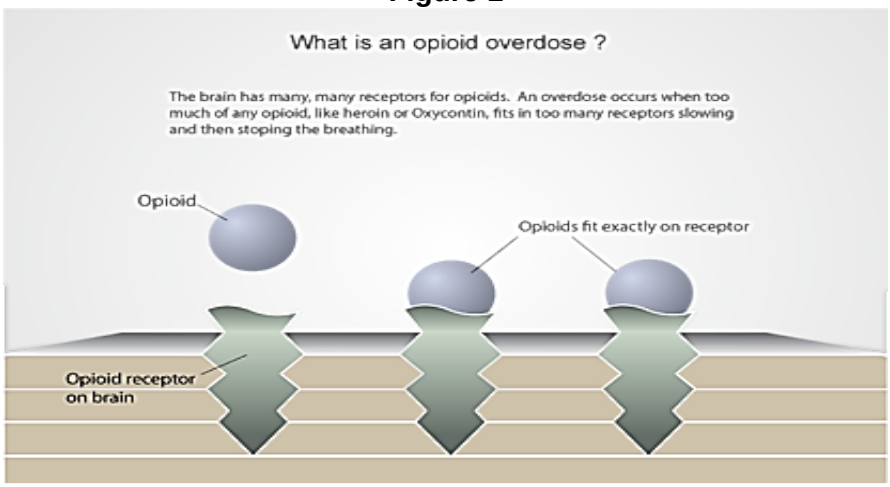
[1] World Health Organization, *Opioid Overdose*, https://www.who.int/news-room/fact-sheets/detail/opioid-overdose (last visited Mar. 30, 2021).
[2] Medical News Today, *What is pain, and how do you treat it?* (Sept. 7, 2020), https://www.medicalnewstoday.com/articles/145750#:~:text=People%20feel%20pain%20when%20specific,immediate%20contraction%20of%20the%20muscles (last visited Mar. 18, 2021).
[3] Gjermund Henriksen, Frode Willoch*, Imaging of Opioid Receptors in the Central Nervous System,* Brain (2008) 131 (5): 1171-1196.
[4] *Id*.
[5] *Id*.
[6] U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, *SAMHSA Opioid Overdose Toolkit: Facts for Community Members* (2018).
[7] Florida Department of Law Enforcement, *Drugs Identified in Deceased Persons by Florida Medical Examiners 2019 Report,* (Nov. 2020).
[8] United Nations Office on Drugs and Crime, World Drug Report 2019, *Global Overview of Drug Demand and Supply* (Jun. 2019), https://wdr.unodc.org/wdr2019/prelaunch/WDR19_Booklet_2_DRUG_DEMAND.pdf (last visited Mar. 30, 2021).
[9] *Supra* note 1.
[10] National Institute on Drug Abuse, *How Do Opioids Affect the Brain and Body?,* (June 2020) http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/how-do-opioids-affect-brain-body (last visited Mar. 18. 2021).

psychological and physical dependence.[11] This dependence is characterized by a strong desire to take opioids, impaired control over opioid use, persistent opioid use despite harmful consequences, a higher priority given to opioid use than to other activities and obligations, and a physical withdrawal reaction when opioids are discontinued.[12]

An overabundance of opioids in the body can lead to a fatal overdose. In addition to their presence in major pain pathways, opioid receptors are also located in the respiratory control centers of the brain.[13] Opioids disrupt the transmission of signals for respiration in the identical manner that they disrupt the transmission of pain signals (figure 1). This leads to a reduction, and potentially cessation, of an individual's respiration. Oxygen starvation will eventually stop vital organs like the heart, then the brain, and can lead to unconsciousness, coma, and possible death.[14] Within 3-5 minutes without oxygen, brain damage starts to occur, soon followed by death.[15] However, this does not occur instantaneously as people will commonly stop breathing slowly, minutes to hours after the drug or drugs were used.[16] An opioid overdose can be identified by a combination of three signs and symptoms referred to as the "opioid overdose triad":[17]

- Pinpoint pupils.
- Unconsciousness.
- Respiratory depression.

Figure 1



Source: Maya Doe-Simkins, MPH, Boston Medical Center.

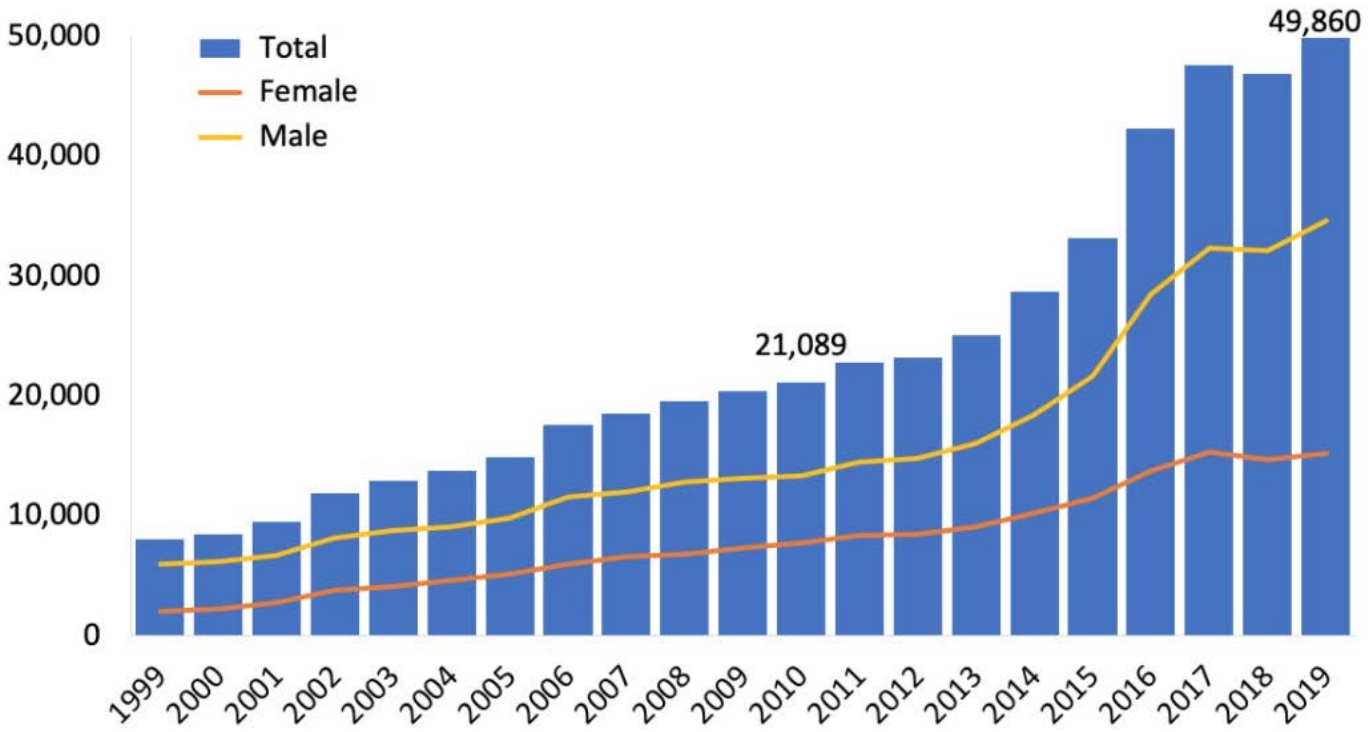
The rise in opioid overdose deaths can be outlines in three distinct waves:

1. The first wave began with increase prescribing of opioids in the 1990s, with overdose deaths involving prescription opioids increasing since at least 1999.
2. The second wave began in 2010, with rapid increase in overdose deaths involving heroin.
3. The third wave began in 2013 with significant increases in overdose deaths involving synthetic opioids, particularly those involving illicitly manufactured fentanyl. The market for illicitly manufactured fentanyl continues to change, and it can be found in combination with heroin, counterfeit pills, and cocaine.[18]

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[11] *Supra* note 6.
[12] *Supra* note 1.
[13] Pattinson, K.T.S., *Opioids and the Control of Respiration*, BJA, Vol. 100, Issue 6, Pages 747-758. http://bja.oxfordjournals.org/content/100/6/747.full (last visited Mar. 18, 2021).
[14] Harm Reduction Coalition, *Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects*, (Aug. 31, 2020) http://harmreduction.org/our-work/overdose-prevention/ (last visited Mar. 18, 2021).
[15] *Id*.
[16] *Id*.
[17] *Supra* note 1.
[18] Centers for Disease Control and Prevention, *Understanding the Epidemic*, https://www.cdc.gov/drugoverdose/epidemic/index.html (last visited Mar. 30, 2021).

More than 70,000 Americans died from drug-involved overdose in 2019, including illicit drugs and prescription opioids.[19] Overall, drug overdose deaths increased from 2018 to 2019 with 70,630 drug overdoses reported in 2019.[20] The following graph provides information on the total number of U.S. overdose deaths involving any opioid[21] from 1999 to 2019.[22] Opioid-involved overdose deaths increased from 21,088 in 2010 to 47,600 in 2017 and remained steady in 2018 with 46,802.[23] This was following by a significant increase in 2019 to 49,860 overdose deaths.[24]



In 2019, Florida reported 5,268 opioid overdose deaths.[25] This was an 11.9 percent increase from 2018.[26] Florida also experienced 4,152 opioid and 10,464 all drug non-fatal overdoses between July and September 2019.[27]

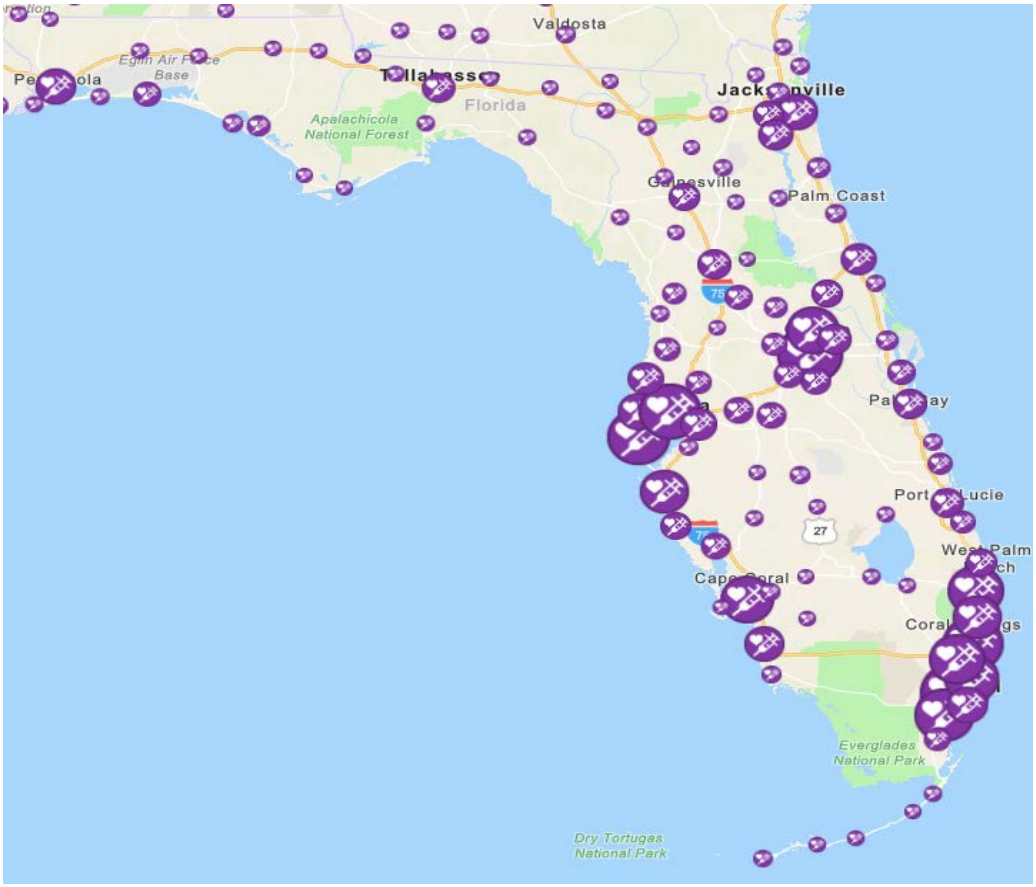
Opioid Antagonist

An opioid antagonist, such as Narcan or Naloxone, is a drug that blocks the effects of exogenously administered opioids. Opioid antagonists are used in opioid overdoses to counteract life-threatening depression of the central nervous system and respiratory system, allowing an overdose victim to breathe normally.[28] This occurs because opioid antagonists create a stronger bond with opioid receptors than opioids. This forces the opioids from the opioid receptors and allows the transmission of signals for respiration to resume.[29] This effect lasts only for a short period of time[30] with the narcotic

[19] National institute on Drug Abuse, *Overdose Death Rates*, https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates (last visited Mar. 30, 2021).
[20] *Id*.
[21] Any opioid includes prescription opioids (natural and semi-synthetic opioids and methadone), heroin and synthetic opioids other than methadone (primarily fentanyl).
[22] *Id*.
[23] *Id*.
[24] *Id*.
[25] Center for Disease Control and Prevention, *Drug Overdose Deaths*, https://www.cdc.gov/drugoverdose/data/statedeaths/drug-overdose-death-2019.html (last visited Mar. 30, 2021).
[26] Center for Disease Control and Prevention, *2018-2019 Drug Overdose Death Rate Increase*, https://www.cdc.gov/drugoverdose/data/statedeaths/drug-overdose-death-2019.html (last visited Mar. 30, 2021).
[27] Florida Department of Health, *Non-Fatal Opioid and All Drug Overdose Surveillance Report, Florida Q4-2019*, http://www.floridahealth.gov/statistics-and-data/fl-dose/_documents/non-fatal-od-2019-q4.pdf
[28] Harm Reduction Coalition, *Understanding Naloxone,* (Sept. 8, 2020) http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/ (last visited Mar. 18, 2021).
[29] *Supra* note 13.

effect of the opioids returning if still present in large quantities in the body. In this scenario, additional doses of an opioid antagonist would be required and it is why it is generally recommended that anyone who has experienced an overdose seek medical attention.

In February 2019, Florida issued a statewide Standing Order for Naloxone. The Standing Order authorizes pharmacists to dispense certain naloxone formulations to emergency responders for administration to persons exhibiting signs of opioid overdose.[31] Under the Standing Order, emergency responders, including law enforcement, firefighters, paramedics, and emergency medical technicians, can go to a pharmacy or community-based program for training on opioid antagonist administration and receive an opioid antagonist without a patient-specific prescription. Access to naloxone is available at most pharmacies in Florida. The following map provides information on pharmacy locations where naloxone is available with or without a prescription.[32]



Florida law allows an authorized health care practitioner to prescribe and dispense an emergency opioid antagonist to a patient or caregiver, and pharmacists may dispense an emergency opioid antagonist pursuant to a prescription or to a non-patient-specific standing order.[33] Current law defines a "caregiver" as a family member, friend, or *person* in a position to have recurring contact with a person at risk of experiencing an opioid overdose.[34] Current law broadly defines a "person" to include

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[30] The half-life for a common opioid antagonist in adults ranged from 30 to 81 minutes. Acute opiate withdrawal is a potential side-effect of naloxone; however, this would be time limited to the half-life of naloxone.
[31] Florida Department of Health, State of Florida, *Statewide Standing Order for Naloxone* (Feb. 25, 2019), http://www.floridahealth.gov/licensing-and-regulation/ems-system/_documents/standing-order-naloxone.pdf (last visited Mar. 30, 2021).
[32] New America, *National Naloxone Access Map*, https://opioidepidemic.maps.arcgis.com/home/item.html?id=153b0c32fefc432eae6a0e8439b9f56b (last visited Mar. 30, 2021). The National Naloxone Map accumulates data from many difference sources, with participation from thousands of CVS, Walmart, and Walgreens pharmacies, along with other independent distributors. The map is meant to be a community effort, and contributing locations is encouraged to participate, to make it the best possible representation of resources. The map is not complete, and naloxone prescription needs and costs vary by state, but this effort represents over 25,000 locations to obtain naloxone.
[33] S. 381.887, F.S.
[34] S. 381.887(1)(c), F.S.

individuals and children.[35] Therefore, an authorized health care practitioner may prescribed any person falling under the definition an emergency opioid antagonist.

Any person prescribed an opioid antagonist, or distributed an emergency opioid antagonist pursuant to a non-patient-specific standing order, may store and possess approved emergency opioid antagonists. In an emergency, when a physician is not immediately available, that person may administer the emergency opioid antagonists to an individual believed in good faith to be experiencing an opioid overdose, regardless of whether that person has a prescription for an emergency opioid antagonist.[36] Current law also allows emergency responders and crime laboratory personnel to possess, store, and administer emergency opioid antagonists.

A person who possess, administers, prescribes, dispenses, or stores an approved emergency opioid antagonist is afforded the civil liability immunity protections under s. 768.13, F.S. (Good Samaritan Act).

Prescription Drug Disposal

Currently, the recommended method of disposing unused prescription medications is to take them to a drug take-back location.[37] However, if there is not a drug take-back location in the area or if the person cannot go to one promptly, the U.S. Food and Drug Administration (FDA) provides two recommendations:

- That drugs on the drug flus list be disposed of immediately by being flushed down a toilet. The FDA has identified and created a list of drugs that are either dangerous to be kept unused for an extended period of time or are sought-after for their misuse and abuse potential. Many of the drugs on the flush list are prescription opioids.[38]
- If the drug is not on the flush list, the FDA recommends that the drug be mixed with an unappealing substance in a sealed container and thrown away in the trash.[39]
- In either case, the FDA also recommends that all personal information on the prescription label be deleted before throwing away or recycling the drug container.

Drug Disposal Products

In April 2019, 70 percent of the U.S. population lived less than five miles from collection sites.[40] If collection sites, take-back events, or mail-back programs are not feasible, commercial products to facilitate in-home disposal exist for patients that may not want to dispose of products in the trash. There are numerous drug disposal products available, many of which are sold directly to consumers. In-home disposal products are proprietary substances that patients can mix with their unused drugs, including opioids, before disposing them in the trash.[41] The products use a variety of method to dispose of drugs and make them non-retrievable, including activated carbon, bentonite clay, mixtures of calcium hypochlorite with other ingredients, and other proprietary methods not fully described by the products. Vendors of in-home disposal products indicate the products can prevent misuse of opioids by rending drugs non-retrievable and by motivating patients to dispose of unused opioids.[42]

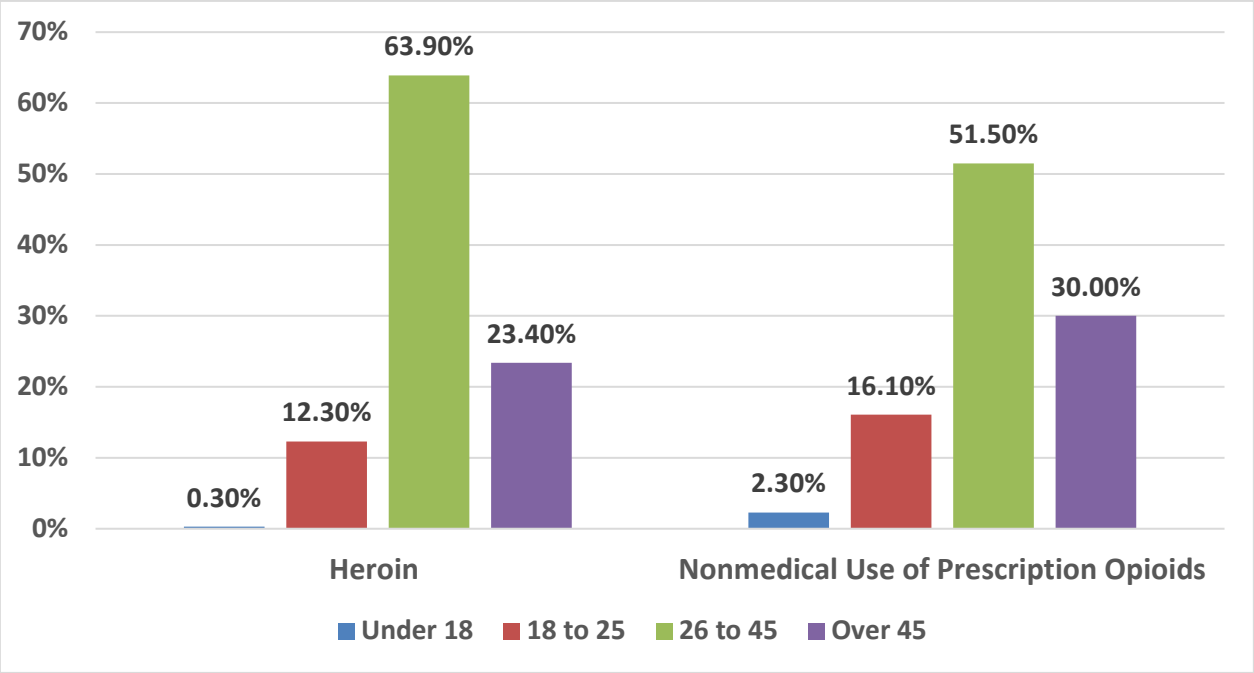
Emergency Response to Overdose

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[35] S. 1.01 (3), F.S.
[36] *Id*.
[37] Theriot, Jonathan, et al., *Opioid Antagonists*, (Jul. 27, 2020), https://www.ncbi.nlm.nih.gov/books/NBK537079/#:~:text=3%5D%5B4%5D-,The%20two%20most%20commonly%20used%20centrally%20acting%20opioid%20receptor%20antagonists,depression%20associated%20with%20opioid%20use (last visited Mar. 22, 2021).
[38] U.S. Food and Drug Administration, *Drug Disposal: FDA's Flush List for Certain Medicines*, (Oct. 1, 2020) https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-fdas-flush-list-certain-medicines (last visited Mar. 22, 2021).
[39] *Id*.
[40] United States Government Accountability Office, *Prescription Opioids, Patient Options for Safe and Effective Disposal of Unused Opioids,* (Sept. 2019), https://www.gao.gov/assets/gao-19-650.pdf (last visited Mar. 29, 2021).
[41] *Id*.
[42] *Id*.

In 2017, U.S. drug overdose deaths increased 9.6% from 2016. Emergency departments treated 967,615 nonfatal drug overdoses in 2017.[43] From 2016 to 2017, rates for nonfatal overdoses increased for those involving all drugs (4.3%), all opioids (3.1%), nonherion opioids (3.6%), heroin (3.6%), and cocaine (32.9%).[44]

The following table provides information on emergency department visits related to heroin and nonmedical use of prescription opioids by age from April 2019 to December 2020.[45] Patients aged 26 to 45 accounted for more than half (52%) of emergency department visits related to non-medical use of prescription opioids.[46]



Florida Emergency Response to Overdoses Reporting Requirements

Current law allows emergency medical technician[47] (EMT) and paramedics[48] who provide basic and advanced life support services to report controlled substances overdoses to the Department of Health (DOH). A report must contain:

- The date and time of the overdose.
- The address of where the patient was picked up or where the overdose took place.
- Whether an emergency opioid antagonist was administered.
- Whether the overdose was fatal or non-fatal.

Additionally, the report must include the approximate age and gender of the patient and the suspected controlled substance involved in the overdose only if permitted by its reporting mechanism. Reporters must attempt to make the report within 120 hours.

[43] Centers for Disease Control and Prevention, *Nonfatal Drug Overdoses Treated in Emergency Departments – United States, 2016-2017,* (Apr. 3, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6913a3.htm (last visited Mar. 30, 2021).
[44] *Id*.
[45] U.S. Department of Health, Substance Abuse and Mental Health services Administration, *DAWN: Heroin and Nonmedical Use of Prescription Opioids,* https://www.samhsa.gov/data/sites/default/files/reports/rpt32814/DAWN%20Opioids%20Profile.pdf (last visited Mar. 22, 2021).
[46] *Id*.
[47] S. 401.23(11), F.S., defines an EMT as a person who is certified by DOH to perform basic life support.
[48] S. 401.23(17), F.S., defines a paramedic as a person who is certified by DOH to perform basic and advanced life support.

A report must be filed with DOH using the Emergency Medical Tracking and Reporting System (EMSTARS),[49] the Washington/Baltimore High Intensity Drug Tracking Overdoes Detection Mapping Application Program,[50] or other program identified by DOH in rule.

Reporting of such incidents is currently voluntary, and only about 30 percent of all emergency responding units utilize it.[51]

DOH established the Florida Drug Overdose Surveillance and Epidemiology (FL-DOSE) program using federal grant funding from the Center for Disease Control and Prevention (CDC).[52] The FL-DOSE program allows for a collaborative and targeted response to the growing drug overdose challenge through timely dissemination of surveillance data. The program supports resources necessary to:

- Monitor non-fatal drug overdose visits at Florida's emergency departments and hospitals.
- Leverage Florida's existing incident-level Emergency Medical Services data collection system to calculate drug overdose indicators.
- Collect, abstract, and input fatal overdose data from Florida's Vital Statistics Death Certificates and Medical Examiners' reports for target counties into the CDC's National Violence Death Registry System's State Unintentional Drug Overdose Reporting system.
- Communicate surveillance results to key stakeholders at state and local levels.

Opioid Public Education Campaigns

DOH, through Overdose Data to Action (OD2A) funding, recently launched a statewide media campaign to increase awareness and education on overdose prevention utilizing campaign materials from the Centers for Disease Control and Prevention Rx Awareness campaign.[53] This evidence-driven campaign tells real stories of people whose lives have been torn apart by opioid use and abuse to raise awareness.[54] In addition to state level efforts, these campaign materials are available and accessible to County Health Departments in support of local initiatives and prevention efforts.[55] In addition to this media campaign, there are various prevention efforts throughout Florida to increase education and awareness about the risks of prescription drug and opioid misuse. Current statewide awareness campaigns and initiatives include:

- The Department of Children and Families' Opioid Overdose Prevention Awareness campaign, launched in 2018, to educate the public on the signs and symptoms of opioid overdose, how to use an opioid antagonist to reverse an opioid overdose, and where to access an opioid antagonist in Florida.
- First Lady Casey DeSantis Hope for Healing Florida initiative, which is a multi-agency mental health and substance abuse campaign.
- The Florida Dose of Reality website, launch by the Florida Office of Attorney General in September 2018, provides information on the dangers of opioid misuse, safe storage of opioids, advice for prescribing providers, students, teachers, parents, veterans, business owners and others.

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[49] DOH maintains the EMSTARS to collect data and analyze the incident level data from EMS agencies for benchmarking and quality improvement initiatives. The electronic patient care records submitted by licensed EMS agencies to EMSTARS are confidential and exempt pursuant to s. 401.30(4), F.S.

[50] The Washington/Baltimore High Intensity Drug Trafficking Area (HIDTA) is a federal grant program administered by the White House Office of National Drug Control Policy which provides resources to assist federal, state, local, and tribal agencies coordinate activities that address drug trafficking. HIDTA created an app, known as the Overdose Detection Mapping Application Program, which allows EMS agencies to report overdose incidents that are then transmitted in real time with electronic map showing the location, date, time, and incident type. The app does not allow EMS agencies to report on the patient's age or gender or suspected controlled substance involved in the overdose.

[51] Florida Attorney General, Florida's Opioid Epidemic: Recommendations and Best Practices (Jan. 25, 2021), https://myfloridalegal.com/webfiles.nsf/WF/TDGT-B9UTV9/$file/AG+Opioid+Working+Group+Report+Final+2-28-2019.pdf (last visited Mar. 30, 2021).

[52] Florida Department of Health, Florida Drug Overdose Surveillance and Epidemiology (FL-DOSE), http://www.floridahealth.gov/statistics-and-data/fl-dose/index.html (last visited Mar. 30, 2021).

[53] Florida Department of Health, *2021 Agency Bill Analysis for HB 1091* (Mar. 12, 2021).

[54] *Id*.

[55] *Id*.

Effect of Proposed Changes

HB 1091 amends s. 381.887, F.S., to specify that the purpose of the section is for the prescribing, ordering, and dispensing of emergency opioid antagonists. The bill requires DOH to develop and implement a statewide awareness campaign to educate the public regarding:

- Risk factors of opioid overdoses.
- Signs and symptoms of opioid overdoses.
- How to respond to opioid overdoses.
- Safe storage and administration of emergency opioid antagonists.
- Safe disposal of opioids including, but not limited to, permanent prescription drug donation boxes and at-home drug deactivation and disposal systems.

The bill allows a pharmacist to order an emergency opioid antagonist with an autoinjection delivery system or intranasal application delivery system for a patient or caregiver for use in accordance with s. 381.887, F.S. It further allows a pharmacist to dispense an emergency opioid antagonist pursuant to a prescription by an authorized health care practitioner. Pharmacists may dispense an emergency opioid antagonist with an autoinjection delivery system or intranasal application delivery system, which must be appropriately labeled with instructions for use, pursuant to a pharmacist order or pursuant to a non-patient standing order.

The bill expressly authorizes personnel of a law enforcement agency or other agency, including, but not limited to, correctional probation officers and child protective investigators to possess, store, and administer emergency opioid antagonists. Personnel of a law enforcement agency or other agency are immune from civil liability or criminal liability as a result of administering an emergency opioid antagonist.

The bill also amends s. 401.253, F.S., to require a basic life support service or advanced life support service that treats and releases, or transports to a medical facility, a person in response to an emergency call for suspected or actual overdose of a controlled substance to report such incident to DOH.

B. SECTION DIRECTORY:

Section 1: Amending s. 381.887, F.S., relating to emergency treatment for suspected opioid overdose.
Section 2: Amending s. 401.253, F.S., relating to reporting of controlled substance.
Section 3: Providing an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH will incur an insignificant fiscal impact to implement the bill's provisions. DOH will incur both a recurring and nonrecurring expense should the bill pass. DOH anticipates needing 2 FTEs at a total costs of $231,582 in recurring costs for salaries and benefits to implement the bill's provisions. Additionally, DOH estimates $500,000 in non-recurring and $50,000 in recurring costs to implement a statewide targeted awareness campaign.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DOH has sufficient rulemaking authority to implement the bill's provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to substance abuse prevention; amending s. 381.887, F.S.; revising provisions relating to the prescribing, ordering, and dispensing of emergency opioid antagonists to certain persons; requiring the Department of Health to develop and implement a statewide awareness campaign to educate the public regarding opioid overdoses, the safe storage and administration of emergency opioid antagonists, and the safe disposal of opioids; authorizing a pharmacist to order an emergency opioid antagonists; authorizing certain persons dispensed opioid antagonists without a prescription to store and possess and, in certain emergency situations, to administer opioid antagonists; providing certain authorized persons immunity from civil or criminal liability for administering emergency opioid antagonists under certain circumstances; authorizing personnel of law enforcement agencies and other agencies and certain other persons to administer emergency opioid antagonists under certain circumstances; amending s. 401.253, F.S.; requiring basic life support services or advanced life support services to report incidents involving a suspected or actual overdose of a controlled substance; providing

an effective date.

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

Section 1. Subsections (2), (3), and (4) of section 381.887, Florida Statutes, are amended to read:

381.887 Emergency treatment for suspected opioid overdose.—

(2)(a) The purpose of this section is to provide for the prescribing, ordering, and dispensing ~~prescription~~ of emergency opioid antagonists ~~an emergency opioid antagonist~~ to patients and caregivers and to encourage the prescribing, ordering, and dispensing ~~prescription~~ of emergency opioid antagonists by authorized health care practitioners.

(b) The Department of Health shall develop and implement a statewide awareness campaign to educate the public regarding:

1. Risk factors of opioid overdoses;

2. Signs and symptoms of opioid overdoses;

3. How to respond to opioid overdoses;

4. Safe storage and administration of emergency opioid antagonists; and

5. Safe disposal of opioids including, but not limited to, permanent prescription drug donation boxes and at-home drug deactivation and disposal systems.

(3)(a) An authorized health care practitioner may prescribe and dispense an emergency opioid antagonist, and a

pharmacist may order an emergency opioid antagonist with an autoinjection delivery system or intranasal application delivery system, to a patient or caregiver for use in accordance with this section.

(b) A pharmacist may dispense an emergency opioid antagonist pursuant to ~~such~~ a prescription by an authorized health care practitioner. A pharmacist may dispense ~~a prescription or pursuant to a non-patient-specific standing order for~~ an emergency opioid antagonist with an autoinjection delivery system or intranasal application delivery system, which must be appropriately labeled with instructions for use, pursuant to a pharmacist order or pursuant to a non-patient standing order.

(c) A patient or caregiver is authorized to store and possess emergency opioid antagonists and, in an emergency situation when a physician is not immediately available, administer the emergency opioid antagonist to a person believed in good faith to be experiencing an opioid overdose, regardless of whether that person has a prescription for an emergency opioid antagonist.

(4) The following persons are authorized to possess, store, and administer emergency opioid antagonists as clinically indicated and are immune from any civil liability or criminal liability as a result of administering an emergency opioid antagonist:

(a) Emergency responders, including, but not limited to, law enforcement officers, paramedics, and emergency medical technicians.

(b) Crime laboratory personnel for the statewide criminal analysis laboratory system as described in s. 943.32, including, but not limited to, analysts, evidence intake personnel, and their supervisors.

(c) Personnel of a law enforcement agency or other agency, including, but not limited to, correctional probation officers and child protective investigators who, while acting within the scope or course of employment, come into contact with a controlled substance or a person who is at risk of experiencing an opioid overdose.

Section 2. Paragraph (a) of subsection (1) of section 401.253, Florida Statutes, is amended to read:

401.253 Reporting of controlled substance overdoses.—

(1)(a) A basic life support service or advanced life support service that ~~which~~ treats and releases, or transports to a medical facility, a person in response to an emergency call for a suspected or actual overdose of a controlled substance must ~~may~~ report such incidents to the department. Such reports must be made using the Emergency Medical Service Tracking and Reporting System or other appropriate method with secure access, including, but not limited to, the Washington/Baltimore High Intensity Drug Trafficking Overdose Detection Mapping

Application Program or other program identified by the department in rule. If a basic life support service or advanced life support service reports such incidents, it must ~~shall~~ make its best efforts to make the report to the department within 120 hours after it responds to the incident.

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

HB 1233

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1233 Genetic Counseling Patient Protection Act
SPONSOR(S): Silvers
TIED BILLS: HB 1235 **IDEN./SIM. BILLS:** SB 1770

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Professions & Public Health Subcommittee		Morris	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

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

Genetic counselors provide individuals information about how genetic conditions might affect them or their families. Genetic counselors collect personal and family history and use such information to determine how likely it is that an individual or his or her family member has a genetic condition. Genetic counselors are not licensed or regulated in this state.

HB 1233 creates the "Genetic Counseling Patient Protection Act," requiring DOH to regulate and license genetic counselors. The bill:

- Creates requirements for initial licensure and renewal for genetic counselors;
- Authorizes DOH to adopt rules regarding continuing education requirements;
- Subjects genetic counselors to disciplinary action if they commit specified prohibited acts;
- Authorizes DOH to deny an application for licensure or impose penalties on a licensee who commits specified prohibited acts; and
- Exempts active duty commissioned medical officers of the United States Armed Forces or Public Health Service and licensed health care practitioners from the requirements of the genetic counselor practice act.

The bill also makes technical and conforming changes.

The bill has a significant, negative fiscal impact on DOH. The bill has no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Health Care Professional Licensure

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners. MQA works in conjunction with 22 boards and 4 councils to license and regulate 7 types of health care facilities and more than 40 health care professions.[1] Each profession is regulated by an individual practice act and by ch. 456, F.S., which provides general regulatory and licensure authority for MQA. MQA is statutorily responsible for the following boards and professions established within the division:[2]

- The Board of Acupuncture, created under ch. 457, F.S.;
- The Board of Medicine, created under ch. 458, F.S.;
- The Board of Osteopathic Medicine, created under ch. 459, F.S.;
- The Board of Chiropractic Medicine, created under ch. 460, F.S.;
- The Board of Podiatric Medicine, created under ch. 461, F.S.;
- Naturopathy, as provided under ch. 462, F.S.;
- The Board of Optometry, created under ch. 463, F.S.;
- The Board of Nursing, created under part I of ch. 464, F.S.;
- Nursing assistants, as provided under part II of ch. 464, F.S.;
- The Board of Pharmacy, created under ch. 465, F.S.;
- The Board of Dentistry, created under ch. 466, F.S.;
- Midwifery, as provided under ch. 467, F.S.;
- The Board of Speech-Language Pathology and Audiology, created under part I of ch. 468, F.S.;
- The Board of Nursing Home Administrators, created under part II of ch. 468, F.S.;
- The Board of Occupational Therapy, created under part III of ch. 468, F.S.;
- Respiratory therapy, as provided under part V of ch. 468, F.S.;
- Dietetics and nutrition practice, as provided under part X of ch. 468, F.S.;
- The Board of Athletic Training, created under part XIII of ch. 468, F.S.;
- The Board of Orthotists and Prosthetists, created under part XIV of ch. 468, F.S.;
- Electrolysis, as provided under ch. 478, F.S.;
- The Board of Massage Therapy, created under ch. 480, F.S.;
- The Board of Clinical Laboratory Personnel, created under part III of ch. 483, F.S.;
- Medical physicists, as provided under part IV of ch. 483, F.S.;
- The Board of Opticianry, created under part I of ch. 484, F.S.;
- The Board of Hearing Aid Specialists, created under part II of ch. 484, F.S.;
- The Board of Physical Therapy Practice, created under ch. 486, F.S.;
- The Board of Psychology, created under ch. 490, F.S.;
- School psychologists, as provided under ch. 490, F.S.;
- The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, created under ch. 491, F.S.; and
- Emergency medical technicians and paramedics, as provided under part III of ch. 401, F.S.

Genetic Counseling

[1] Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2019-2020*, p. 6, http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/2019-2020-annual-report.pdf (last visited on March 26, 2021).
[2] Id.

Advances in genetic technology and research have increased the amount of information available to individuals and providers and increased the demand for genetic services, including genetic testing, diagnosis and interpretation of test results, and genetic counseling.[3] Genetic test results can help diagnose, confirm, or indicate increased risk for developing a particular condition, which genetic counseling can help explain the results and available treatment options.

Genetic counseling gives individuals information about how genetic conditions might affect them or their families. Genetic counselors collect personal and family history and use such information to determine how likely it is that an individual or his or her family member has a genetic condition. Based on such information, a genetic counselor helps an individual determine if a genetic test is suitable. Genetic counseling after genetic testing can help an individual better understand his or her test results and treatment options.[4]

Individuals seek genetic counseling for multiple reasons, including to:[5]

- Address prenatal concerns about factors that might affect a baby during infancy, including genetic conditions and birth defects;
- Address concerns if a child is showing signs and symptoms of a genetic disorder, including abnormal newborn screening results, intellectual or developmental disabilities, or birth defects;
- Determine if an individual is at risk of being affected by a health condition, including hereditary breast and ovarian cancer, muscular dystrophy, Huntington's disease, and sickle cell disease.

Genetic counselors who wish to become certified must pass a certification examination issued by the American Board of Genetic Counseling (ABGC).[6] The primary qualification to sit for the certification examination is a master's degree in genetic counseling from a program accredited by the Accreditation Council for Genetic Counseling.[7] States currently issuing a genetic counselor license require individuals to pass the ABCG certification examination.[8]

Genetic counselors primarily practice in hospital settings and can work in all medical specialties or practice in one specialty area, such as pediatrics, oncology, or cardiology.[9] They assess individuals or families with or at risk for genetic conditions, and provide counseling and education on test results. Genetic counselors are not physicians; they typically work in conjunction with medical geneticists to provide genetic services.[10] Medical geneticists will order genetic testing and interpret the results and a genetic counselor will provide further education on the results and how they may affect an individual or their family.[11]

Twenty-nine states require licensure for genetic counselors.[12] Florida does not require licensure and there are approximately 127 genetic counselors providing services in this state.[13]

Sunrise Act

[3] United States Government Accountability Office, Report to Congressional Committees: Genetic Services – Information on Genetic Counselor and Medical Geneticist Workforces (July 2020), https://www.gao.gov/assets/gao-20-593.pdf (last visited March 26, 2021).
[4] Centers for Disease Control and Prevention, *Genetic Counseling,* https://www.cdc.gov/genomics/gtesting/genetic_counseling.htm (last visited March 26, 2021).
[5] Id.
[6] American Board of Genetic Counseling, Inc., *Certification Qualifications,* https://www.abgc.net/becoming-certified/do-i-qualify/ (last visited March 26, 2021). Certification is valid for 5 years, after which time the genetic counselor must seek recertification. The University of South Florida has the only certified genetic counseling training program in Florida.
[7] Id.
[8] Id.
[9] Id.
[10] Medical geneticists are physicians who specialist in medical genetics and conduct genetic testing and provide diagnoses.
[11] *Supra*, note 6.
[12] National Society of Genetic Counselors, *States Issuing Licenses for Genetic Counselors,* https://www.nsgc.org/Policy-Research-and-Publications/State-Licensure-for-Genetic-Counselors/States-Issuing-Licenses (last visited March 26, 2021). States requiring licensure of generic counselors include: Alabama, Arkansas, California, Connecticut, Delaware, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, Nebraska, New Hampshire, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Pennsylvania, South Dakota, Tennessee, Utah, Virginia, and Washington.
[13] Department of Health, Agency Analysis of 2021 House Bill 1233 (March 22, 2021).

Generally, a sunrise review is a formal process where a legislature scrutinizes legislation proposing to regulate an unregulated profession or occupation by requiring a cost-benefit analysis before the legislation is enacted.[14] The Sunrise Act requires the Legislature to consider certain factors before determining whether to regulate an unregulated profession or occupation.[15] Proponents of regulation must file information about the regulation's potential impacts, costs, and benefits upon request.[16]

Section 11.62, F.S., is Florida's sunrise review, which is called the Sunrise Act. The Sunrise Act states that regulation should not be adopted unless it is:[17]

- Necessary to protect the public health, safety, or welfare from significant and discernible harm or damage;
- Exercised only to the extent necessary to prevent the harm; and
- Limited so as not to unnecessarily restrict entry into the practice of the profession or adversely affect public access to the professional services.

In determining whether to regulate a profession or occupation, the Sunrise Act requires the Legislature to consider the following:

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

Genetic Counselor Sunrise Act Questionnaire

A Sunrise Act questionnaire has been completed by The Florida Association of Genetic Counselors (FLAGC).[18] FLAGC is seeking licensure and regulation of genetic counselors to protect the health, safety, and welfare of the public.[19] Florida does not license or regulate genetic counselors.

[14] National Conference of State Legislatures, Improving Occupational Licensing with Sunrise and Sunset Review Acts, https://www.ncsl.org/research/labor-and-employment/improving-occupational-licensing-with-sunrise-and-sunset-reviews.aspx (last visited March 26, 2021).
[15] S. 11.62, F.S.
[16] S. 11.62(4), F.S.
[17] S. 11.62(2), F.S.
[18] The Florida Association of Genetic Counselors, Sunrise Review for Proposed Licensing of Genetic Counselors (on file with the Professions and Public Health Subcommittee staff).
[19] Id.

Effect of the Bill

HB 1233 creates the "Genetic Counseling Patient Protection Act," adding genetic counselors to the list of health care practitioners requiring licensing and regulation by DOH.

The bill creates the scope of practice for genetic counselors, requiring them to advise individuals or families affected by or at risk of genetic disorders. Genetic counselors may provide services to help an individual or family:

- Understand a diagnosis and the probable cause and management of such diagnosis;
- Understand heredity and the risk of an occurring medical condition;
- Consider alternatives to genetic counseling for addressing the risk of an occurring medical condition;
- Choose an appropriate course of action, taking into consideration the risks, family goals, and ethical and religious standards, and to acting in accordance with that decision; and
- Adjust to a diagnosis and the risk of an occurring medical condition.

The bill creates requirements for licensure as a genetic counselor and requires DOH to issue a license to an applicant who:

- Submits an application on a form approved by DOH;
- Is of good moral character;
- Has earned a:
    - Master's degree from a genetic counseling program or an equivalent program as determined by the ABCG Counseling or the Canadian Association of Genetic Counselors; or
    - Doctoral degree from a medical genetics program accredited by the American Board of Genetics and Genomics or the Canadian College of Medical Geneticists.
- Passes the examination for certification as:
    - A genetic counselor by the ABCG, the American Board of Genetics and Genomics, or the Canadian Association of Genetic Counselors; or
    - A medical or clinical geneticist by the American Board of Medical Genetics and Genomics or the Canadian College of Medical Geneticists.

The bill authorizes DOH to issue a temporary license for up to two years to applicants who meet all the requirements for licensure, except for the examination requirement if the applicant is eligible to sit for the next available certification examination issued by the American Board of Genetic Counseling.

The bill requires DOH to renew the license of a genetic counselor upon receipt of a renewal application. The bill also requires DOH to adopt rules on continuing education requirements consistent with the ABCG.

The bill prohibits a person from:

- Making a false or fraudulent statement in any application, affidavit, or statement presented to DOH;
- Practicing genetic counseling, holding himself or herself out as a genetic counselor, or providing genetic counseling services without obtaining a license from DOH; and
- Using the title "genetic counselor" or any other title, designation, words, letters, or abbreviations which indicate a person is authorized to practice genetic counseling unless such person holds a valid license or is exempt from such licensure.

The bill makes it a second degree misdemeanor to violate any of the above prohibitions, punishable by a fine of up to $500 and imprisonment of up to 60 days. The bill authorizes DOH to discipline a genetic counselor, or deny an application for licensure as a genetic counselor, if an applicant or licensee:

- Fraudulently attempts to obtain, obtains, or renews a license as a genetic counselor;

- Has a license revoked, suspended, or otherwise acted against, including licensure denial, in another jurisdiction;
- Is convicted, found guilty of, or pleads no contest to a crime in any jurisdiction that directly related to the practice of genetic counseling, including violations of federal law;
- Makes or files a false report that the licensee knows is false;
- Intentionally or negligently fails to file a report required by state or federal law, or willfully impedes, obstructs or induces another person to impede or obstruct such filing;
- Knowingly advertises genetic counseling services in a fraudulent, false, deceptive, or misleading manner;
- Violates a DOH-issued disciplinary order or fails to comply with a DOH-issued subpoena;
- Practices with a revoked, suspended, or inactive license;
- Commits gross or repeated malpractice, or fails to deliver genetic counseling services at an acceptable level of care;
- Displays unprofessional conduct, including failure to conform to minimum standards set by the practice act and DOH rule, including:
    - Practicing beyond the scope of practice of a genetic counselor;
    - Failing to refer a patient to a health care practitioner if the licensed genetic counselor is unwilling or unable to provide services;
    - Failing to maintain confidentiality; and
    - Financially exploiting the patient or his or her family.
- Violates the genetic counseling practice act.

The bill exempts active duty commissioned medical officers of the United States Armed Forces or the United States Public Health Service and health care practitioners licensed in this state, other than licensed genetic counselors, from the requirements of the genetic counseling practice act.

The bill makes conforming technical and conforming changes.

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

B. SECTION DIRECTORY:

Section 1: Creates Part III of ch. 483, F.S., the “Genetic Counseling Patient Protection Act.”
Section 2: Amends s. 456.001, F.S., relating to definitions.
Section 3: Amends s. 20.43, F.S., relating to Department of Health.
Section 4: Provides an effective date of July 1, 2021.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH estimates a need for 3 FTE and 1 OPS positions to implement the bill.[20] The total estimated cost for the first year is $225,876: $137,826 recurring FTE salary, $35,359 non-recurring OPS costs, $33,878 recurring expenses, $17,716 non-recurring expenses, and $1,097 in human resources costs.[21]

DOH will experience an increase in workload associated with developing applications, rulemaking, and technology updates which can be absorbed within current resources.[22]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Genetic counselors may incur costs associated with obtaining licensure by DOH.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking authority to implement its provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[20] *Supra*, note 13.
[21] Id.
[22] Id.

A bill to be entitled

An act relating to Genetic Counseling Patient Protection Act; creating part III of ch. 483, F.S., titled "Genetic Counseling"; providing a short title, legislative findings and intent, and definitions; providing licensure and licensure renewal requirements; requiring the Department of Health to adopt by rule continuing education requirements; prohibiting certain acts; providing penalties and grounds for disciplinary action; authorizing the department to enter an order denying licensure or imposing other penalties; providing exemptions; amending s. 456.001, F.S.; revising the definition of the term "health care practitioner" to include licensed genetic counselors; amending s. 20.43, F.S.; correcting a cross-reference relating to the department's responsibilities for health care practitioners; providing an effective date.

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

Section 1. Part III of chapter 483, Florida Statutes, consisting of sections 483.911, 483.912, 483.913, 483.914, 483.915, 483.916, 483.917, and 483.918, is created to read:

PART III

GENETIC COUNSELING

483.911 Short title.—This part may be cited as the "Genetic Counseling Patient Protection Act."

483.912 Legislative findings and intent.—The sole legislative purpose for enacting this part is to ensure that every genetic counselor practicing in this state meets minimum requirements for safe practice. The Legislature finds that the delivery of genetic counseling services by unskilled and incompetent persons presents a danger to public health and safety. Because it is difficult for the public to make informed choices related to genetic counseling services and since the consequences of uninformed choices can seriously endanger public health and safety, it is the intent of the Legislature to prohibit the delivery of genetic counseling services by persons who are determined to possess less than minimum competencies or who otherwise present a danger to the public.

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

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

(2) "Genetic counselor" means a person licensed under this part to practice genetic counseling.

(3) "Practice of genetic counseling" means the process of advising an individual or family affected by or at risk of genetic disorders, including services to help an individual or family:

(a) Understand a diagnosis, the probable cause, and available management.

(b) Understand how heredity contributes and the risk of occurrence.

(c) Consider alternatives to genetic counseling for addressing the risk of occurrence.

(d) Choose a course of action appropriate to the individual or family, taking into consideration their risks, family goals, and ethical and religious standards, and to act in accordance with that decision.

(e) Adjust to a diagnosis and the risk of occurrence.

483.914 Licensure requirements.—

(1) A person desiring to be licensed as a genetic counselor under this part must apply to the department on a form approved by the department.

(2) The department shall issue a license to each applicant who:

(a) Has completed an application.

(b) Is of good moral character.

(c) Provides satisfactory documentation of having earned:

1. A master's degree from a genetic counseling training program or an equivalent program as determined by the American Board of Genetic Counseling, Inc., or the Canadian Association of Genetic Counsellors; or

2. A doctoral degree from a medical genetics training

program accredited by the American Board of Medical Genetics and Genomics or the Canadian College of Medical Geneticists.

(d) Has passed the examination for certification as:

1. A genetic counselor by the American Board of Genetic Counseling, Inc., the American Board of Medical Genetics and Genomics, or the Canadian Association of Genetic Counsellors; or

2. A medical or clinical geneticist by the American Board of Medical Genetics and Genomics or the Canadian College of Medical Geneticists.

(3) The department may issue a temporary license for up to 2 years to an applicant who meets all of the requirements for licensure except for the examination requirement in this section and is eligible to sit for the next available certification examination administered by the American Board of Genetic Counseling, Inc.

483.915 Licensure renewal and continuing education requirements.—

(1) The department shall renew a license upon receipt of a renewal application.

(2) The department shall adopt by rule continuing education requirements consistent with nationally accepted standards of the American Board of Genetic Counseling, Inc.

483.916 Prohibitions; penalties.—

(1) A person may not:

(a) Make a false or fraudulent statement in any

application, affidavit, or statement presented to the department.

(b) Practice genetic counseling or hold himself or herself out as a genetic counselor or as being able to practice genetic counseling or to render genetic counseling services without a license issued under this part, unless exempt from licensure under this part.

(c) Use the title "genetic counselor" or any other titles, designations, words, letters, abbreviations, or devices tending to indicate that the person is authorized to practice genetic counseling, unless that person holds a current license as a genetic counselor issued under this part or is exempt from licensure under this part.

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

483.917 Grounds for disciplinary action; penalties.—

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

(a) Attempting to obtain, obtaining, or renewing a license under this part by fraudulent misrepresentation.

(b) Having a license revoked, suspended, or otherwise acted against, including the denial of licensure in another jurisdiction.

(c) Being convicted or found guilty of, or entered a plea

of nolo contendere to, regardless of adjudication, a crime in any jurisdiction that directly relates to the practice of genetic counseling, including a violation of any federal law or regulation regarding genetic counseling.

(d) Making or filing a report or record that the licensee knows is false, intentionally or negligently failing to file a report or record required by state or federal law, willfully impeding or obstructing such filing, or inducing another person to impede or obstruct such filing. Such reports or records include only reports or records that are signed by a person who is licensed under this part.

(e) Knowingly advertising services related to genetic counseling in a fraudulent, false, deceptive, or misleading manner.

(f) Violating a previous order of the department entered in a disciplinary hearing or failing to comply with a subpoena issued by the department.

(g) Practicing with a revoked, suspended, or inactive license.

(h) Gross or repeated malpractice or the failure to deliver genetic counseling services with that level of care and skill which is recognized by a reasonably prudent licensed genetic counselor as being acceptable under similar conditions and circumstances.

(i) Unprofessional conduct, including any departure from

or failure to conform to the minimal prevailing standards of acceptable practice under this part and department rule such as:

1. Practicing or offering to practice beyond the scope permitted by law or accepting and performing genetic counseling services the licensee knows, or has reason to know, the licensee is not competent to perform.

2. Failing to refer a patient to a health care practitioner as defined in s. 456.001 if the licensee is unable or unwilling to provide genetic counseling services to the patient.

3. Failing to maintain the confidentiality of any information received under this part or failing to maintain the confidentiality of patient records pursuant to s. 456.057, unless such information or records are released by the patient or otherwise authorized or required by law to be released.

4. Exercising influence on the patient or family in such a manner as to exploit the patient or family for financial gain of the licensee.

(j) Violating this part or chapter 456, or any rules adopted pursuant thereto.

(2) The department may enter an order denying licensure or imposing penalties against an applicant for licensure or a licensee who is found guilty of violating subsection (1) or s. 483.916.

483.918 Exemptions.—This part does not apply to:

(1) A commissioned medical officer of the United States Armed Forces or the United States Public Health Service while on active duty or while acting within the scope of his or her military or public health responsibilities.

(2) A health care practitioner as defined in s. 456.001, other than a genetic counselor licensed under this part, who is practicing within the scope of his or her training, education, and licensure, and who is doing work of a nature consistent with such training, education, and licensure.

Section 2. Subsection (4) of section 456.001, Florida Statutes, is amended to read:

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

(4) "Health care practitioner" means any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part I, ~~or~~ part II, or part III, of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

Section 3. Subsection (8) of section 20.43, Florida Statutes, is amended to read:

20.43 Department of Health.—There is created a Department of Health.

(8) The department may hold copyrights, trademarks, and service marks and enforce its rights with respect thereto,

except such authority does not extend to any public records relating to the department's responsibilities for health care practitioners regulated under ~~part II of~~ chapter 456 ~~455~~.

Section 4. This act shall take effect July 1, 2021.

COMMITTEE/SUBCOMMITTEE ACTION

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

Committee/Subcommittee hearing bill: Professions & Public Health Subcommittee

Representative Silvers offered the following:

Amendment

Remove lines 30-90 and insert:

483.912 Legislative findings and intent.—The sole legislative purpose for enacting this part is to ensure that every genetic counselor practicing in this state meets minimum requirements for safe practice. The Legislature finds that the delivery of genetic counseling services by unskilled and incompetent persons presents a danger to public health and safety. Because it is difficult for the public to make informed choices related to genetic counseling services and since the consequences of uninformed choices can seriously endanger public health and safety, it is the intent of the Legislature to

prohibit the delivery of genetic counseling services by persons who are determined to possess less than minimum competencies or who otherwise present a danger to the public.

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

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

(2) "Genetic counselor" means a person licensed under this part to practice genetic counseling.

(3) "Scope of practice of genetic counseling" means the process of advising an individual or a family affected by or at risk of genetic disorders, including:

(a) Obtaining and evaluating individual and family medical histories to determine risk for genetic or medical conditions and diseases in an individual, his or her offspring, and other family members.

(b) Discussing the clinical features, family history, means of diagnosis, genetic and environmental factors, and management of risk for genetic or medical conditions and diseases.

(c) Identifying, ordering, and coordinating genetic laboratory tests and other diagnostic studies as appropriate for the genetic assessment.

(d) Integrating genetic laboratory test results and other diagnostic studies with individual and family medical histories to assess and communicate risk factors for genetic or medical conditions and diseases.

(e) Explaining the clinical implications of genetic laboratory tests and other diagnostic studies and the results.

(f) Evaluating the individual's or the family's responses to the condition or risk of recurrence and provide client-centered counseling and anticipatory guidance.

(g) Identifying and utilizing community resources that provide medical, educational, financial, and psychosocial support and advocacy.

(h) Providing written documentation of medical, genetic, and counseling information for individuals, families, and health care professionals.

(i) Referring individuals to a physician for diagnosis and treatment.

483.914 Licensure requirements.—

(1) A person desiring to be licensed as a genetic counselor under this part must apply to the department on a form approved by the department.

(2) The department shall issue a license, valid for a period of 2 years after the date of issuance, to each applicant who:

(a) Has completed an application.

(b) Is of good moral character.

(c) Provides satisfactory documentation of having earned:

1. A master's degree from a genetic counseling training program or an equivalent program as determined by the

Accreditation Council of Genetic Counseling or its successor or equivalent; or

2. A doctoral degree from a medical genetics training program accredited by the American Board of Medical Genetics and Genomics or the Canadian College of Medical Geneticists.

(d) Has passed the examination for certification as:

1. A genetic counselor by the American Board of Genetic Counseling, Inc., the American Board of Medical Genetics and Genomics, or the Canadian Association of Genetic Counsellors; or

2. A medical or clinical geneticist by the American Board of Medical Genetics and Genomics or the Canadian College of Medical Geneticists.

(3) The department may issue a temporary license for up to 2 years to an applicant who meets all of the requirements for licensure except for the examination requirement in this section and is eligible to sit for the next available certification examination.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1235 Fees
SPONSOR(S): Silvers
TIED BILLS: HB 1233 **IDEN./SIM. BILLS:** SB 1772

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Professions & Public Health Subcommittee		Morris	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Genetic counselors provide individuals information about how genetic conditions might affect them or their families. Genetic counselors collect personal and family history and use such information to determine how likely it is that an individual or his or her family member has a genetic condition. Genetic counselors are not licensed or regulated in this state.

HB 1233 creates the "Genetic Counseling Patient Protection Act," requiring the Department of Health (DOH) to regulate and license genetic counselors.

HB 1235, which is linked to HB 1233, requires DOH to adopt rules relating to the issuance and annual renewal of genetic counselor licenses. The bill authorizes DOH to charge an application fee of $25 for a genetic counselor license. The bill also authorizes an annual renewal fee not to exceed $25. The bill allows DOH to waive the fee by rule. Proceeds from the collected fees must be deposited into the DOH Administrative Trust Fund and used for the administration of genetic counselor licensure.

The bill will have an indeterminate, positive fiscal impact on DOH.

The bill will be effective on the same date that HB 1233 or similar legislation takes effect.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Legislation Imposing or Raising State Fees or Taxes

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

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

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

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

Health Practitioner Licensure Fees

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

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

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

[1] Fla. Const. art. VII, s. 19(a)-(b). The amendment appeared on the 2018 ballot as Amendment 5.
[2] Fla. Const. art. VII, s. 19(d).
[3] Fla. Const. art. VII, s. 19(e).
[4] Fla. Const. art. VII s. 19(c).
[5] Pursuant to s. 456.001(4), F.S., health care practitioners are defined to include acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists, midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, counselors, and psychotherapists, among others.
[6] Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2019-2020*, http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/2019-2020-annual-report.pdf (last visited March 26, 2021).
[7] Section 456.025(1), F.S.
[8] Id.

- Similar to fees imposed on similar licensure types; and
- No more than 10 percent greater than the actual cost to regulate that profession for the previous biennium.

Genetic Counselors

Genetic counselors provide individuals information about how genetic conditions might affect them or their families. Genetic counselors collect personal and family history and use such information to determine how likely it is that an individual or his or her family member has a genetic condition. Based on such information, a genetic counselor helps an individual determine if a genetic test is suitable. Genetic counseling after genetic testing can help an individual better understand his or her test results and treatment options.[9]

Currently, genetic counselors are not licensed or regulated in this state and no fees are assessed for initial licensure or renewal.

Effect of the Bill

HB 1235, which is linked to HB 1233, authorizes DOH to adopt rules relating to the procedures for issuance and annual renewal of genetic counselor licenses, including an application and renewal fee not to exceed $25. The bill authorizes DOH to waive such fees by rule. Proceeds from collected fees must be deposited in the Administrative Trust Fund within DOH and used for the regulation of genetic counselors.

The bill becomes effective on the same date as HB 1233 or similar legislation.

B. SECTION DIRECTORY:

Section 1: Creates s. 483.919, F.S., relating to licensure of genetic counselors.
Section 2: Provides an effective date of the same date that HB 1233 or similar legislation takes effect.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Genetic counselor applicants for licensure will be assessed an application fee of up to $25 for issuance and annual renewal of a license. The total amount of revenue DOH will receive from such fees is indeterminate because the number of genetic counselors who will apply for licensure is not predictable.

2. Expenditures:

   DOH will incur costs associated with the regulation of licensees, rulemaking, and technology updates, the impact of which is indeterminate.[10]

[9] Centers for Disease Control and Prevention, *Genetic Counseling,* https://www.cdc.gov/genomics/gtesting/genetic_counseling.htm (last visited March 26, 2021).
[10] Department of Health, Agency Analysis of 2021 House Bill 1235 (March 22, 2021).

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Genetic counselor license applicants will have to pay an application fee and annual renewal fee. The bill authorizes DOH to set the application and annual renewal fees, but neither fee may exceed $25.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

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

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking needed for implementation.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to fees; creating s. 483.919, F.S.; requiring the Department of Health to adopt by rule procedures for the issuance and annual renewal of genetic counselor licenses, including a specified application fee; authorizing the department to waive payment of the fee by rule; providing for the deposit and use of fee proceeds; providing a contingent effective date.

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

Section 1. Section 483.919, Florida Statutes, is created to read:

483.919 Licensure of genetic counselors.—The department shall adopt by rule procedures for the issuance and annual renewal of a genetic counselor license, including an application fee not to exceed $25 for such issuance and annual renewal. The department may waive payment of the fee by rule. Proceeds from fees collected pursuant to this section shall be deposited in the Administrative Trust Fund within the Department of Health and used for the administration of genetic counselor licensure.

Section 2. This act shall take effect on the same date that HB 1233 or similar legislation takes effect if such legislation is adopted in the same legislative session or an

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

extension thereof and becomes a law.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1345 Pharmaceutical Products Containing Cannabis
SPONSOR(S): Persons-Mulicka and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1738

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Criminal Justice & Public Safety Subcommittee	16 Y, 0 N	Padgett	Hall
2) Professions & Public Health Subcommittee		Guzzo	McElroy
3) Judiciary Committee			

SUMMARY ANALYSIS

Federal and state law both classify controlled substances into five schedules. The scheduling determination for a controlled substance is based on a substance's potential for abuse, accepted medical use, and potential for addiction. The classifications range from a Schedule I substance, which has a high potential for abuse, with no accepted medical use, and high potential for addiction; to a Schedule V substance, which has a low potential for abuse, an accepted medical use, and a mild potential for addiction. With the exception of Epidiolex, which is the only pharmaceutical product derived from the cannabis plant approved for medical use by the U.S. Food and Drug Administration (FDA), cannabis and compounds derived from cannabis are listed in Schedule I of both federal and Florida law.

HB 1345 amends s. 893.03(1)(c)7., F.S., to exclude from Schedule I any pharmaceutical product containing cannabis that has been approved by the FDA. The Legislature retains the authority to schedule a pharmaceutical product through future legislation, including as a Schedule I controlled substance.

Although there are currently no other FDA approved pharmaceutical products besides Epidiolex derived from the cannabis plant, the bill would prevent any future pharmaceutical product from being automatically placed in Schedule I, which includes controlled substances that have no currently accepted medical use.

Preventing an FDA approved pharmaceutical product derived from the cannabis plant from being automatically included in Schedule I could increase the availability of the product to Florida residents, and allow doctors and pharmacies to prescribe and dispense such a product without burdensome regulations and reporting requirements.

The bill does not appear to have a fiscal impact on state or local governments.

The bill is effective upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Florida Law

Controlled Substances

Chapter 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act, classifies controlled substances into five categories, called schedules. These schedules regulate the manufacture, distribution, preparation, and dispensing of the substances listed therein. The distinguishing factors between the different drug schedules are the "potential for abuse"[1] of the substance and whether there is a currently accepted medical use for the substance.[2]

The controlled substance schedules are as follows:

- Schedule I substances have a high potential for abuse and currently have no accepted medical use in the United States, including substances such as cannabis and heroin.[3]
- Schedule II substances have a high potential for abuse and have a currently accepted but severely restricted medical use in the United States, including substances such as raw opium, fentanyl, and codeine.[4]
- Schedule III substances have a potential for abuse less than the substances contained in Schedules I and II and have a currently accepted medical use in the United States, including substances such as stimulants and anabolic steroids.[5]
- Schedule IV substances have a low potential for abuse relative to substances in Schedule III and have a currently accepted medical use in the United States, including substances such as benzodiazepines and barbiturates.[6]
- Schedule V substances have a low potential for abuse relative to the substances in Schedule IV and have a currently accepted medical use in the United States, including substances such as mixtures that contain small quantities of opiates, narcotics, or stimulants.[7]

A prescriber[8] or dispenser[9] of controlled substances in Florida is required to consult the Prescription Drug Monitoring Program (PDMP) system each time a controlled substance is prescribed or dispensed to a patient age 16 or over unless a statutory exemption applies.[10] A dispenser is required to report to the PDMP each time a controlled substance in schedules II, III, IV, and V are dispensed to a patient.[11]

Attorney General

[1] S. 893.035(3)(a), F.S., defines "potential for abuse" to mean that a substance has properties as a central nervous system stimulant or depressant or a hallucinogen that create a substantial likelihood of its being: 1) used in amounts that create a hazard to the user's health or safety of the community; 2) diverted from legal channels and distributed through illegal channels; or 3) taken on the user's own initiative rather than on the basis of professional medical advice.
[2] *See* s. 893.03, F.S.
[3] S. 893.03(1), F.S.
[4] S. 893.03(2), F.S.
[5] S. 893.03(3), F.S.
[6] S. 893.03(4), F.S.
[7] S. 893.03(5), F.S.
[8] "Prescriber" means a prescribing physician, prescribing practitioner, or other prescribing health care practitioner authorized by the laws of this state to order controlled substances. S. 893.055(1)(k), F.S.
[9] "Dispenser" means a dispensing health care practitioner, pharmacy, or pharmacist licensed to dispense controlled substances in or into this state. S. 893.055(1)(e), F.S.
[10] S. 893.055, F.S.
[11] S. 893.055(3), F.S. Schedule I substances are not included because, by definition, a Schedule I substance has no accepted medical use and therefore is not prescribed or dispensed.

The Legislature delegated to the Florida Attorney General the authority to adopt rules rescheduling or deleting controlled substances from a schedule if reduced control of a substance is in the best interest of the public.[12] In making this determination, the Attorney General is required to give great weight to the scheduling of the substance under federal law and consider scientific evidence of a substance's medical benefits.[13] The Attorney General also has the authority to schedule or reschedule any substance which is not already controlled under s. 893.03, F.S., if the substance has the potential for abuse.[14]

Federal Law

The Federal Controlled Substances Act[15] (CSA) also classifies controlled substances into schedules based on the potential for abuse and whether there is a currently accepted medical use for the substance. The Drug Enforcement Administration (DEA) is required to consider the following when determining where to schedule a substance:[16]

- The substance's actual or relative potential for abuse;
- Scientific evidence of the substance's pharmacological effect, if known;
- The state of current scientific knowledge regarding the substance;
- The substance's history and current pattern of abuse;
- The scope, duration, and significance of abuse;
- What, if any, risk there is to public health;
- The substance's psychic or physiological dependence liability; and
- Whether the substance is an immediate precursor of a substance already controlled.

A controlled substance subject to regulation under the CSA is subject to strict distribution and inventory controls. The CSA requires a controlled substance to be tracked and inventoried from the time it is manufactured or imported until it is dispensed to a patient.[17] Additionally, the CSA also restricts how specified controlled substances may be prescribed, requires minimum security precautions for controlled substances, and requires each person or entity authorized to handle a controlled substance to register with the DEA.[18]

Epidiolex

Epidiolex, which is currently the only prescription pharmaceutical approved by the U.S. Food and Drug Administration (FDA) containing cannabidiol, a non-psychoactive compound derived from the cannabis plant, is used to treat seizures associated with Lennox-Gastaut syndrome or Dravet syndrome.[19] Since Epidiolex is derived from the cannabis plant, it would have been designated a Schedule I controlled substance under state and federal law. However, on June 25, 2018, the FDA approved Epidiolex for use in patients two years of age or older.[20] The DEA responded by rescheduling Epidiolex in schedule V of the federal Controlled Substances Act effective September 27, 2018.[21] Although Epidiolex was still subject to the requirements under the CSA, the rescheduling allowed doctors to legally prescribe Epidiolex to patients. In 2018, the Florida Attorney General rescheduled Epidiolex by emergency rule[22] as a Schedule V controlled substance, and in 2019, the Legislature formally rescheduled Epidiolex in statute as a Schedule V controlled substance.[23]

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[12] S. 893.0355, F.S.
[13] *Id.*
[14] S. 893.035, F.S.
[15] 21 U.S.C. § 812.
[16] 21 U.S.C. § 811(c).
[17] 21 U.S.C. §827.
[18] 21 U.S.C. Part C.
[19] Greenwich Biosciences, *The Epidiolex Story*, https://www.epidiolex.com/about-epidiolex/story (last visited Mar. 20, 2021).
[20] U.S. Food and Drug Administration, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy,* https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm611046.htm (last visited Mar. 16, 2021).
[21] United State Drug Enforcement Administration, *FDA-approved drug Epidiolex placed in schedule V of Controlled Substance Act*, https://www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act (last visited Mar. 20, 2021).
[22] Office of the Attorney General, Findings of the Attorney General in Support of Emergency Rule 2ER18-1, F.A.C. (Oct. 31, 2018).
[23] Ch. 19-166, Laws of Florida.

On April 6, 2020, the DEA announced it was removing Epidiolex from Schedule V and descheduling it entirely, meaning Epidiolex is no longer subject to the CSA and its tracking and monitoring requirements.[24] Epidiolex remains a Schedule V controlled substance under Florida law.[25]

Effect of Proposed Changes

HB 1345 amends s. 893.03(1)(c)7., F.S., to exclude from Schedule I any pharmaceutical product containing cannabis that has been approved by the FDA. The Legislature retains the authority to schedule a pharmaceutical product through future legislation, including as a Schedule I controlled substance.

Although there are currently no other FDA approved pharmaceutical products derived from the cannabis plant besides Epidiolex, the bill would prevent any future pharmaceutical product from being automatically placed in Schedule I, which includes controlled substances that have no currently accepted medical use.

The bill is effective upon becoming a law.

B. SECTION DIRECTORY:

Section 1: Amends s. 893.03, F.S., relating to standards and schedules.
Section 2: Provides the bill is effective upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Preventing an FDA approved pharmaceutical product derived from the cannabis plant from being automatically included in Schedule I could increase the availability of the product to Florida residents, and allow doctors and pharmacies to prescribe and dispense such a product without burdensome regulations and reporting requirements.

[24] GW Pharmaceuticals, *GW Pharmaceuticals plc and Its U.S. Subsidiary Greenwich Biosciences, Inc. Announce That Epidiolex (cannabidiol) Oral Solution Has Been Descheduled And Is No Longer A Controlled Substance*, April 6, 2020, https://ir.gwpharm.com/news-releases/news-release-details/gw-pharmaceuticals-plc-and-its-us-subsidiary-greenwich-1 (last visited Mar. 20, 2021)
[25] S. 893.03(5)(d), F.S.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to pharmaceutical products containing cannabis; amending s. 893.03, F.S.; excluding from Schedule I cannabis if it is contained within a pharmaceutical product approved by the United States Food and Drug Administration; providing an effective date.

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

Section 1. Paragraph (c) of subsection (1) of section 893.03, Florida Statutes, is amended to read:

893.03 Standards and schedules.—The substances enumerated in this section are controlled by this chapter. The controlled substances listed or to be listed in Schedules I, II, III, IV, and V are included by whatever official, common, usual, chemical, trade name, or class designated. The provisions of this section shall not be construed to include within any of the schedules contained in this section any excluded drugs listed within the purview of 21 C.F.R. s. 1308.22, styled "Excluded Substances"; 21 C.F.R. s. 1308.24, styled "Exempt Chemical Preparations"; 21 C.F.R. s. 1308.32, styled "Exempted Prescription Products"; or 21 C.F.R. s. 1308.34, styled "Exempt Anabolic Steroid Products."

(1) SCHEDULE I.—A substance in Schedule I has a high

potential for abuse and has no currently accepted medical use in treatment in the United States and in its use under medical supervision does not meet accepted safety standards. The following substances are controlled in Schedule I:

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following hallucinogenic substances or that contains any of their salts, isomers, including optical, positional, or geometric isomers, homologues, nitrogen-heterocyclic analogs, esters, ethers, and salts of isomers, homologues, nitrogen-heterocyclic analogs, esters, or ethers, if the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation or class description:

1. Alpha-Ethyltryptamine.

2. 4-Methylaminorex (2-Amino-4-methyl-5-phenyl-2-oxazoline).

3. Aminorex (2-Amino-5-phenyl-2-oxazoline).

4. DOB (4-Bromo-2,5-dimethoxyamphetamine).

5. 2C-B (4-Bromo-2,5-dimethoxyphenethylamine).

6. Bufotenine.

7. Cannabis, except if it is contained within a pharmaceutical product approved by the United States Food and Drug Administration.

8. Cathinone.

9. DET (Diethyltryptamine).

10. 2,5-Dimethoxyamphetamine.

11. DOET (4-Ethyl-2,5-Dimethoxyamphetamine).

12. DMT (Dimethyltryptamine).

13. PCE (N-Ethyl-1-phenylcyclohexylamine) (Ethylamine analog of phencyclidine).

14. JB-318 (N-Ethyl-3-piperidyl benzilate).

15. N-Ethylamphetamine.

16. Fenethylline.

17. 3,4-Methylenedioxy-N-hydroxyamphetamine.

18. Ibogaine.

19. LSD (Lysergic acid diethylamide).

20. Mescaline.

21. Methcathinone.

22. 5-Methoxy-3,4-methylenedioxyamphetamine.

23. PMA (4-Methoxyamphetamine).

24. PMMA (4-Methoxymethamphetamine).

25. DOM (4-Methyl-2,5-dimethoxyamphetamine).

26. MDEA (3,4-Methylenedioxy-N-ethylamphetamine).

27. MDA (3,4-Methylenedioxyamphetamine).

28. JB-336 (N-Methyl-3-piperidyl benzilate).

29. N,N-Dimethylamphetamine.

30. Parahexyl.

31. Peyote.

32. PCPY (N-(1-Phenylcyclohexyl)-pyrrolidine) (Pyrrolidine

analog of phencyclidine).

33. Psilocybin.

34. Psilocyn.

35. *Salvia divinorum*, except for any drug product approved by the United States Food and Drug Administration which contains *Salvia divinorum* or its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, if the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation.

36. Salvinorin A, except for any drug product approved by the United States Food and Drug Administration which contains Salvinorin A or its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, if the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation.

37. Xylazine.

38. TCP (1-[1-(2-Thienyl)-cyclohexyl]-piperidine) (Thiophene analog of phencyclidine).

39. 3,4,5-Trimethoxyamphetamine.

40. Methylone (3,4-Methylenedioxymethcathinone).

41. MDPV (3,4-Methylenedioxypyrovalerone).

42. Methylmethcathinone.

43. Methoxymethcathinone.

44. Fluoromethcathinone.

45. Methylethcathinone.

46. CP 47,497 (2-(3-Hydroxycyclohexyl)-5-(2-methyloctan-2-yl)phenol) and its dimethyloctyl (C8) homologue.

47. HU-210 [(6aR,10aR)-9-(Hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol].

48. JWH-018 (1-Pentyl-3-(1-naphthoyl)indole).

49. JWH-073 (1-Butyl-3-(1-naphthoyl)indole).

50. JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole).

51. BZP (Benzylpiperazine).

52. Fluorophenylpiperazine.

53. Methylphenylpiperazine.

54. Chlorophenylpiperazine.

55. Methoxyphenylpiperazine.

56. DBZP (1,4-Dibenzylpiperazine).

57. TFMPP (Trifluoromethylphenylpiperazine).

58. MBDB (Methylbenzodioxolylbutanamine) or (3,4-Methylenedioxy-N-methylbutanamine).

59. 5-Hydroxy-AMT (5-Hydroxy-alpha-methyltryptamine).

60. 5-Hydroxy-N-methyltryptamine.

61. 5-MeO-MiPT (5-Methoxy-N-methyl-N-isopropyltryptamine).

62. 5-MeO-AMT (5-Methoxy-alpha-methyltryptamine).

63. Methyltryptamine.

64. 5-MeO-DMT (5-Methoxy-N,N-dimethyltryptamine).

65. 5-Me-DMT (5-Methyl-N,N-dimethyltryptamine).

66. Tyramine (4-Hydroxyphenethylamine).
67. 5-MeO-DiPT (5-Methoxy-N,N-Diisopropyltryptamine).
68. DiPT (N,N-Diisopropyltryptamine).
69. DPT (N,N-Dipropyltryptamine).
70. 4-Hydroxy-DiPT (4-Hydroxy-N,N-diisopropyltryptamine).
71. 5-MeO-DALT (5-Methoxy-N,N-Diallyltryptamine).
72. DOI (4-Iodo-2,5-dimethoxyamphetamine).
73. DOC (4-Chloro-2,5-dimethoxyamphetamine).
74. 2C-E (4-Ethyl-2,5-dimethoxyphenethylamine).
75. 2C-T-4 (4-Isopropylthio-2,5-dimethoxyphenethylamine).
76. 2C-C (4-Chloro-2,5-dimethoxyphenethylamine).
77. 2C-T (4-Methylthio-2,5-dimethoxyphenethylamine).
78. 2C-T-2 (4-Ethylthio-2,5-dimethoxyphenethylamine).
79. 2C-T-7 (4-(n)-Propylthio-2,5-dimethoxyphenethylamine).
80. 2C-I (4-Iodo-2,5-dimethoxyphenethylamine).
81. Butylone (3,4-Methylenedioxy-alpha-methylaminobutyrophenone).
82. Ethcathinone.
83. Ethylone (3,4-Methylenedioxy-N-ethylcathinone).
84. Naphyrone (Naphthylpyrovalerone).
85. Dimethylone (3,4-Methylenedioxy-N,N-dimethylcathinone).
86. 3,4-Methylenedioxy-N,N-diethylcathinone.
87. 3,4-Methylenedioxy-propiophenone.
88. 3,4-Methylenedioxy-alpha-bromopropiophenone.

89. 3,4-Methylenedioxy-propiophenone-2-oxime.

90. 3,4-Methylenedioxy-N-acetylcathinone.

91. 3,4-Methylenedioxy-N-acetylmethcathinone.

92. 3,4-Methylenedioxy-N-acetylethcathinone.

93. Bromomethcathinone.

94. Buphedrone (alpha-Methylamino-butyrophenone).

95. Eutylone (3,4-Methylenedioxy-alpha-ethylaminobutyrophenone).

96. Dimethylcathinone.

97. Dimethylmethcathinone.

98. Pentylone (3,4-Methylenedioxy-alpha-methylaminovalerophenone).

99. MDPPP (3,4-Methylenedioxy-alpha-pyrrolidinopropiophenone).

100. MDPBP (3,4-Methylenedioxy-alpha-pyrrolidinobutyrophenone).

101. MOPPP (Methoxy-alpha-pyrrolidinopropiophenone).

102. MPHP (Methyl-alpha-pyrrolidinohexanophenone).

103. BTCP (Benzothiophenylcyclohexylpiperidine) or BCP (Benocyclidine).

104. F-MABP (Fluoromethylaminobutyrophenone).

105. MeO-PBP (Methoxypyrrolidinobutyrophenone).

106. Et-PBP (Ethylpyrrolidinobutyrophenone).

107. 3-Me-4-MeO-MCAT (3-Methyl-4-Methoxymethcathinone).

108. Me-EABP (Methylethylaminobutyrophenone).

109. Etizolam.

110. PPP (Pyrrolidinopropiophenone).

111. PBP (Pyrrolidinobutyrophenone).

112. PVP (Pyrrolidinovalerophenone) or (Pyrrolidinopentiophenone).

113. MPPP (Methyl-alpha-pyrrolidinopropiophenone).

114. JWH-007 (1-Pentyl-2-methyl-3-(1-naphthoyl)indole).

115. JWH-015 (1-Propyl-2-methyl-3-(1-naphthoyl)indole).

116. JWH-019 (1-Hexyl-3-(1-naphthoyl)indole).

117. JWH-020 (1-Heptyl-3-(1-naphthoyl)indole).

118. JWH-072 (1-Propyl-3-(1-naphthoyl)indole).

119. JWH-081 (1-Pentyl-3-(4-methoxy-1-naphthoyl)indole).

120. JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole).

121. JWH-133 ((6aR,10aR)-6,6,9-Trimethyl-3-(2-methylpentan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromene).

122. JWH-175 (1-Pentyl-3-(1-naphthylmethyl)indole).

123. JWH-201 (1-Pentyl-3-(4-methoxyphenylacetyl)indole).

124. JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole).

125. JWH-210 (1-Pentyl-3-(4-ethyl-1-naphthoyl)indole).

126. JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole).

127. JWH-251 (1-Pentyl-3-(2-methylphenylacetyl)indole).

128. JWH-302 (1-Pentyl-3-(3-methoxyphenylacetyl)indole).

129. JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole).

130. HU-211 ((6aS,10aS)-9-(Hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-

ol).

131. HU-308 ([(1R,2R,5R)-2-[2,6-Dimethoxy-4-(2-methyloctan-2-yl)phenyl]-7,7-dimethyl-4-bicyclo[3.1.1]hept-3-enyl] methanol).

132. HU-331 (3-Hydroxy-2-[(1R,6R)-3-methyl-6-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-2,5-cyclohexadiene-1,4-dione).

133. CB-13 (4-Pentyloxy-1-(1-naphthoyl)naphthalene).

134. CB-25 (N-Cyclopropyl-11-(3-hydroxy-5-pentylphenoxy)-undecanamide).

135. CB-52 (N-Cyclopropyl-11-(2-hexyl-5-hydroxyphenoxy)-undecanamide).

136. CP 55,940 (2-[3-Hydroxy-6-propanol-cyclohexyl]-5-(2-methyloctan-2-yl)phenol).

137. AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole).

138. AM-2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl)indole).

139. RCS-4 (1-Pentyl-3-(4-methoxybenzoyl)indole).

140. RCS-8 (1-(2-Cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole).

141. WIN55,212-2 ((R)-(+)-[2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-naphthalenylmethanone).

142. WIN55,212-3 ([(3S)-2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-naphthalenylmethanone).

143. Pentedrone (alpha-Methylaminovalerophenone).
144. Fluoroamphetamine.
145. Fluoromethamphetamine.
146. Methoxetamine.
147. Methiopropamine.
148. Methylbuphedrone (Methyl-alpha-methylaminobutyrophenone).
149. APB ((2-Aminopropyl)benzofuran).
150. APDB ((2-Aminopropyl)-2,3-dihydrobenzofuran).
151. UR-144 (1-Pentyl-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).
152. XLR11 (1-(5-Fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).
153. Chloro UR-144 (1-(Chloropentyl)-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).
154. AKB48 (N-Adamant-1-yl 1-pentylindazole-3-carboxamide).
155. AM-2233(1-[(N-Methyl-2-piperidinyl)methyl]-3-(2-iodobenzoyl)indole).
156. STS-135 (N-Adamant-1-yl 1-(5-fluoropentyl)indole-3-carboxamide).
157. URB-597 ((3'-(Aminocarbonyl)[1,1'-biphenyl]-3-yl)-cyclohexylcarbamate).
158. URB-602 ([1,1'-Biphenyl]-3-yl-carbamic acid, cyclohexyl ester).

159. URB-754 (6-Methyl-2-[(4-methylphenyl)amino]-1-benzoxazin-4-one).

160. 2C-D (4-Methyl-2,5-dimethoxyphenethylamine).

161. 2C-H (2,5-Dimethoxyphenethylamine).

162. 2C-N (4-Nitro-2,5-dimethoxyphenethylamine).

163. 2C-P (4-(n)-Propyl-2,5-dimethoxyphenethylamine).

164. 25I-NBOMe (4-Iodo-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).

165. MDMA (3,4-Methylenedioxymethamphetamine).

166. PB-22 (8-Quinolinyl 1-pentylindole-3-carboxylate).

167. Fluoro PB-22 (8-Quinolinyl 1-(fluoropentyl)indole-3-carboxylate).

168. BB-22 (8-Quinolinyl 1-(cyclohexylmethyl)indole-3-carboxylate).

169. Fluoro AKB48 (N-Adamant-1-yl 1-(fluoropentyl)indazole-3-carboxamide).

170. AB-PINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide).

171. AB-FUBINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide).

172. ADB-PINACA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide).

173. Fluoro ADBICA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(fluoropentyl)indole-3-carboxamide).

174. 25B-NBOMe (4-Bromo-2,5-dimethoxy-[N-(2-

methoxybenzyl)]phenethylamine).

175. 25C-NBOMe (4-Chloro-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).

176. AB-CHMINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide).

177. FUB-PB-22 (8-Quinolinyl 1-(4-fluorobenzyl)indole-3-carboxylate).

178. Fluoro-NNEI (N-Naphthalen-1-yl 1-(fluoropentyl)indole-3-carboxamide).

179. Fluoro-AMB (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-1-(fluoropentyl)indazole-3-carboxamide).

180. THJ-2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl)indazole).

181. AM-855 ((4aR,12bR)-8-Hexyl-2,5,5-trimethyl-1,4,4a,8,9,10,11,12b-octahydronaphtho[3,2-c]isochromen-12-ol).

182. AM-905 ((6aR,9R,10aR)-3-[(E)-Hept-1-enyl]-9-(hydroxymethyl)-6,6-dimethyl-6a,7,8,9,10,10a-hexahydrobenzo[c]chromen-1-ol).

183. AM-906 ((6aR,9R,10aR)-3-[(Z)-Hept-1-enyl]-9-(hydroxymethyl)-6,6-dimethyl-6a,7,8,9,10,10a-hexahydrobenzo[c]chromen-1-ol).

184. AM-2389 ((6aR,9R,10aR)-3-(1-Hexyl-cyclobut-1-yl)-6a,7,8,9,10,10a-hexahydro-6,6-dimethyl-6H-dibenzo[b,d]pyran-1,9 diol).

185. HU-243 ((6aR,8S,9S,10aR)-9-(Hydroxymethyl)-6,6-

dimethyl-3-(2-methyloctan-2-yl)-8,9-ditritio-7,8,10,10a-tetrahydro-6aH-benzo[c]chromen-1-ol).

186. HU-336 ((6aR,10aR)-6,6,9-Trimethyl-3-pentyl-6a,7,10,10a-tetrahydro-1H-benzo[c]chromene-1,4(6H)-dione).

187. MAPB ((2-Methylaminopropyl)benzofuran).

188. 5-IT (2-(1H-Indol-5-yl)-1-methyl-ethylamine).

189. 6-IT (2-(1H-Indol-6-yl)-1-methyl-ethylamine).

190. Synthetic Cannabinoids.—Unless specifically excepted or unless listed in another schedule or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, mixture, or preparation that contains any quantity of a synthetic cannabinoid found to be in any of the following chemical class descriptions, or homologues, nitrogen-heterocyclic analogs, isomers (including optical, positional, or geometric), esters, ethers, salts, and salts of homologues, nitrogen-heterocyclic analogs, isomers, esters, or ethers, whenever the existence of such homologues, nitrogen-heterocyclic analogs, isomers, esters, ethers, salts, and salts of isomers, esters, or ethers is possible within the specific chemical class or designation. Since nomenclature of these synthetically produced cannabinoids is not internationally standardized and may continually evolve, these structures or the compounds of these structures shall be included under this subparagraph, regardless of their specific numerical designation of atomic positions covered, if it can be

determined through a recognized method of scientific testing or analysis that the substance contains properties that fit within one or more of the following categories:

a. Tetrahydrocannabinols.—Any tetrahydrocannabinols naturally contained in a plant of the genus *Cannabis*, the synthetic equivalents of the substances contained in the plant or in the resinous extracts of the genus *Cannabis*, or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity, including, but not limited to, Delta 9 tetrahydrocannabinols and their optical isomers, Delta 8 tetrahydrocannabinols and their optical isomers, Delta 6a,10a tetrahydrocannabinols and their optical isomers, or any compound containing a tetrahydrobenzo[c]chromene structure with substitution at either or both the 3-position or 9-position, with or without substitution at the 1-position with hydroxyl or alkoxy groups, including, but not limited to:

(I) Tetrahydrocannabinol.

(II) HU-210 ((6aR,10aR)-9-(Hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol).

(III) HU-211 ((6aS,10aS)-9-(Hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol).

(IV) JWH-051 ((6aR,10aR)-9-(Hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromene).

(V) JWH-133 ((6aR,10aR)-6,6,9-Trimethyl-3-(2-methylpentan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromene).

(VI) JWH-057 ((6aR,10aR)-6,6,9-Trimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromene).

(VII) JWH-359 ((6aR,10aR)-1-Methoxy-6,6,9-trimethyl-3-(2,3-dimethylpentan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromene).

(VIII) AM-087 ((6aR,10aR)-3-(2-Methyl-6-bromohex-2-yl)-6,6,9-trimethyl-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol).

(IX) AM-411 ((6aR,10aR)-3-(1-Adamantyl)-6,6,9-trimethyl-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol).

(X) Parahexyl.

b. Naphthoylindoles, Naphthoylindazoles, Naphthoylcarbazoles, Naphthylmethylindoles, Naphthylmethylindazoles, and Naphthylmethylcarbazoles.—Any compound containing a naphthoylindole, naphthoylindazole, naphthoylcarbazole, naphthylmethylindole, naphthylmethylindazole, or naphthylmethylcarbazole structure, with or without substitution on the indole, indazole, or carbazole ring to any extent, whether or not substituted on the naphthyl ring to any extent, including, but not limited to:

(I) JWH-007 (1-Pentyl-2-methyl-3-(1-naphthoyl)indole).

(II) JWH-011 (1-(1-Methylhexyl)-2-methyl-3-(1-naphthoyl)indole).

(III) JWH-015 (1-Propyl-2-methyl-3-(1-naphthoyl)indole).

(IV) JWH-016 (1-Butyl-2-methyl-3-(1-naphthoyl)indole).

(V) JWH-018 (1-Pentyl-3-(1-naphthoyl)indole).

(VI) JWH-019 (1-Hexyl-3-(1-naphthoyl)indole).

(VII) JWH-020 (1-Heptyl-3-(1-naphthoyl)indole).

(VIII) JWH-022 (1-(4-Pentenyl)-3-(1-naphthoyl)indole).

(IX) JWH-071 (1-Ethyl-3-(1-naphthoyl)indole).

(X) JWH-072 (1-Propyl-3-(1-naphthoyl)indole).

(XI) JWH-073 (1-Butyl-3-(1-naphthoyl)indole).

(XII) JWH-080 (1-Butyl-3-(4-methoxy-1-naphthoyl)indole).

(XIII) JWH-081 (1-Pentyl-3-(4-methoxy-1-naphthoyl)indole).

(XIV) JWH-098 (1-Pentyl-2-methyl-3-(4-methoxy-1-naphthoyl)indole).

(XV) JWH-116 (1-Pentyl-2-ethyl-3-(1-naphthoyl)indole).

(XVI) JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole).

(XVII) JWH-149 (1-Pentyl-2-methyl-3-(4-methyl-1-naphthoyl)indole).

(XVIII) JWH-164 (1-Pentyl-3-(7-methoxy-1-naphthoyl)indole).

(XIX) JWH-175 (1-Pentyl-3-(1-naphthylmethyl)indole).

(XX) JWH-180 (1-Propyl-3-(4-propyl-1-naphthoyl)indole).

(XXI) JWH-182 (1-Pentyl-3-(4-propyl-1-naphthoyl)indole).

(XXII) JWH-184 (1-Pentyl-3-[(4-methyl)-1-naphthylmethyl]indole).

(XXIII) JWH-193 (1-[2-(4-Morpholinyl)ethyl]-3-(4-methyl-1-naphthoyl)indole).

(XXIV) JWH-198 (1-[2-(4-Morpholinyl)ethyl]-3-(4-methoxy-1-naphthoyl)indole).

(XXV) JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole).

(XXVI) JWH-210 (1-Pentyl-3-(4-ethyl-1-naphthoyl)indole).

(XXVII) JWH-387 (1-Pentyl-3-(4-bromo-1-naphthoyl)indole).

(XXVIII) JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole).

(XXIX) JWH-412 (1-Pentyl-3-(4-fluoro-1-naphthoyl)indole).

(XXX) JWH-424 (1-Pentyl-3-(8-bromo-1-naphthoyl)indole).

(XXXI) AM-1220 (1-[(1-Methyl-2-piperidinyl)methyl]-3-(1-naphthoyl)indole).

(XXXII) AM-1235 (1-(5-Fluoropentyl)-6-nitro-3-(1-naphthoyl)indole).

(XXXIII) AM-2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl)indole).

(XXXIV) Chloro JWH-018 (1-(Chloropentyl)-3-(1-naphthoyl)indole).

(XXXV) Bromo JWH-018 (1-(Bromopentyl)-3-(1-naphthoyl)indole).

(XXXVI) AM-2232 (1-(4-Cyanobutyl)-3-(1-naphthoyl)indole).

(XXXVII) THJ-2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl)indazole).

(XXXVIII) MAM-2201 (1-(5-Fluoropentyl)-3-(4-methyl-1-naphthoyl)indole).

(XXXIX) EAM-2201 (1-(5-Fluoropentyl)-3-(4-ethyl-1-naphthoyl)indole).

(XL) EG-018 (9-Pentyl-3-(1-naphthoyl)carbazole).

(XLI) EG-2201 (9-(5-Fluoropentyl)-3-(1-naphthoyl)carbazole).

c. Naphthoylpyrroles.—Any compound containing a naphthoylpyrrole structure, with or without substitution on the pyrrole ring to any extent, whether or not substituted on the naphthyl ring to any extent, including, but not limited to:

(I) JWH-030 (1-Pentyl-3-(1-naphthoyl)pyrrole).

(II) JWH-031 (1-Hexyl-3-(1-naphthoyl)pyrrole).

(III) JWH-145 (1-Pentyl-5-phenyl-3-(1-naphthoyl)pyrrole).

(IV) JWH-146 (1-Heptyl-5-phenyl-3-(1-naphthoyl)pyrrole).

(V) JWH-147 (1-Hexyl-5-phenyl-3-(1-naphthoyl)pyrrole).

(VI) JWH-307 (1-Pentyl-5-(2-fluorophenyl)-3-(1-naphthoyl)pyrrole).

(VII) JWH-309 (1-Pentyl-5-(1-naphthalenyl)-3-(1-naphthoyl)pyrrole).

(VIII) JWH-368 (1-Pentyl-5-(3-fluorophenyl)-3-(1-naphthoyl)pyrrole).

(IX) JWH-369 (1-Pentyl-5-(2-chlorophenyl)-3-(1-naphthoyl)pyrrole).

(X) JWH-370 (1-Pentyl-5-(2-methylphenyl)-3-(1-naphthoyl)pyrrole).

d. Naphthylmethylenindenes.—Any compound containing a

naphthylmethylenindene structure, with or without substitution at the 3-position of the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent, including, but not limited to, JWH-176 (3-Pentyl-1-(naphthylmethylene)indene).

e. Phenylacetylindoles and Phenylacetylindazoles.—Any compound containing a phenylacetylindole or phenylacetylindazole structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the phenyl ring to any extent, including, but not limited to:

(I) JWH-167 (1-Pentyl-3-(phenylacetyl)indole).

(II) JWH-201 (1-Pentyl-3-(4-methoxyphenylacetyl)indole).

(III) JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole).

(IV) JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole).

(V) JWH-251 (1-Pentyl-3-(2-methylphenylacetyl)indole).

(VI) JWH-302 (1-Pentyl-3-(3-methoxyphenylacetyl)indole).

(VII) Cannabipiperidiethanone.

(VIII) RCS-8 (1-(2-Cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole).

f. Cyclohexylphenols.—Any compound containing a cyclohexylphenol structure, with or without substitution at the 5-position of the phenolic ring to any extent, whether or not substituted on the cyclohexyl ring to any extent, including, but not limited to:

(I) CP 47,497 (2-(3-Hydroxycyclohexyl)-5-(2-methyloctan-2-

yl)phenol).

(II) Cannabicyclohexanol (CP 47,497 dimethyloctyl (C8) homologue).

(III) CP-55,940 (2-(3-Hydroxy-6-propanol-cyclohexyl)-5-(2-methyloctan-2-yl)phenol).

g. Benzoylindoles and Benzoylindazoles.—Any compound containing a benzoylindole or benzoylindazole structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the phenyl ring to any extent, including, but not limited to:

(I) AM-679 (1-Pentyl-3-(2-iodobenzoyl)indole).

(II) AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole).

(III) AM-1241 (1-[(N-Methyl-2-piperidinyl)methyl]-3-(2-iodo-5-nitrobenzoyl)indole).

(IV) Pravadoline (1-[2-(4-Morpholinyl)ethyl]-2-methyl-3-(4-methoxybenzoyl)indole).

(V) AM-2233 (1-[(N-Methyl-2-piperidinyl)methyl]-3-(2-iodobenzoyl)indole).

(VI) RCS-4 (1-Pentyl-3-(4-methoxybenzoyl)indole).

(VII) RCS-4 C4 homologue (1-Butyl-3-(4-methoxybenzoyl)indole).

(VIII) AM-630 (1-[2-(4-Morpholinyl)ethyl]-2-methyl-6-iodo-3-(4-methoxybenzoyl)indole).

h. Tetramethylcyclopropanoylindoles and Tetramethylcyclopropanoylindazoles.—Any compound containing a

tetramethylcyclopropanoylindole or tetramethylcyclopropanoylindazole structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the tetramethylcyclopropyl group to any extent, including, but not limited to:

(I) UR-144 (1-Pentyl-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).

(II) XLR11 (1-(5-Fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).

(III) Chloro UR-144 (1-(Chloropentyl)-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).

(IV) A-796,260 (1-[2-(4-Morpholinyl)ethyl]-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).

(V) A-834,735 (1-[4-(Tetrahydropyranyl)methyl]-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).

(VI) M-144 (1-(5-Fluoropentyl)-2-methyl-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).

(VII) FUB-144 (1-(4-Fluorobenzyl)-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).

(VIII) FAB-144 (1-(5-Fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropanoyl)indazole).

(IX) XLR12 (1-(4,4,4-Trifluorobutyl)-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).

(X) AB-005 (1-[(1-Methyl-2-piperidinyl)methyl]-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).

i. Adamantoylindoles, Adamantoylindazoles, Adamantylindole carboxamides, and Adamantylindazole carboxamides.—Any compound containing an adamantoyl indole, adamantoyl indazole, adamantyl indole carboxamide, or adamantyl indazole carboxamide structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the adamantyl ring to any extent, including, but not limited to:

(I) AKB48 (N-Adamant-1-yl 1-pentylindazole-3-carboxamide).

(II) Fluoro AKB48 (N-Adamant-1-yl 1-(fluoropentyl)indazole-3-carboxamide).

(III) STS-135 (N-Adamant-1-yl 1-(5-fluoropentyl)indole-3-carboxamide).

(IV) AM-1248 (1-(1-Methylpiperidine)methyl-3-(1-adamantoyl)indole).

(V) AB-001 (1-Pentyl-3-(1-adamantoyl)indole).

(VI) APICA (N-Adamant-1-yl 1-pentylindole-3-carboxamide).

(VII) Fluoro AB-001 (1-(Fluoropentyl)-3-(1-adamantoyl)indole).

j. Quinolinylindolecarboxylates, Quinolinylindazolecarboxylates, Quinolinylindolecarboxamides, and Quinolinylindazolecarboxamides.—Any compound containing a quinolinylindole carboxylate, quinolinylindazole carboxylate, isoquinolinylindole carboxylate, isoquinolinylindazole carboxylate, quinolinylindole carboxamide, quinolinylindazole carboxamide, isoquinolinylindole carboxamide, or

isoquinolinylindazole carboxamide structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the quinoline or isoquinoline ring to any extent, including, but not limited to:

(I) PB-22 (8-Quinolinyl 1-pentylindole-3-carboxylate).

(II) Fluoro PB-22 (8-Quinolinyl 1-(fluoropentyl)indole-3-carboxylate).

(III) BB-22 (8-Quinolinyl 1-(cyclohexylmethyl)indole-3-carboxylate).

(IV) FUB-PB-22 (8-Quinolinyl 1-(4-fluorobenzyl)indole-3-carboxylate).

(V) NPB-22 (8-Quinolinyl 1-pentylindazole-3-carboxylate).

(VI) Fluoro NPB-22 (8-Quinolinyl 1-(fluoropentyl)indazole-3-carboxylate).

(VII) FUB-NPB-22 (8-Quinolinyl 1-(4-fluorobenzyl)indazole-3-carboxylate).

(VIII) THJ (8-Quinolinyl 1-pentylindazole-3-carboxamide).

(IX) Fluoro THJ (8-Quinolinyl 1-(fluoropentyl)indazole-3-carboxamide).

k. Naphthylindolecarboxylates and Naphthylindazolecarboxylates.—Any compound containing a naphthylindole carboxylate or naphthylindazole carboxylate structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the naphthyl ring to any extent, including, but not limited to:

(I) NM-2201 (1-Naphthalenyl 1-(5-fluoropentyl)indole-3-carboxylate).

(II) SDB-005 (1-Naphthalenyl 1-pentylindazole-3-carboxylate).

(III) Fluoro SDB-005 (1-Naphthalenyl 1-(fluoropentyl)indazole-3-carboxylate).

(IV) FDU-PB-22 (1-Naphthalenyl 1-(4-fluorobenzyl)indole-3-carboxylate).

(V) 3-CAF (2-Naphthalenyl 1-(2-fluorophenyl)indazole-3-carboxylate).

l. Naphthylindole carboxamides and Naphthylindazole carboxamides.—Any compound containing a naphthylindole carboxamide or naphthylindazole carboxamide structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the naphthyl ring to any extent, including, but not limited to:

(I) NNEI (N-Naphthalen-1-yl 1-pentylindole-3-carboxamide).

(II) Fluoro-NNEI (N-Naphthalen-1-yl 1-(fluoropentyl)indole-3-carboxamide).

(III) Chloro-NNEI (N-Naphthalen-1-yl 1-(chloropentyl)indole-3-carboxamide).

(IV) MN-18 (N-Naphthalen-1-yl 1-pentylindazole-3-carboxamide).

(V) Fluoro MN-18 (N-Naphthalen-1-yl 1-(fluoropentyl)indazole-3-carboxamide).

m. Alkylcarbonyl indole carboxamides, Alkylcarbonyl indazole carboxamides, Alkylcarbonyl indole carboxylates, and Alkylcarbonyl indazole carboxylates.—Any compound containing an alkylcarbonyl group, including 1-amino-3-methyl-1-oxobutan-2-yl, 1-methoxy-3-methyl-1-oxobutan-2-yl, 1-amino-1-oxo-3-phenylpropan-2-yl, 1-methoxy-1-oxo-3-phenylpropan-2-yl, with an indole carboxamide, indazole carboxamide, indole carboxylate, or indazole carboxylate, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the alkylcarbonyl group to any extent, including, but not limited to:

(I) ADBICA, (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentylindole-3-carboxamide).

(II) Fluoro ADBICA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(fluoropentyl)indole-3-carboxamide).

(III) Fluoro ABICA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(fluoropentyl)indole-3-carboxamide).

(IV) AB-PINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide).

(V) Fluoro AB-PINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(fluoropentyl)indazole-3-carboxamide).

(VI) ADB-PINACA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide).

(VII) Fluoro ADB-PINACA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(fluoropentyl)indazole-3-carboxamide).

(VIII) AB-FUBINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide).

(IX) ADB-FUBINACA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide).

(X) AB-CHMINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide).

(XI) MA-CHMINACA (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide).

(XII) MAB-CHMINACA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide).

(XIII) AMB (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide).

(XIV) Fluoro-AMB (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-1-(fluoropentyl)indazole-3-carboxamide).

(XV) FUB-AMB (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide).

(XVI) MDMB-CHMINACA (N-(1-Methoxy-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide).

(XVII) MDMB-FUBINACA (N-(1-Methoxy-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide).

(XVIII) MDMB-CHMICA (N-(1-Methoxy-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indole-3-carboxamide).

(XIX) PX-1 (N-(1-Amino-1-oxo-3-phenylpropan-2-yl)-1-(5-fluoropentyl)indole-3-carboxamide).

(XX) PX-2 (N-(1-Amino-1-oxo-3-phenylpropan-2-yl)-1-(5-

fluoropentyl)indazole-3-carboxamide).

(XXI) PX-3 (N-(1-Amino-1-oxo-3-phenylpropan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide).

(XXII) PX-4 (N-(1-Amino-1-oxo-3-phenylpropan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide).

(XXIII) MO-CHMINACA (N-(1-Methoxy-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxylate).

n. Cumylindolecarboxamides and Cumylindazolecarboxamides.—Any compound containing a N-(2-phenylpropan-2-yl) indole carboxamide or N-(2-phenylpropan-2-yl) indazole carboxamide structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the phenyl ring of the cumyl group to any extent, including, but not limited to:

(I) CUMYL-PICA (N-(2-Phenylpropan-2-yl)-1-pentylindole-3-carboxamide).

(II) Fluoro CUMYL-PICA (N-(2-Phenylpropan-2-yl)-1-(fluoropentyl)indole-3-carboxamide).

o. Other Synthetic Cannabinoids.—Any material, compound, mixture, or preparation that contains any quantity of a Synthetic Cannabinoid, as described in sub-subparagraphs a.-n.:

(I) With or without modification or replacement of a carbonyl, carboxamide, alkylene, alkyl, or carboxylate linkage between either two core rings, or linkage between a core ring and group structure, with or without the addition of a carbon or

replacement of a carbon;

(II) With or without replacement of a core ring or group structure, whether or not substituted on the ring or group structures to any extent; and

(III) Is a cannabinoid receptor agonist, unless specifically excepted or unless listed in another schedule or contained within a pharmaceutical product approved by the United States Food and Drug Administration.

191. Substituted Cathinones.—Unless specifically excepted, listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, mixture, or preparation, including its salts, isomers, esters, or ethers, and salts of isomers, esters, or ethers, whenever the existence of such salts is possible within any of the following specific chemical designations:

a. Any compound containing a 2-amino-1-phenyl-1-propanone structure;

b. Any compound containing a 2-amino-1-naphthyl-1-propanone structure; or

c. Any compound containing a 2-amino-1-thiophenyl-1-propanone structure,

whether or not the compound is further modified:

(I) With or without substitution on the ring system to any

extent with alkyl, alkylthio, thio, fused alkylenedioxy, alkoxy, haloalkyl, hydroxyl, nitro, fused furan, fused benzofuran, fused dihydrofuran, fused tetrahydropyran, fused alkyl ring, or halide substituents;

(II) With or without substitution at the 3-propanone position with an alkyl substituent or removal of the methyl group at the 3-propanone position;

(III) With or without substitution at the 2-amino nitrogen atom with alkyl, dialkyl, acetyl, or benzyl groups, whether or not further substituted in the ring system; or

(IV) With or without inclusion of the 2-amino nitrogen atom in a cyclic structure, including, but not limited to:

(A) Methcathinone.

(B) Ethcathinone.

(C) Methylone (3,4-Methylenedioxymethcathinone).

(D) 2,3-Methylenedioxymethcathinone.

(E) MDPV (3,4-Methylenedioxypyrovalerone).

(F) Methylmethcathinone.

(G) Methoxymethcathinone.

(H) Fluoromethcathinone.

(I) Methylethcathinone.

(J) Butylone (3,4-Methylenedioxy-alpha-methylaminobutyrophenone).

(K) Ethylone (3,4-Methylenedioxy-N-ethylcathinone).

(L) BMDP (3,4-Methylenedioxy-N-benzylcathinone).

(M) Naphyrone (Naphthylpyrovalerone).

(N) Bromomethcathinone.

(O) Buphedrone (alpha-Methylaminobutyrophenone).

(P) Eutylone (3,4-Methylenedioxy-alpha-ethylaminobutyrophenone).

(Q) Dimethylcathinone.

(R) Dimethylmethcathinone.

(S) Pentylone (3,4-Methylenedioxy-alpha-methylaminovalerophenone).

(T) Pentedrone (alpha-Methylaminovalerophenone).

(U) MDPPP (3,4-Methylenedioxy-alpha-pyrrolidinopropiophenone).

(V) MDPBP (3,4-Methylenedioxy-alpha-pyrrolidinobutyrophenone).

(W) MPPP (Methyl-alpha-pyrrolidinopropiophenone).

(X) PPP (Pyrrolidinopropiophenone).

(Y) PVP (Pyrrolidinovalerophenone) or (Pyrrolidinopentiophenone).

(Z) MOPPP (Methoxy-alpha-pyrrolidinopropiophenone).

(AA) MPHP (Methyl-alpha-pyrrolidinohexanophenone).

(BB) F-MABP (Fluoromethylaminobutyrophenone).

(CC) Me-EABP (Methylethylaminobutyrophenone).

(DD) PBP (Pyrrolidinobutyrophenone).

(EE) MeO-PBP (Methoxypyrrolidinobutyrophenone).

(FF) Et-PBP (Ethylpyrrolidinobutyrophenone).

(GG) 3-Me-4-MeO-MCAT (3-Methyl-4-Methoxymethcathinone).

(HH) Dimethylone (3,4-Methylenedioxy-N,N-dimethylcathinone).

(II) 3,4-Methylenedioxy-N,N-diethylcathinone.

(JJ) 3,4-Methylenedioxy-N-acetylcathinone.

(KK) 3,4-Methylenedioxy-N-acetylmethcathinone.

(LL) 3,4-Methylenedioxy-N-acetylethcathinone.

(MM) Methylbuphedrone (Methyl-alpha-methylaminobutyrophenone).

(NN) Methyl-alpha-methylaminohexanophenone.

(OO) N-Ethyl-N-methylcathinone.

(PP) PHP (Pyrrolidinohexanophenone).

(QQ) PV8 (Pyrrolidinoheptanophenone).

(RR) Chloromethcathinone.

(SS) 4-Bromo-2,5-dimethoxy-alpha-aminoacetophenone.

192. Substituted Phenethylamines.—Unless specifically excepted or unless listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, mixture, or preparation, including its salts, isomers, esters, or ethers, and salts of isomers, esters, or ethers, whenever the existence of such salts is possible within any of the following specific chemical designations, any compound containing a phenethylamine structure, without a beta-keto group, and without a benzyl group attached to the amine group, whether or not the compound is

further modified with or without substitution on the phenyl ring to any extent with alkyl, alkylthio, nitro, alkoxy, thio, halide, fused alkylenedioxy, fused furan, fused benzofuran, fused dihydrofuran, or fused tetrahydropyran substituents, whether or not further substituted on a ring to any extent, with or without substitution at the alpha or beta position by any alkyl substituent, with or without substitution at the nitrogen atom, and with or without inclusion of the 2-amino nitrogen atom in a cyclic structure, including, but not limited to:

a. 2C-B (4-Bromo-2,5-dimethoxyphenethylamine).

b. 2C-E (4-Ethyl-2,5-dimethoxyphenethylamine).

c. 2C-T-4 (4-Isopropylthio-2,5-dimethoxyphenethylamine).

d. 2C-C (4-Chloro-2,5-dimethoxyphenethylamine).

e. 2C-T (4-Methylthio-2,5-dimethoxyphenethylamine).

f. 2C-T-2 (4-Ethylthio-2,5-dimethoxyphenethylamine).

g. 2C-T-7 (4-(n)-Propylthio-2,5-dimethoxyphenethylamine).

h. 2C-I (4-Iodo-2,5-dimethoxyphenethylamine).

i. 2C-D (4-Methyl-2,5-dimethoxyphenethylamine).

j. 2C-H (2,5-Dimethoxyphenethylamine).

k. 2C-N (4-Nitro-2,5-dimethoxyphenethylamine).

l. 2C-P (4-(n)-Propyl-2,5-dimethoxyphenethylamine).

m. MDMA (3,4-Methylenedioxymethamphetamine).

n. MBDB (Methylbenzodioxolylbutanamine) or (3,4-Methylenedioxy-N-methylbutanamine).

o. MDA (3,4-Methylenedioxyamphetamine).

p. 2,5-Dimethoxyamphetamine.
q. Fluoroamphetamine.
r. Fluoromethamphetamine.
s. MDEA (3,4-Methylenedioxy-N-ethylamphetamine).
t. DOB (4-Bromo-2,5-dimethoxyamphetamine).
u. DOC (4-Chloro-2,5-dimethoxyamphetamine).
v. DOET (4-Ethyl-2,5-dimethoxyamphetamine).
w. DOI (4-Iodo-2,5-dimethoxyamphetamine).
x. DOM (4-Methyl-2,5-dimethoxyamphetamine).
y. PMA (4-Methoxyamphetamine).
z. N-Ethylamphetamine.
aa. 3,4-Methylenedioxy-N-hydroxyamphetamine.
bb. 5-Methoxy-3,4-methylenedioxyamphetamine.
cc. PMMA (4-Methoxymethamphetamine).
dd. N,N-Dimethylamphetamine.
ee. 3,4,5-Trimethoxyamphetamine.
ff. 4-APB (4-(2-Aminopropyl)benzofuran).
gg. 5-APB (5-(2-Aminopropyl)benzofuran).
hh. 6-APB (6-(2-Aminopropyl)benzofuran).
ii. 7-APB (7-(2-Aminopropyl)benzofuran).
jj. 4-APDB (4-(2-Aminopropyl)-2,3-dihydrobenzofuran).
kk. 5-APDB (5-(2-Aminopropyl)-2,3-dihydrobenzofuran).
ll. 6-APDB (6-(2-Aminopropyl)-2,3-dihydrobenzofuran).
mm. 7-APDB (7-(2-Aminopropyl)-2,3-dihydrobenzofuran).
nn. 4-MAPB (4-(2-Methylaminopropyl)benzofuran).

oo. 5-MAPB (5-(2-Methylaminopropyl)benzofuran).

pp. 6-MAPB (6-(2-Methylaminopropyl)benzofuran).

qq. 7-MAPB (7-(2-Methylaminopropyl)benzofuran).

rr. 5-EAPB (5-(2-Ethylaminopropyl)benzofuran).

ss. 5-MAPDB (5-(2-Methylaminopropyl)-2,3-dihydrobenzofuran),

which does not include phenethylamine, mescaline as described in subparagraph 20., substituted cathinones as described in subparagraph 191., N-Benzyl phenethylamine compounds as described in subparagraph 193., or methamphetamine as described in subparagraph (2)(c)5.

193. N-Benzyl Phenethylamine Compounds.—Unless specifically excepted or unless listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, mixture, or preparation, including its salts, isomers, esters, or ethers, and salts of isomers, esters, or ethers, whenever the existence of such salts is possible within any of the following specific chemical designations, any compound containing a phenethylamine structure without a beta-keto group, with substitution on the nitrogen atom of the amino group with a benzyl substituent, with or without substitution on the phenyl or benzyl ring to any extent with alkyl, alkoxy, thio, alkylthio, halide, fused alkylenedioxy, fused furan, fused

benzofuran, or fused tetrahydropyran substituents, whether or not further substituted on a ring to any extent, with or without substitution at the alpha position by any alkyl substituent, including, but not limited to:

a. 25B-NBOMe (4-Bromo-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).

b. 25B-NBOH (4-Bromo-2,5-dimethoxy-[N-(2-hydroxybenzyl)]phenethylamine).

c. 25B-NBF (4-Bromo-2,5-dimethoxy-[N-(2-fluorobenzyl)]phenethylamine).

d. 25B-NBMD (4-Bromo-2,5-dimethoxy-[N-(2,3-methylenedioxybenzyl)]phenethylamine).

e. 25I-NBOMe (4-Iodo-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).

f. 25I-NBOH (4-Iodo-2,5-dimethoxy-[N-(2-hydroxybenzyl)]phenethylamine).

g. 25I-NBF (4-Iodo-2,5-dimethoxy-[N-(2-fluorobenzyl)]phenethylamine).

h. 25I-NBMD (4-Iodo-2,5-dimethoxy-[N-(2,3-methylenedioxybenzyl)]phenethylamine).

i. 25T2-NBOMe (4-Methylthio-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).

j. 25T4-NBOMe (4-Isopropylthio-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).

k. 25T7-NBOMe (4-(n)-Propylthio-2,5-dimethoxy-[N-(2-

methoxybenzyl)]phenethylamine).

l. 25C-NBOMe (4-Chloro-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).

m. 25C-NBOH (4-Chloro-2,5-dimethoxy-[N-(2-hydroxybenzyl)]phenethylamine).

n. 25C-NBF (4-Chloro-2,5-dimethoxy-[N-(2-fluorobenzyl)]phenethylamine).

o. 25C-NBMD (4-Chloro-2,5-dimethoxy-[N-(2,3-methylenedioxybenzyl)]phenethylamine).

p. 25H-NBOMe (2,5-Dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).

q. 25H-NBOH (2,5-Dimethoxy-[N-(2-hydroxybenzyl)]phenethylamine).

r. 25H-NBF (2,5-Dimethoxy-[N-(2-fluorobenzyl)]phenethylamine).

s. 25D-NBOMe (4-Methyl-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine),

which does not include substituted cathinones as described in subparagraph 191.

194. Substituted Tryptamines.—Unless specifically excepted or unless listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, mixture, or preparation containing a 2-(1H-indol-3-yl)ethanamine, for

example tryptamine, structure with or without mono- or di-substitution of the amine nitrogen with alkyl or alkenyl groups, or by inclusion of the amino nitrogen atom in a cyclic structure, whether or not substituted at the alpha position with an alkyl group, whether or not substituted on the indole ring to any extent with any alkyl, alkoxy, halo, hydroxyl, or acetoxy groups, including, but not limited to:

a. Alpha-Ethyltryptamine.

b. Bufotenine.

c. DET (Diethyltryptamine).

d. DMT (Dimethyltryptamine).

e. MET (N-Methyl-N-ethyltryptamine).

f. DALT (N,N-Diallyltryptamine).

g. EiPT (N-Ethyl-N-isopropyltryptamine).

h. MiPT (N-Methyl-N-isopropyltryptamine).

i. 5-Hydroxy-AMT (5-Hydroxy-alpha-methyltryptamine).

j. 5-Hydroxy-N-methyltryptamine.

k. 5-MeO-MiPT (5-Methoxy-N-methyl-N-isopropyltryptamine).

l. 5-MeO-AMT (5-Methoxy-alpha-methyltryptamine).

m. Methyltryptamine.

n. 5-MeO-DMT (5-Methoxy-N,N-dimethyltryptamine).

o. 5-Me-DMT (5-Methyl-N,N-dimethyltryptamine).

p. 5-MeO-DiPT (5-Methoxy-N,N-Diisopropyltryptamine).

q. DiPT (N,N-Diisopropyltryptamine).

r. DPT (N,N-Dipropyltryptamine).

s. 4-Hydroxy-DiPT (4-Hydroxy-N,N-diisopropyltryptamine).

t. 5-MeO-DALT (5-Methoxy-N,N-Diallyltryptamine).

u. 4-AcO-DMT (4-Acetoxy-N,N-dimethyltryptamine).

v. 4-AcO-DiPT (4-Acetoxy-N,N-diisopropyltryptamine).

w. 4-Hydroxy-DET (4-Hydroxy-N,N-diethyltryptamine).

x. 4-Hydroxy-MET (4-Hydroxy-N-methyl-N-ethyltryptamine).

y. 4-Hydroxy-MiPT (4-Hydroxy-N-methyl-N-isopropyltryptamine).

z. Methyl-alpha-ethyltryptamine.

aa. Bromo-DALT (Bromo-N,N-diallyltryptamine),

which does not include tryptamine, psilocyn as described in subparagraph 34., or psilocybin as described in subparagraph 33.

195. Substituted Phenylcyclohexylamines.—Unless specifically excepted or unless listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, mixture, or preparation containing a phenylcyclohexylamine structure, with or without any substitution on the phenyl ring, any substitution on the cyclohexyl ring, any replacement of the phenyl ring with a thiophenyl or benzothiophenyl ring, with or without substitution on the amine with alkyl, dialkyl, or alkoxy substituents, inclusion of the nitrogen in a cyclic structure, or any combination of the above, including, but not limited to:

a. BTCP (Benzothiophenylcyclohexylpiperidine) or BCP

(Benocyclidine).

b. PCE (N-Ethyl-1-phenylcyclohexylamine)(Ethylamine analog of phencyclidine).

c. PCPY (N-(1-Phenylcyclohexyl)-pyrrolidine)(Pyrrolidine analog of phencyclidine).

d. PCPr (Phenylcyclohexylpropylamine).

e. TCP (1-[1-(2-Thienyl)-cyclohexyl]-piperidine)(Thiophene analog of phencyclidine).

f. PCEEA (Phenylcyclohexyl(ethoxyethylamine)).

g. PCMPA (Phenylcyclohexyl(methoxypropylamine)).

h. Methoxetamine.

i. 3-Methoxy-PCE ((3-Methoxyphenyl)cyclohexylethylamine).

j. Bromo-PCP ((Bromophenyl)cyclohexylpiperidine).

k. Chloro-PCP ((Chlorophenyl)cyclohexylpiperidine).

l. Fluoro-PCP ((Fluorophenyl)cyclohexylpiperidine).

m. Hydroxy-PCP ((Hydroxyphenyl)cyclohexylpiperidine).

n. Methoxy-PCP ((Methoxyphenyl)cyclohexylpiperidine).

o. Methyl-PCP ((Methylphenyl)cyclohexylpiperidine).

p. Nitro-PCP ((Nitrophenyl)cyclohexylpiperidine).

q. Oxo-PCP ((Oxophenyl)cyclohexylpiperidine).

r. Amino-PCP ((Aminophenyl)cyclohexylpiperidine).

196. W-15, 4-chloro-N-[1-(2-phenylethyl)-2-piperidinylidene]-benzenesulfonamide.

197. W-18, 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]-2-piperidinylidene]-benzenesulfonamide.

198. AH-7921, 3,4-dichloro-N-[[1-(dimethylamino)cyclohexyl]methyl]-benzamide.

199. U47700, trans-3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide.

200. MT-45, 1-cyclohexyl-4-(1,2-diphenylethyl)-piperazine, dihydrochloride.

Section 2. This act shall take effect upon becoming a law.