Tab 1	**SB 140** by **Rodriguez**; (Identical to CS/H 00385) Fees/Professional Counselors Licensure Compact

Tab 2	**SB 1506** by **Rodriguez**; (Identical to H 01387) Department of Health					
~~354844~~	A	S	WD	HP, Harrell	Delete L.659 - 672.	03/28 10:47 AM
771024	A	S	RCS	HP, Rodriguez	Delete L.665 - 672:	03/28 10:47 AM
974128	A	S	RCS	HP, Rodriguez	Delete L.1269 - 1890:	03/28 10:47 AM

Tab 3	**SB 612** by **Yarborough (CO-INTRODUCERS) Gruters, Davis, Book, Osgood**; (Similar to CS/H 00483) Prevention of Blood Clots					
558772	D	S	RCS	HP, Yarborough	Delete everything after	03/28 10:47 AM

Tab 4	**SB 514** by **Hooper (CO-INTRODUCERS) Perry**; (Identical to H 00795) Private Instructional Personnel

Tab 5	**SB 1596** by **Garcia**; (Compare to CS/H 01471) Provider Accountability					
584094	A	S	RCS	HP, Garcia	btw L.374 - 375:	03/28 10:47 AM

Tab 6	**SB 454** by **Avila**; (Similar to CS/H 01133) Physician Assistant Licensure					
333290	A	S	RCS	HP, Avila	Delete L.24 - 81:	03/28 10:47 AM

Tab 7	**SB 1232** by **Brodeur**; (Identical to H 00997) Telehealth Prescribing					
536114	A	S	UNFAV	HP, Book	btw L.27 - 28:	03/28 10:47 AM
132784	A	S	UNFAV	HP, Book	btw L.27 - 28:	03/28 10:47 AM

Tab 8	**SB 344** by **Brodeur**; (Compare to CS/CS/H 00387) Physician Certifications for the Medical Use of Marijuana					
889518	A	S	RS	HP, Brodeur	Delete L.23 - 104:	03/28 10:47 AM
958848	SA	S	RCS	HP, Brodeur	Delete L.23 - 104:	03/28 10:47 AM

Tab 9	**SB 1550** by **Brodeur (CO-INTRODUCERS) Rodriguez, Wright, Perry**; (Similar to H 01509) Prescription Drugs					
100780	D	S	RCS	HP, Brodeur	Delete everything after	03/28 10:47 AM
297190	AA	S	RCS	HP, Brodeur	Delete L.610 - 623:	03/28 10:47 AM
555656	AA	S	RCS	HP, Brodeur	Delete L.1179 - 1180:	03/28 10:47 AM

Tab 10	**SB 1552** by **Brodeur**; (Compare to H 01509) Public Records/Pharmacy Benefit Managers					
795932	A	S	RCS	HP, Brodeur	Delete L.190 - 196:	03/28 10:47 AM
626324	A	S	RCS	HP, Brodeur	Delete L.236:	03/28 10:47 AM

The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Burton, Chair
Senator Brodeur, Vice Chair

MEETING DATE: Monday, March 27, 2023
TIME: 3:00—6:00 p.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Burton, Chair; Senator Brodeur, Vice Chair; Senators Albritton, Avila, Book, Broxson, Burgess, Calatayud, Davis, Garcia, Harrell, and Osgood

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**SB 140** Rodriguez (Identical CS/H 385)	Fees/Professional Counselors Licensure Compact; Authorizing member states of the Professional Counselors Licensure Compact to charge individuals a fee for the privilege to practice under the compact, etc. HP 03/27/2023 Favorable AHS FP	Favorable Yeas 12 Nays 0
2	**SB 1506** Rodriguez (Identical H 1387)	Department of Health; Prohibiting certain research in this state relating to enhanced potential pandemic pathogens; prohibiting medical marijuana treatment centers from producing marijuana products that are attractive to children or manufactured in specified manners; requiring local registrars to electronically file all live birth, death, and fetal death records in their respective jurisdictions in the department's electronic registration system; revising the types of health care practitioners who may make certain determinations of death; extending the timeframe for the confidentiality of certain birth records; revising the scope of practice for audiologists, as it relates to hearing aids to apply to prescription hearing aids only, etc. HP 03/27/2023 Fav/CS RC	Fav/CS Yeas 12 Nays 0
3	**SB 612** Yarborough (Similar CS/H 483)	Prevention of Blood Clots; Citing this act as the "Emily Adkins Blood Clot Prevention Act"; requiring the Agency for Health Care Administration, in conjunction with the Department of Health, to establish a blood clot and pulmonary embolism prevention policy workgroup; providing for membership, meetings, and duties of the workgroup; requiring the agency to submit a final report on the workgroup's findings and recommendations by a specified date; providing for expiration of the workgroup, etc. HP 03/27/2023 Fav/CS AHS FP	Fav/CS Yeas 12 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	**SB 514** Hooper (Identical H 795)	Private Instructional Personnel; Revising the definition of the term "private instructional personnel" to include registered behavioral technicians employed by certain providers, etc. ED 03/14/2023 Favorable HP 03/27/2023 Favorable RC	Favorable Yeas 12 Nays 0
5	**SB 1596** Garcia (Compare H 1471)	Provider Accountability; Revising the rights of residents of nursing home facilities; providing additional disqualifying offenses for purposes of background screening of employees of certain health care providers; creating a cause of action for ex parte injunctive relief against continued unlicensed activity relating to health care provider facilities; authorizing the Agency for Health Care Administration to petition the court for such injunctive relief; providing for ex parte temporary injunctive relief under certain circumstances, etc. HP 03/27/2023 Fav/CS CF RC	Fav/CS Yeas 12 Nays 0
6	**SB 454** Avila (Similar CS/H 1133)	Physician Assistant Licensure; Revising requirements for an applicant for licensure as a physician assistant, etc. HP 03/27/2023 Fav/CS HE RC	Fav/CS Yeas 12 Nays 0
7	**SB 1232** Brodeur (Identical H 997)	Telehealth Prescribing; Revising the circumstances under which a telehealth provider may use telehealth to prescribe certain controlled substances, etc. HP 03/27/2023 Favorable JU RC	Favorable Yeas 12 Nays 0
8	**SB 344** Brodeur (Compare CS/CS/H 387)	Physician Certifications for the Medical Use of Marijuana; Authorizing qualified physicians to perform patient examinations and evaluations through telehealth for renewals of physician certifications for the medical use of marijuana, etc. HP 03/27/2023 Fav/CS AHS FP	Fav/CS Yeas 12 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
9	**SB 1550** Brodeur (Similar H 1509, Linked S 1552)	Prescription Drugs; Citing this act as the "Prescription Drug Reform Act"; specifying additional prohibited acts related to the Florida Drug and Cosmetic Act; requiring certain drug manufacturers to notify the Department of Business and Professional Regulation of reportable drug price increases on a specified form on the effective date of such increase; requiring such manufacturers to submit certain reports to the department by a specified date each year; providing requirements for certain contracts between a pharmacy benefit manager and a pharmacy benefits plan or program or a participating pharmacy; requiring the office to review certain referrals and investigate them under certain circumstances, etc. HP 03/27/2023 Fav/CS FP	Fav/CS Yeas 12 Nays 0
10	**SB 1552** Brodeur (Compare H 1509, Linked S 1550)	Public Records/Pharmacy Benefit Managers; Providing an exemption from public records requirements for examination and investigation reports and work papers relating to pharmacy benefit managers; expanding a public records exemption for the books and records of administrators held by the Office of Insurance Regulation for purposes of examination, audit, and inspection to incorporate the inclusion of pharmacy benefit managers as administrators under the Florida Insurance Code; providing for future legislative review and repeal of the exemption; providing statements of public necessity, etc. HP 03/27/2023 Fav/CS FP	Fav/CS Yeas 12 Nays 0
	Other Related Meeting Documents		

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 140
INTRODUCER:	Senator Rodriguez
SUBJECT:	Fees/Professional Counselors Licensure Compact
DATE:	March 24, 2023
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Brown	HP	**Favorable**
2.			AHS	
3.			FP	

I. Summary:

SB 140 amends the Professional Counselors Licensure Compact found in s. 491.017, F.S., to authorize Florida, a member state, to charge a fee for granting the privilege to practice professional counseling in member states. The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling (board) within the Department of Health (DOH) would be responsible for adopting rules to impose the fee if this bill becomes law.

The Professional Counselors Licensure Compact was enacted into law by the Florida Legislature in 2022.[1] The act's effective date was conditioned upon enactment of the Compact into law by 10 states. Nineteen states have now enacted the Compact into law.[2] Accordingly, the Professional Counselors Licensure Compact is now effective in Florida.

The Florida Constitution requires that legislation that imposes or authorizes new state taxes or fees,[3] or that raises existing state taxes or fees,[4] must be approved by two-thirds of the membership of each house of the Legislature, and the tax or fee provisions must be passed in a separate bill that contains no other subject.[5] SB 140 authorizes the imposition of fees on Florida-licensed mental health professionals who desire to practice in member states pursuant to the compact. As such, the Florida Constitution may require that such a fee provision must be approved in a stand-alone bill by two-thirds of the membership of each house of the Legislature.

SB 140 has an insignificant fiscal impact on the DOH.

[1] Ch. 2022-63, Laws of Fla.
[2] See the 2023 Compact Map, available at: https://counselingcompact.org/map/ (last visited Mar 22, 2023). The member states are Alabama, Arkansas, Colorado, Delaware, Florida, Georgia, Kentucky, Louisiana, Maine, Maryland, Mississippi, Nebraska, New Hampshire, North Carolina, Ohio, Tennessee, Utah, West Virginia, and Wyoming.
[3] FLA. CONST. art VII, s. 19(a).
[4] FLA. CONST. art VII, s. 19(b).
[5] FLA. CONST. art VII, s. 19(e).

The bill provides an effective date of July 1, 2023.

II. Present Situation:

Professional Counselors Licensure Compact

The Professional Counselors Licensure Compact (counseling compact) was enacted into law in the 2022 Legislative Session[6] and is now effective. The act's effective date was conditioned upon enactment of the Compact into law by 10 states. Nineteen states have now enacted the Compact into law[7] and are considered member states.

The counseling compact facilitates interstate practice of licensed professional counseling by counselors licensed in their home state[8] to practice in a member state without the necessity to obtain an additional license from the member state. It also facilitates the delivery of professional counseling services through telehealth technology.[9]

The counseling compact defines a "licensed professional counselor" to mean a counselor licensed by a member state, regardless of the title used by that state, to independently assess, diagnose, and treat behavioral health conditions.[10] Within the definition section of ch. 491, F.S., relating to clinical, counseling, and psychotherapy, "licensed professional counselor" means a clinical social worker, marriage and family therapist, or mental health counselor authorized to provide services under [the counseling compact].[11]

The counseling compact establishes the Counseling Compact Commission which is an instrumentality of the compact states consisting of one voting delegate, appointed by each member state's licensing board.[12]

The board within the DOH is the licensing board responsible for rulemaking and administering ch. 491, F.S., and in particular, the counseling compact. The board has appointed a delegate who is participating in the activities of the Commission.[13] The duties of the Commission include, among other things, to provide for the development, operation, and maintenance of a data system and to adopt rules to achieve the purposes of the compact.[14] The data system and rules are under

[6] *Supra* note 1.
[7] *Supra* note 2.
[8] "Home State" is defined in the counseling compact to mean the member state that is the licensee's primary state of residence. See Article II (11) of the Professional Counselor Licensure Compact in s. 491.017, F.S.
[9] Section 456.47, F.S., authorizes certain Florida-licensed health care practitioners, which includes a clinical social worker, marriage and family therapist, or mental health counselor licensed under ch. 491, F.S.; practitioners licensed under a multistate health care licensure compact of which Florida is a member; or a licensed health care professional in another state who registers with the applicable board in Florida to provide services through telehealth for persons located in Florida. However, it does not authorize the Florida-licensed health care practitioners to provide services to out-of-state patients. Whether Florida licensed practitioners can treat patients in other states is governed by laws in those states.
[10] See Article II (15) of the Professional Counselor Licensure Compact in s. 491.017, F.S.
[11] Section 491.003(5), F.S.
[12] See Article IX (1) and (2) of the Professional Counselor Licensure Compact in s. 491.017, F.S.
[13] Email from the Department of Health to staff of the Senate Health Policy Committee, January 27, 2023, on file with the Senate Committee on Health Policy.
[14] See Articles X and XII of the Professional Counselor Licensure Compact in s. 491.017, F.S.

development so full implementation and the issuance of the privilege to practice under the counseling compact is anticipated but is not yet available.

There are approximately 16,682 Licensed Mental Health Counselors in the state. The number of applicants who will apply for a privilege to practice under the compact is indeterminate; applications are expected to open in late 2023 or early 2024.[15]

Fee Authority

The Counseling Compact Model Legislation[16] includes a provision that member states may charge a fee for granting the privilege to practice. However, the counseling compact enacted by the 2022 Florida Legislature, did not include this provision ostensibly because of the Constitutional requirement for a separate bill for new state taxes or fees. See Section IV of this analysis.

In 2016, the Florida Legislature enacted the Nurse Licensure Compact, which similarly authorizes Registered Nurses (RN) and Licensed Practical Nurses (LPN) with a multistate license to practice in other member states.[17] An RN or LPN in Florida applying for the multistate upgrade to their license must pay a one-time $100 fee.[18]

III. Effect of Proposed Changes:

The bill amends the Professional Counselors Licensure Compact to authorize a member state to charge a fee for granting the privilege to practice professional counseling in member states. If enacted, the board may impose a fee for licensing or otherwise designating licensed practitioners to practice in member states in accordance with the counseling compact. This fee might offset the cost of implementing and administering the counseling compact.

The effective date of the bill is July 1, 2023.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

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[15] Department of Health, *Florida Department of Health Agency Bill Analysis for SB 140,* January 27, 2023, on file with the Senate Committee on Health Policy.
[16] Counseling Compact Model Legislation, at line 3, available at: https://counselingcompact.org/wp-content/uploads/2022/03/Final_Counseling_Compact_3.1.22.pdf (last visited Mar 22, 2023).
[17] Ch. 2016-130, Laws of Fla.
[18] Fla. Bd. of Nursing, Fla Dep't of Health, Frequently Asked Questions, Question "When I renew, will I receive the multi-state license automatically?" at https://floridasnursing.gov/enhanced-nurse-licensure-compact-faqs/ (last visited Mar 22, 2023).

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

Article VII, section 19, of the Florida Constitution requires that a new state tax or fee, as well as an increased state tax or fee, must be approved by two-thirds of the membership of each house of the Legislature and must be contained in a separate bill that contains no other subject. Article VII, section 19(d)(1), of the Florida Constitution defines "fee" to mean "any charge or payment required by law, including any fee for services, fee or cost for licenses, and charge for service.

SB 140 authorizes the imposition of fees for a license for the privilege to practice professional counseling in member states. As such, the Florida Constitution may require that such a fee provision be approved in a stand-alone bill by two-thirds of the membership of each house of the Legislature.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The bill authorizes the board, within the DOH, to impose a fee on an applicant for the privilege to practice under the compact in member states without the need for multiple licenses.

B. Private Sector Impact:

Obtaining a license to practice professional counseling in member states pursuant to the compact is optional. The exact amount of the fee that may be adopted by rule is unknown at this time. However, under the Nurse Licensure Compact an RN or LPN in Florida applying for the multistate upgrade to their license must pay a one-time $100 fee.

C. Government Sector Impact:

The board will incur costs for rulemaking if it chooses to impose a fee for issuing a license to practice professional counseling in member states pursuant to the compact.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 491.017 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Rodriguez

40-00109-23 2023140__

A bill to be entitled

An act relating to fees; amending s. 491.017, F.S.; authorizing member states of the Professional Counselors Licensure Compact to charge individuals a fee for the privilege to practice under the compact; providing an effective date.

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

Section 1. Present subsections (3), (4), and (5) of Article III of section 491.017, Florida Statutes, are redesignated as subsections (4), (5), and (6), respectively, and a new subsection (3) is added to Article III of that section, to read:

491.017 Professional Counselors Licensure Compact.—The Professional Counselors Licensure Compact is hereby enacted and entered into by this state with all other jurisdictions legally joining therein in the form substantially as follows:

ARTICLE III

STATE PARTICIPATION

(3) A member state may charge a fee for granting the privilege to practice.

Section 2. This act shall take effect July 1, 2023.

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

The Florida Senate

Committee Agenda Request

To: Senator Colleen Burton, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 19, 2023

I respectfully request that **Senate Bill #140**, relating to Fees/Professional Counselors Licensure Compact, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Ana Maria Rodriguez
Florida Senate, District 40

File signed original with committee office

S-020 (03/2004)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3/27/23
Meeting Date

HP
Committee

140
Bill Number or Topic

Amendment Barcode (if applicable)

Name Corinne Mixon

Phone 850 766-5795

Address 511 N. Adams
Street

Email

City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** **Waive Speaking:** ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing: Fl. Mental Health Counselors Association

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 1506
INTRODUCER:	Health Policy Committee and Senator Rodriguez
SUBJECT:	Department of Health
DATE:	March 29, 2023 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Vanwinkle	Brown	HP	**Fav/CS**
2.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary

CS/SB 1506 revises statutes relating to the Department of Health (DOH). The bill:

- Creates s. 381.87, F.S., to prohibit research that is reasonably likely to create an enhanced potential pandemic pathogen (ePPP) or that has been determined by the U.S. Department of Health and Human Services (HHS), or other federal agency or state agency, to create such a pathogen. The bill defines terms, and requires researchers applying for funding to disclose in the application if the research meets the definition of ePPP research.
- Makes several revisions to statutes governing the DOH medical marijuana program, including:
  - Defining the term "attractive to children" and expanding a prohibition that edibles not be attractive to children;
  - Expanding the DOH rulemaking authority to require the DOH to adopt rules it deems necessary to protect the health and safety of qualified patients and minors;
  - Amending background screening provisions related to medical marijuana and certified marijuana testing laboratories (CMTL).
- Updates ch. 382, F.S., vital statistics, to make electronic filing mandatory, when possible.
- Updates statutes relating to the determination of brain death to account for cases in which a patient's treating practitioner is an autonomous advanced practice registered nurse (A-APRN).
- Amends s. 382.025, F.S., to increase the age at which birth records will remain confidential and exempt, from 100 years of age to 125 years of age.
- Removes a requirement for emergency medical technicians (EMTs) and paramedics applying to the DOH for licensure to do so "under oath" and replaces the legal term with an

attestation, and removes the obsolete National Standard Curriculum from the training materials.

- Amends s. 401.34, F.S., to delete obsolete same-day grading of EMT and paramedic examinations, walk-in eligibility for determinations and examinations, and the fees for EMT and paramedic examination reviews.
- Amends s. 401.272, F.S., to eliminate an EMT's or paramedic's ability to partner with local county health departments; and
  - Requires EMTs and paramedics to practice under the medical direction of a physician through two-way voice communication or established standing orders or protocols when providing Basic Life Support (BLS), Advanced Life Support (ALS), and health promotion and wellness activities in a nonemergency environment;
  - Deletes the required supervision of an EMT and paramedic by a medical director in a nonemergency environment;
  - Eliminates blood pressure screening from the activities an EMT or paramedic may perform only under medical direction in a nonemergency environment.
- Amends s. 401.435, F.S., to remove the obsolete term "first responder" and replaces it with "emergency medical responder."
- Amends s. 464.203, F.S., to exempt certified nursing assistant (CNA) applicants who have completed an approved training program from the licensure requirement of taking the skills-demonstration portion of the examination.
- Amends numerous sections of Part I, ch. 468 and Part II, ch. 484, F.S., to narrow the scope of regulated practice for audiologists and hearing aid specialists to the dispensing of prescription hearing aids; and
  - Defines "air conduction hearing aid", "hearing aid," "over-the-counter (OTC) hearing aid" and "prescription hearing aid" for both audiologists and hearing aid specialists to align with new federal ruled permitting the sale of certain OTC hearing aids;
  - Deletes regulation of the sale of OTC hearing aids to consumers with perceived mild to moderate hearing impairment through in-person transactions, by mail, or online;
  - Clarifies that audiologists are not prohibited from fitting, selling, dispensing, servicing, marketing, providing customer support for, or distributing OTC hearing aids to persons 18 years of age or older;
  - Authorizes licensed hearing aid specialists to service, market, sell, dispense, provide customer support for, and distribute prescription and OTC hearing aids;
  - Clarifies the OTC hearing aids may not be sold to minors; and
  - Removes restrictions and criminal penalties for the sale or distribution of hearing aids through the mail.

The bill directs the Division of Law Revision to replace the phrase "the effective date of this act" with the date the act becomes law.

The bill provides an effective date of July 1, 2023, unless otherwise indicated.

II. Present Situation:

The Department of Health

The DOH is responsible for the protection and promotion of the health of Florida residents and visitors through organized state and community efforts, including, among other things, the responsibility to identify, diagnose, and conduct surveillance of diseases and health conditions in the state, accumulate the health statistics necessary to establish trends, and regulate health care practitioners for the preservation of the health, safety, and welfare of the public.[1]

Enhanced Potential Pandemic Pathogen Research

Since 2012, with the emergence of gain of function (GOF) research,[2] a lack of oversight monitoring this sort of research has been noted. The risk of this type of research was addressed by a report from the HHS Inspector General after concerns that the early onset of the COVID-19 pandemic in 2019 stemmed from SARS-like coronavirus research in Wuhan, China. The HHS report found that while the National Institutes of Health (NIH) oversight of research being performed by EcoHealth Alliance (EcoHealth)[3] with NIH grant funding was adequate in certain areas, it was insufficient in monitoring EcoHealth's compliance with federal requirements in other areas. Specifically, the NIH did not ensure EcoHealth submitted a progress report in a timely manner that contained evidence of a virus with growth that should have been reported immediately; did not ensure EcoHealth publicly reported required sub-award data; misused grant funds; and did not follow proper procedures to terminate the award to EcoHealth.[4]

Laboratories that conduct GOF research are classified in biosafety levels (BSL) ranging from one through four, with Biosafety Level Four (BSL-4) posing the greatest risk. The BSLs are used to identify the protective measures needed in a laboratory setting to protect, workers, the environment, and the public.

BSL-1 laboratories are used to study infectious agents or toxins not known to consistently cause disease in healthy adults. BSL-2 laboratories are used to study moderate-risk infectious agents or toxins that pose a risk if accidentally inhaled, swallowed, or exposed to the skin. BSL-3

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[1] Section 20.43, F.S.

[2] Congressional Research Service, IN FOCUS, *Global Pandemics: Gain-of-Function Research of Concern*, Nov. 21, 2022, available at https://crsreports.congress.gov/product/pdf/IF/IF12021 (last visited Mar. 23, 2023). Gain-of-Function (GOF) research is a broad area of scientific inquiry where an organism gains a new property or an existing property is altered. The terms gain of function and loss of function refer to any genetic mutation in an organism that either confers a new or enhanced ability or causes the loss of an ability. Such changes often occur naturally. Additionally, scientists can induce some changes to organisms through experimentation.

[3] EcoHealth Alliance, *Local Conservation. Global Health.*, available at https://www.ecohealthalliance.org/about (last visited Mar. 23, 2023. EcoHealth Alliance is an international nonprofit dedicated to a 'One Health' approach to protecting the health of people, animals and the environment from emerging infectious diseases. The organization formed with the merger of two highly respected organizations, Wildlife Trust and the Consortium for Conservation Medicine. The urgent concern for wildlife conservation and the overall health of our planet has led EcoHealth Alliance to become an environmental science and public health leader working to prevent pandemics in global hotspot regions across the globe and to promote conservation.

[4] U.S. Department of Health and Human Services, *Office of Inspector General: The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, Jan., 2023, available at https://oig.hhs.gov/oas/reports/region5/52100025.pdf (last visited Mar. 23, 2023).

laboratories are used to study infectious agents or toxins that may be transmitted through the air and cause potentially lethal infection through inhalation exposure. BSL-4 laboratories are used to study infectious agents or toxins that pose a high risk of aerosol-transmitted laboratory infections and life-threatening disease for which no vaccine or therapy is available.[5]

According to the DOH, there are no known BSL-4 laboratories in the State of Florida.[6,7]

Medical Marijuana

Amendment 2

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

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

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

Medical Marijuana Related Background Screening

Section 381.986, F.S., requires background screening for any person who registers as an qualified patient's caregiver[10] as well as the owners, operators, board members, managers, and employees of a MMTC. Individuals who are required to undergo background screening must pass a level 2 background screening. In addition to the disqualifying offenses included in s. 435.04, F.S., the section adds an arrest awaiting final disposition for, being found guilty of, regardless of adjudication, or entering a plea of nolo contendere or guilty to an offense under chapter 837,[11] chapter 895,[12] or chapter 896[13] or similar law of another jurisdiction.

Section 381.988, F.S., establishes requirements for persons or entities seeking to be certified as a CMTL. Among the requirements, s. 381.988(1)(d), F.S., requires all owners and managers, but not employees, of a CMTL to pass a level 2 background screening.

Both sections specify that:

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[5] *Id.*
[6] Department of Health, 2023 Agency Legislative Bill Analysis, *Senate Bill 1506* (on file with the Senate Committee on Health Policy).
[7] *See also* Global Biolabs, available at https://www.globalbiolabs.org/map (last visited Mar. 23, 2023).
[8] Chapter 2017-232, Laws of Fla.
[9] Chapter 2014-157, Laws of Fla.
[10] Under subsection (6) of s. 381.986, F.S.
[11] Perjury.
[12] Offenses concerning racketeering and illegal debts.
[13] Offenses related to financial transactions.

- Individuals required to undergo a background screening must submit a full set of fingerprints to the DOH or to a vendor, entity, or agency authorized by s. 943.053(13), F.S. The DOH, vendor, entity, or agency must forward the fingerprints to the Department of Law Enforcement (FDLE) for state processing, and the FDLE must forward the fingerprints to the Federal Bureau of Investigation (FBI) for national processing.
- Fees for state and federal fingerprint processing and retention will be borne by the individual or, in the case of CMTLs, the owners or managers of the CMTL. The state cost for fingerprint processing must be as provided in s. 943.053(3)(e), F.S.,[14] for records provided to persons or entities other than those specified as exceptions therein.
- Fingerprints submitted to the FDLE must be retained by the FDLE as provided in s. 943.05(2)(g) and (h), F.S., and enrolled in the FBI's national retained print arrest notification program. Any arrest record identified must be reported to the DOH.

Level 2 Background Screening

Section 435.04, F.S., establishes the standards for level 2 background screenings. The section specifies that a background screening under its provisions must include fingerprinting for statewide criminal history records checks through the FDLE and a national criminal history records checks through the FBI, and may include local criminal records checks through local law enforcement agencies. Fingerprints submitted must be submitted electronically to the FDLE and agencies may contract with one or more vendors to perform all or part of the electronic fingerprinting.

In order to pass a level 2 background screening, the individual being screened may not have been arrested for and are awaiting final disposition of, have been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to, or have been adjudicated delinquent and the record has not been sealed or expunged for any of the offenses listed in the section or similar provisions in other jurisdictions. The section provides additional disqualifying offenses applicable to participation in the Medicaid program.

Exemptions

Section 435.07, F.S., allows heads of agencies to grant an exemption from disqualification for an employee who would be disqualified under s. 435.04, F.S., or other background screening provisions. These exemptions may be granted for:

- Felonies for which at least three years have elapsed since the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court for the disqualifying felony;
- Misdemeanors prohibited under any of the statutes cited in this chapter or under similar statutes of other jurisdictions for which the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court;
- Offenses that were felonies when committed but that are now misdemeanors and for which the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court; or

[14] The fee is $24 per name submitted.

- Findings of delinquency. For offenses that would be felonies if committed by an adult and the record has not been sealed or expunged, the exemption may not be granted until at least three years have elapsed since the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court for the disqualifying offense.

In order to be granted an exemption, the employee seeking the exemption must provide clear and convincing evidence that he or she should not be disqualified from employment. The employing, or potentially employing, agency may consider crimes committed or that he or she has been arrested for after the disqualifying offense, even if the crime is not itself a disqualifying offense. The decision regarding whether to grant an exemption is subject to the due process provisions in ch. 120, F.S. Additionally, the section specifies that disqualification cannot be removed if the employee is seeking a child care position, if the employee is a sex offender, or if the disqualifying offense is one of a list of specified offenses.

Vital Statistics

The Office of Vital Statistics,[15] housed within the DOH, is responsible for compiling, storing, and preserving the vital records of the state. Vital records[16] are the official certificates or reports of birth, death, fetal death, marriage, dissolution of marriage, certain name changes, and data related to these records.

Florida officially began collecting birth and death records in 1917. Two years later, the state became a nationally recognized death registration jurisdiction. In 1924, the state became a nationally recognized birth registration jurisdiction. Since 1927, marriage and dissolution records have been filed with the Office of Vital Statistics.[17] In addition to the state office, which operates under the direction of the state registrar, district offices operate under the direction of local registrars.

Local Registrars

Each local registrar is charged with the enforcement of the provisions of ch. 382, F.S., and the rules adopted pursuant thereto, in his or her district, and must report to the DOH any violations. A local registrar must make blank forms available and examine each certificate of live birth, death, or fetal death when presented to determine if it has been fully completed as required by law. All birth, death, and fetal death certificates must be typewritten in permanent black ink. A certificate is not complete if it does not supply each item of information required or satisfactorily account for any omissions.

A local registrar, immediately upon appointment, must designate one or more deputy registrars to act on behalf of the local registrar, and if authorized by the DOH, to sign as registrar in

[15] The vital statistics statutes consistently refer to the "Office" of Vital Statistics and not the "Bureau" of Vital Statistics. For example, s*ee* s. 382.003, F.S. While the statutes refer to an Office of Vital Statistics, the DOH has established this responsibility at the bureau level. *See* the DOH's organizational chart available at https://www.floridahealth.gov/about/_documents/orgchart.pdf (last visited Mar. 23, 2023).
[16] Section 382.002(17), F.S.
[17] Department of Health, *Florida Vital Statistics Annual Report 2021*, Dec. 2022, p. *vii*, available at http://www.flpublichealth.com/VSbook/PDF/2021/VSCOMP.pdf (last visited Mar. 23, 2023).

attestation of the date of registration and may also make and preserve local records of birth, death, and fetal death certificates registered in the manner required by the DOH. The local registrar must monthly transmit to the DOH all original certificates registered. If no births, deaths, or fetal deaths occurred in a month, the local registrar or deputy must, on the seventh day of the following month, report that fact to the DOH on a DOH approved form.[18]

Death, Fetal Death, and Nonviable Birth Registration

A certificate for each death and fetal death in Florida must be filed electronically on the DOH electronic death registration system or filed, on a form prescribed by the DOH, with the DOH or the local registrar within five days after such death and prior to final disposition, and must be registered by the DOH correctly completed and filed. The certificate must include the decedent's social security number, if available, and the following:

- The decedent's name of record and aliases or "also known as" (AKA) names, if requested by the informant;
- The place of death. If unknown, then the registration district in which the dead body or fetus is found within five days after the occurrence; and
- If the death occurs in a moving conveyance, then the death must be registered in the district in which the dead body was first removed from such conveyance.

The funeral director who first assumes custody of a dead body or fetus must file the certificate of death or fetal death. In the absence of the funeral director, the physician, PA, A-APRN , or other person in attendance at or after the death or the district medical examiner of the county in which the death occurred or the body was found, must file the certificate of death or fetal death. The person who files the certificate must obtain personal data from a legally authorized person[19] or the best qualified person or source available. The medical certification of cause of death must be furnished to the funeral director, either in person or via certified mail or electronic transfer, by the physician, PA, A-APRN, or medical examiner responsible for furnishing such information. For fetal deaths, the physician, PA, A-APRN, midwife, or hospital administrator must provide any medical or health information to the funeral director within 72 hours after expulsion or extraction.

The state registrar may receive electronically a certificate of death, fetal death, or nonviable birth which is required to be filed with the registrar under ch. 382, F.S., through facsimile or other electronic transfer for the purpose of filing. The receipt of a certificate of death, fetal death, or nonviable birth by electronic transfer constitutes delivery to the state registrar as required by law.[20]

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[18] Section 382.005, F.S.

[19] *See* s .497.005(43), F.S., which defines a "legally authorized person," in order of the priority as follows: 1)The decedent, when written inter vivos authorizations and directions are provided by the decedent; 2) the person designated by the decedent as authorized to direct disposition pursuant to Pub. L. No. 109-163, s. 564, as listed on the decedent's U.S. Department of Defense Record of Emergency Data, DD Form 93, or its successor form, if the decedent died while in military service as described in 10 U.S.C. s. 1481(a)(1)-(8) in any branch of the United States Armed Forces, United States Reserve Forces, or National Guard; 3) the surviving spouse, unless the spouse has been arrested for committing an act of domestic violence as defined in s. 741.28, F.S., against the deceased that resulted in or contributed to the decedent's death; 4) a son or daughter who is 18 years of age or older; 5) a parent; 6) a brother or sister who is 18 years of age or older; 7) a grandchild who is 18 years of age or older; 8) a grandparent; or 9) any person in the next degree of kinship.

[20] Section 382.008, F.S.

Brain Death Recognition

Where respiratory and circulatory functions are maintained by artificial means to preclude a determination that these functions have ceased, Florida law permits the occurrence of death to be determined where there is the irreversible cessation of the functioning of the entire brain, including the brain stem.

This determination of brain death must be made in accordance with currently accepted reasonable medical standards by two physicians who may be allopathic or osteopathic physicians. One physician must be the treating physician and the other must be a board-eligible or board-certified neurologist, neurosurgeon, internist, pediatrician, surgeon, or anesthesiologist.

The patient's next of kin must be notified as soon as practicable of the procedures for the legal determination of brain death. The medical records must reflect the notice given, and, if notice was not given, the medical records must reflect the attempts to identify and notify the next of kin.

No recovery is permitted, nor may criminal proceedings be instituted, against a physician or licensed medical facility that makes a determination of brain death under Florida law or when acting in reliance on it, if such determination is made in accordance with the accepted standard of care[21] by such physician or facility. Except for a diagnosis of brain death, the standard set forth under this Florida law is not the exclusive standard for determining death or for the withdrawal of life support system.[22]

Birth Registration

A certificate for each live birth that occurs in this state must be filed within five days after the birth. The certificate may be filed with the local registrar of the district where the birth occurred or submitted electronically to the state registrar. Responsibility for filing the certificate is assigned to various persons depending upon where the birth occurs. If the birth occurs in a hospital, birth center, or other health care facility, or in route thereto, the person in charge of the facility is responsible for filing the certificate. The health care practitioner in attendance is responsible for providing the facility with the information required by the birth certificate. If the birth occurs outside a facility and a physician, certified nurse midwife, midwife, or a public health nurse employed by the DOH who was in attendance, must file the certificate.[23]

New Certificate of Live Birth

The clerk of court in which any proceeding for adoption, annulment of an adoption, affirmation of parental status, or determination of paternity is to be registered, must within 30 days after the final disposition, forward to the DOH a certified copy of the court order, or a report of the proceedings upon a form furnished by the DOH, together with sufficient information to identify

[21] Section 766.102, F.S., does not set forth the "acceptable standard of care" as used in s. 382.009, F.S., to determine brain death; but defines the *prevailing professional standard of care* for a given health care provider as that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers.
[22] Section 382.009, F.S.
[23] Section 382.013, F.S.

the original birth certificate and to enable the preparation of a new birth certificate. The clerk of court must implement a monitoring and quality control plan to ensure that all judicial determinations of paternity are reported to the DOH. The DOH must track paternity determinations reported monthly by the county, monitor compliance within the 30 day timeframe, and report the data to the clerks of court quarterly.[24]

Marriage Licenses

On or before the fifth day of each month, the county court judge or clerk of the circuit court must transmit all original marriage licenses, with endorsements, received during the preceding calendar month, to the DOH. Any marriage licenses issued and not returned, or any marriage licenses returned but not recorded, must be reported by the issuing county court judge or clerk of the circuit court to the DOH at the time of transmitting the recorded licenses on forms prescribed and provided by the DOH. If, during any month, no marriage licenses are issued or returned, the county court judge or clerk of the circuit court must report that fact to the DOH upon forms prescribed and furnished by the DOH.[25]

Dissolution of Marriage Records

Clerks of the circuit courts must collect for their services at the time of the filing of a final judgment of dissolution of marriage a fee of up to $10.50, of which 43 percent must be retained by the circuit court as a part of the cost in the cause in which the judgment is granted. The remaining 57 percent must be sent to the Department of Revenue (DOR) for deposit to the DOH account to defray part of the cost of maintaining the dissolution-of-marriage records. A record of each judgment of dissolution of marriage granted by the court during the preceding month, must be transmitted to the DOH, on or before the tenth day of each month, giving the names of parties and such other data as required by DOH prescribed forms, along with an accounting of the funds remitted to the DOR.[26]

Certified Copies of Vital Records and Confidentiality

Except for birth records over 100 years old, which are not under seal pursuant to court order, all birth records of this state are confidential and exempt from inspection and copying by any person desiring to do so, at any reasonable time, under reasonable conditions, and under supervision by the custodian of the public records.[27]

Certified copies of an original birth certificate or a new or amended certificate are confidential and exempt from inspection and copying by any person desiring to do so, at any reasonable time, under reasonable conditions, and under supervision by the custodian of the public records and, upon receipt of a request and payment of the fee, must be issued only as authorized by the DOH and in the form prescribed by the DOH, and only:

- To the registrant, if the registrant is of legal age, is a certified homeless youth, or is a minor who has had the disabilities of nonage removed;[28]

[24] Section 382.015, F.S.
[25] Section 382.021, F.S.
[26] Section 382.023, .F.S.
[27] Section 382.025, F.S. referencing s. 119.07, F.S., the public records law and exemptions.
[28] *See* ss. 743.01 and 743.015, F.S. The removal of the disability of age occurs when a petition is filed in the circuit court by a minor's natural or legal guardian or, if there is none, by a guardian ad litem, to remove the disabilities of nonage for a minor

- To the registrant's parent or guardian or other legal representative;
- Upon receipt of the registrant's death certificate, to the registrant's spouse or to the registrant's child, grandchild, or sibling, if of legal age, or to the legal representative of any of such persons;
- To any person if the birth record is over 100 years old and not under seal pursuant to court order;
- To a law enforcement agency for official purposes;
- To any agency of the state or the United States for official purposes upon approval of the DOH; or
- Upon order of any court of competent jurisdiction.[29]

Emergency Medical Technicians, Paramedics and Community Health Services

EMTs and Paramedics Education

Any person desiring to be certified or recertified as an EMT or paramedic must apply to the DOH under oath on forms provided by the DOH which must contain information reasonably required by the DOH, which may include affirmative evidence of the ability to comply with applicable laws and rules. The DOH must determine whether the applicant meets the statutory and DOH rule requirements and must issue a certificate to any person who meets such requirements.[30]

An applicant for certification or recertification as an EMT or paramedic must:[31]

- Have completed an appropriate training program as follows:
  - For an EMT, a program approved by the DOH as equivalent to the most recent EMT-Basic National Standard Curriculum or the National Emergency Medical Services (EMS) Education Standards of the U.S. Department of Transportation (DOT);
  - For a paramedic, a paramedic training program approved by the DOH as equivalent to the most recent EMT-Paramedic National Standard Curriculum or the National EMS Education Standards of the U.S. DOT.
- Certify under oath[32] that the applicant is not addicted to alcohol or any controlled substance;
- Certify under oath that the applicant is free from any physical or mental defect or disease that might impair the applicant's ability to perform his or her duties;
- Within two years after program completion have passed an examination developed or required by the DOH;
- Hold the following certifications:
  - For an EMT, hold a current American Heart Association (AHA) cardiopulmonary resuscitation course card or an American Red Cross cardiopulmonary resuscitation course card or its equivalent as defined by DOH rule;

age 16 or older due to marriage, dissolution of marriage, or widowhood. Once removed, the minor may assume the management of his or her estate, contract and be contracted with, sue and be sued, and perform all acts that he or she could do as if he or she were an adult.

[29] Section 382.025, F.S.

[30] Section 401.27, F.S.

[31] *Id.*

[32] Section 1.01(5), F.S., defines an oath to include affirmations.

    - For a paramedic hold a certificate in advanced cardiac life support from the AHA or its equivalent as defined by DOH rule.
- Submit the certification fee and the nonrefundable examination fee, required for each examination administered to an applicant; and
- Submit a completed application to the DOH which must be submitted at least 30 calendar days before the next regularly scheduled examination for which the applicant desires to be scheduled.

The DOH certification examination must be offered monthly. The DOH must issue an examination admission notice to the applicant advising him or her of the time and place of the examination for which he or she is scheduled. Individuals achieving a passing score on the certification examination may be issued a temporary certificate with their examination grade report. The DOH must issue an original certification within 45 days after the examination.[33]

Currently the DOH offers EMT and Paramedic examinations daily at testing centers throughout the state using the National Registry for Emergency Medical Technicians (NREMT) examinations. The DOH transitioned to using the NREMT in 2016 due to s. 456.017(1)(c)(2), F.S., mandating that neither the board nor the DOH may administer a state-developed written examination if a national examination has been certified by the DOH.[34]

Emergency Medical Services Training Programs

Any private or public institution in Florida desiring to conduct an approved program for the education of EMTs and paramedics must:

- Submit a completed application on a form provided by the DOH, which must include:
    - Evidence that the institution is in compliance with all applicable requirements of the Department of Education (DOE).
    - Evidence of an affiliation agreement with a hospital that has an emergency department staffed by at least one physician and one registered nurse.
    - Evidence of an affiliation agreement with a current emergency medical services provider that is licensed in this state. Such agreement must include a commitment by the provider to conduct the field experience portion of the education program.
    - Documentation verifying faculty, including:
        - A medical director who is a licensed physician meeting the applicable requirements for EMS medical directors. The medical director must have the duty and responsibility of certifying that graduates have successfully completed all phases of the education program and are proficient in basic or advanced life support techniques, as applicable.
        - A program director responsible for the operation, organization, periodic review, administration, development, and approval of the program.
    - Documentation verifying that the curriculum:
        - Meets the most recent EMT-Basic National Standard Curriculum or the National EMS Education Standards approved by the department for emergency medical technician programs and EMT-Paramedic National Standard Curriculum or the

[33] *Id.*

[34] Department of Health, 2023 Agency Legislative Bill Analysis, *Senate Bill 1506* (on file with the Senate Committee on Health Policy).

National EMS Education Standards approved by the department for paramedic programs.
    - Includes two hours of instruction on the trauma scorecard methodologies for assessment of adult trauma patients and pediatric trauma patients as specified by the DOH by rule.
  - Evidence of sufficient medical and educational equipment to meet EMS training program needs.
- Receive a scheduled site visit from the DOH to the applicant's institution. The site visit must be conducted within 30 days after notification to the institution that the application was accepted. During the site visit, the DOH must determine the applicant's compliance with specific criteria.[35]

Emergency Medical Services in Community Health Care

Florida encourages the more effective utilization of the skills of EMTs and paramedics by enabling them to perform, in partnership with local county health departments, specific additional health care tasks that are consistent with the public health and welfare.[36]

Paramedics or EMTs may perform health promotion and wellness activities and blood pressure screenings in a nonemergency environment, within the scope of their training, and under the direction of a medical director. The term "health promotion and wellness" means the provision of public health programs pertaining to the prevention of illness and injury.[37]

Paramedics may administer immunizations in a nonemergency environment, within the scope of their training, and under the direction of a medical director. There must be a written agreement between the paramedic's medical director and the county health department located in each county in which the paramedic administers immunizations. This agreement must establish the protocols, policies, and procedures under which the paramedic must operate.[38]

Paramedics may provide BLS services[39] and advanced life support (ALS) services[40] to patients receiving acute and post-acute hospital care at home as specified in the paramedic's supervisory relationship with a physician or standing orders[41] A physician who supervises or provides

[35] Section 401. 2701, F.S.
[36] Section 401.272, F.S.
[37] *Id.*
[38] *Id.*
[39] Section 401.23(8) and (9), F.S., defines Basic Life Support (BLS) as any emergency medical service which uses only basic life support techniques. BLS services includes assessment or treatment by a qualified person using techniques described in the EMT-Basic National Standard Curriculum or the National EMS Education Standards of the U.S. DOT and approved by the DOH. The term includes the administration of oxygen and other techniques that have been approved and are performed under conditions specified by DOH rules.
[40] Section 401.23(3) and (4), F.S., defines advanced life support (ALS) services as any emergency medical transport or nontransport service which uses ALS techniques. ALS means the assessment or treatment by a qualified person qualified to use medical techniques such as endotracheal intubation, the administration of drugs or intravenous fluids, telemetry, cardiac monitoring, cardiac defibrillation, and other techniques described in the EMT-Paramedic National Standard Curriculum or the National EMS Education Standards, pursuant to DOH rules.
[41] Section 401.272, F.S. refers to "standing orders" described in ss. 401.265, 458.348, or 459.025. F.S., requires the physician who enters into a standing order relationship with an EMT or paramedic, and the standing orders contemplate the

medical direction to a paramedic who provides BLS services or ALS services to patients receiving acute and post-acute hospital care at home pursuant to a formal supervisory relationship or standing orders is liable for any act or omission of the paramedic acting under the physician's supervision or medical direction when providing such services.[42]

Each medical director under whose direction a paramedic administers immunizations must verify and document that the paramedic has received sufficient training and experience to administer immunizations. The verification must be documented on DOH-developed forms, and the completed forms must be maintained at the service location of the licensee and made available to the DOH upon request.[43]

The DOH may adopt all rules necessary to enforce the provisions relating to a paramedic's administration of immunizations and the performance of health promotion and wellness activities and blood pressure screenings by a paramedic or an EMT in a nonemergency environment.[44]

EMT and Paramedic Certification Fees

Section 401.34, F.S., outlines the fees that the DOH may charge for various applications, permits, duplicate fees, and testing relating to EMT and paramedic services. EMTs pay $75 for the certification application and examination. Paramedics pay $85. The DOH may offer same day grading for EMTs and paramedic; and may offer walk-in eligibility determination and examination to applicants for EMTs and paramedic certifications who pay a nonrefundable fee not to exceed $65, in addition to the certification fee and examination fee. The DOH must establish locations and times for eligibility determinations and examinations. The cost of the EMT or paramedic certification examination review may not exceed $50.

First Responder Agencies and Training

Section 401.435, F.S., authorizes the DOH to adopt by rule the U.S. DOT EMS: First Responder Training Course as the minimum standard for first responder training. In addition, the DOH must adopt rules establishing minimum first responder instructor qualifications. A first responder includes any individual who receives training to render initial care to an ill or injured person, other than a law enforcement officer trained and certified under s. 943.1395(1), F.S., but who does not have the primary responsibility of treating and transporting ill or injured persons. Each first responder agency must take all reasonable efforts to enter into a memorandum of understanding with the EMS licensee within whose territory the agency operates in order to coordinate emergency services at an emergency scene.

The DOH must provide a model memorandum of understanding for this purpose which should include dispatch protocols, the roles and responsibilities of first responder personnel at an emergency scene, and the documentation required for patient care rendered. The term "first

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performance of medical acts, the physician must notify the Board of Medicine or Board of Osteopathic Medicine, as applicable.

[42] *Id.*

[43] *Id.*

[44] Section 401.272, F.S. When a physician enters into a formal supervisory relationship or standing orders with an EMT or paramedic which orders contemplate the performance of medical acts, the physician must notify the Board of Medicine or Board of Osteopathic Medicine, as applicable.

responder agency" includes a law enforcement agency, a fire service agency not licensed ch. 401, F.S., a lifeguard agency, and a volunteer organization that renders, as part of its routine functions, on-scene patient care before EMTs or paramedics arrive.

Certified Nursing Assistants

Florida's regulations of CNAs is found in Part II of ch. 464, F.S. Section 464.201(5), F.S., defines the practice of a CNA as providing care and assisting persons with tasks relating to the activities of daily living. Activities of daily living include tasks associated with: personal care, maintaining mobility, nutrition and hydration, toileting and elimination, assistive devices, safety and cleanliness, data gathering, reporting abnormal signs and symptoms, postmortem care, patient socialization and reality orientation, end-of-life care, cardiopulmonary resuscitation (CPR) and emergency care, patients' rights, documentation of nursing-assistant services, and other tasks that a CNA may perform after training.[45]

A CNA can work in a nursing home, an assisted living facility, other community-based settings, a hospital, or a private home under general supervision.[46] The Board of Nursing (BON), within the DOH, certifies CNAs, who must, among other qualifications, also meet one of the following requirements:

- Completion a 120-hour, BON-approved training program and achieved a minimum score, established by BON rule, on the nursing assistant competency examination, which consists of a BON-approved written portion and skills-demonstration portion and in administered at a site and by personnel approved by the DOH;
- Achievement of a minimum score, or higher, established by BON rule, on the nursing assistant competency examination, which consists of a BON-approved written portion and skills-demonstration portion, site and by personnel approved by the DOH and:
  - Has a high school diploma, or its equivalent; or
  - Is at least 18 years of age.
- Current certification in another state or territory of the United States or the District of Columbia; is listed on that jurisdiction's certified nursing assistant registry; and has not been found to have committed abuse, neglect, or exploitation in that jurisdiction; or
- Completion of the curriculum developed under Enterprise Florida's Jobs and Education Partnership Grant and achieved or exceeded a minimum score, established by BON rule, on the nursing assistant competency examination, which consists of a BON-approved written portion and skills-demonstration portion, and administered at a site and by personnel approved by the DOH.[47]

A CNA must biennially complete 24 hours of in-service training to maintain certification.[48]

[45] Section 464.201, F.S.
[46] 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. 23, 2023).
[47] Section 464.203, F.S., and Fla. Admin. Code R. 64B9-15.006. 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.
[48] Section 464.203(7), F.S.

Hearing Aids

Federal Regulations

The Food and Drug Administration (FDA) Reauthorization Act of 2017 (FDARA), s. 709,[49] directed the FDA to establish a category of OTC hearing aids through rulemaking and set forth various requirements for OTC hearing aids, including defining general controls for reasonable assurance of safety and effectiveness, as well as Federal preemption provisions.

On August 17, 2022, the FDA finalized a rule revising 21 C.F.R. 800,[50] 801,[51] and 874.[52] The FDA's new rule establishes a new category for OTC hearing aids. An OTC hearing aid is an air-conduction hearing aid that does not require implantation or other surgical intervention and is intended for use by a person age 18 or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss.

The device is available OTC, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements for consumers with "perceived mild to moderate hearing impairment who wish to buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance. The rule became effective on October 16, 2022.[53]

The FDA rule includes provisions for simplified labeling, output limits, maximum insertion depth, and conditions for sale and distribution for both OTC and prescription hearing aids. The rule prohibits states from requiring the order, involvement, or intervention of a licensed person for consumers to access over the counter hearing aids, a licensed person may service, market, sell, dispense, provide customer support for, or distribute OTC hearing aids.[54]

Florida Regulations

In Florida, there are currently 1,177 licensed hearing aid specialists, and 1,487 licensed audiologists.[55] Under Florida law, all hearing aids are dispensed by hearing aid specialists and audiologists who are subject to DOH regulation under the Board of Hearing Aid Specialist

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[49]21 U.S.C. 301, Food and Drug Administration Reauthorization Act of 1917, s. 709, *Regulation of Over-The-Counter Hearing Aids*, available at https://www.congress.gov/115/plaws/publ52/PLAW-115publ52.pdf (last visited Mar. 23, 2023).
[50] 21 CFR 800.30, (Mar. 16, 2023) available at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-800#800.30 (last visited Mar. 23, 2023).
[51] 21 CFR 801.60 - 63, (Jan. 17, 2023) available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=801 (last visited Mar. 23, 2023).
[52] 21 CFR 874.5300 available at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-874/subpart-F/section-874.5300 (last visited Mar. 20, 2023).
[53] 21 CFR 800.30, (Mar. 16, 2023) available at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-800#800.30 (last visited Mar. 23, 2023).
[54] 21 CFR 801, (2022).
[55] Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long Range Plan, 2021 - 2022*, available at https://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-2122.pdf (last visited Mar. 23, 2023).

(BHAS) and Board of Speech-Language Pathology and Audiology (BSLPA).[56] Florida law does not currently distinguish between OTC and prescription hearing aids and imposes criminal penalties for dispensing hearing aids by mail to consumers.[57] Florida law does not currently contemplate the sale of hearing aids online.

Scope of Practice

Florida law defines the scope of practice for hearing aid specialists and audiologists and specifies the procedures which each health care practitioner is authorized to perform. Presently, these are the only two health care practitioners who are authorized by law to sell or dispense a hearing aid.

Hearing Aid Specialists

Under s. 484.041, F.S., hearing aid specialists may dispense hearing aids. Dispensing includes conducting and interpreting hearing tests for purposes of selecting suitable hearing aids; making earmolds or ear impressions for the fitting of hearing aids; and providing appropriate counseling regarding a suitable hearing aid device. This also includes all acts pertaining to the selling, renting, leasing, pricing, delivery, and warranty of hearing aids. [58]

Hearing aid specialists are licensed and regulated by the BHAS.[59] Licensure for a hearing aid specialist is in accordance with s. 484.045, F.S. and includes the following requirements:

- Graduation of an accredited high school or its equivalent;
- Meeting one of the qualifying methods:
  - Completing a Florida sponsored training program; or
  - Having a valid, current license as a hearing aid specialist or its equivalent from another state and has been actively practicing[60] in such capacity for at least 12 months; or
  - Is currently certified by the National Board for Certification in Hearing Instrument Sciences (NBC-HIS) and has been actively practicing for at least 12 months.
- Has successfully completed:
  - International Licensing Examination (ILE); or
  - Active certification from the National Board for Certification in Hearing Instrument Sciences (NBC-HIS).
- Completion of a two hour course relating to Florida laws and rules taught by an instructor approved by the BHAS.

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, and to related language and speech disorders.[61] Licensed audiologists may offer, render, plan, direct, conduct, consult, or

[56] *See* Part II, ch. 484 and Part I, ch. 468, respectively.
[57] Section 468.1265, F.S.
[58] Section 484.041(3)(a), F.S.
[59] Section 484.042, F.S.
[60] *See* Fla. Admin. Code R. 64B6-2.002 (2022), which defines "actively practicing" as dispensing hearing aids directly to clients for at least 12 months, as shown by at least two sales receipts per month for at least 12 months, each receipt bearing the applicant's signature and address of place(s) of business.
[61] Section 468.1125(6)(a), F.S.

supervise services to individuals or groups of individuals who have or are suspected of having disorders of hearing, including prevention, identification, evaluation, treatment, consultation, habilitation, rehabilitation, instruction, and research.[62] This includes the fitting and dispensing of hearing aids. They may also provide the following:

- Participate in hearing conservation, evaluation of noise environment, and noise control;
- Conduct and interpret tests of vestibular function and nystagmus, electrophysiologic auditory-evoked potentials, central auditory function, and calibration of measurement equipment used for such purposes;
- Habilitate and rehabilitate, including, but not limited to, hearing aid evaluation, prescription, preparation, fitting and dispensing, assistive listening device selection and orientation, auditory training, aural habilitation, aural rehabilitation, speech conservation, and speechreading;
- Fabricate earmolds;
- Evaluate tinnitus; and
- Conduct speech and language screening, limited to a pass-fail determination for identifying individuals with disorders of communication.[63]

Audiologists are licensed and regulated by the BSLPA.[64] Licensure for audiologists includes, among other requirements, the following:

- Submission of an application and all required fees;
- A doctoral degree with a major emphasis in audiology and:
  - Applicants who have earned a doctoral degree from an approved program before January 1, 2008, must complete 60 semester hours, 24 of which must be in audiology.[65]
  - Applicants who earned a doctoral degree from an approved program after January 1, 2008, must complete 75 semester hours.
  - 300 clock hours of supervised experience (clinical practicum) with at least 200 hours in the area of audiology.
- Eleven months of supervised clinical experience. This requirement may be met if the applicant holds a doctoral degree, meets the requirements of s. 468.1155, F.S., and can demonstrate one year of clinical work experience within the doctoral program.
- Applicants for licensure as an audiologist with a master's degree conferred before January 1, 2008, must document that prior to licensure the applicant completed one-year clinical work experience.
- Passed the licensure examination no more than three years prior to the date of the application.[66]

[62] Section 468.1125(6)(b), F.S.
[63] *Id.*
[64] Section 468.1135, F.S.
[65] Section 468.1155, F.S.
[66] Section 468.1185, F.S. and Fla. Admin. Code R. 64B20-2.005 (2022) The BSDPA has designated the Educational Testing Services Praxis Series Examination in Speech-Language Pathology or Audiology as the licensure examination.

III. Effect of Proposed Changes:

Section 1 - Enhanced Potential Pandemic Pathogen Research

CS/SB 1506 creates s. 381.87, F.S. which prohibits any research in Florida that is reasonably likely to create an enhanced potential pandemic pathogen (ePPP) or that has been determined by HHS, or other federal agency or state agency to create such a pathogen. The bill defines the terms:

- "Enhanced potential pandemic pathogen" (ePPP) is a potential pandemic pathogen that results from enhancing the transmissibility or virulence of a pathogen. The term does not include naturally occurring pathogens circulating in or recovered from nature, regardless of their pandemic potential.
- "Enhanced potential pandemic pathogen (ePPP) research"[67] is research that may be reasonably anticipated to create, transfer, or use potential pandemic pathogens that result from enhancing a pathogen's transmissibility or virulence in humans.
- "Potential pandemic pathogen" is a bacterium, virus, or other microorganism that is likely to be both:
  - Highly transmissible and capable of wide, uncontrollable spread in human populations; and
  - Highly virulent, making it likely to cause significant morbidity or mortality in humans.

The bill requires any researcher applying for state or local funding to conduct research in Florida to disclose in the application if the research meets the definition of ePPP research. The bill authorizes the DOH to exercise its public health enforcement authority under s. 381.0012. F.S., to enjoin any violations of this section.

The bill does not affect research funded prior to its effective date.

Sections 2 and 3 - Office of Medical Marijuana Use

CS/SB 1506 amends s. 381.986, F.S., to defines the term "attractive to children" to mean "the use of any image or words designed or likely to appeal to persons younger than 18 years of age, including, but not limited to, cartoons, toys, animals, food, or depictions of persons younger than 18 years of age; any other likeness to images, characters, or phrases that are popularly used to advertise to persons younger than 18 years of age; or any reasonable likeness to commercially available candy."

The bill expands production requirements that currently are specific to edibles to all types of marijuana products. These include that the products not be:

[67]U.S. Department of Health and Human Services, *Office of Inspector General: The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, Jan., 2023, available at https://oig.hhs.gov/oas/reports/region5/52100025.pdf (last visited Mar. 23, 2023). The report notes at p. 4, that the terms "gain of function (GOF)" and "enhanced potential pandemic pathogen (ePPP)" are both used in Federal Government guidance at different points during the audit period. While these terms may have some distinctions from a scientific perspective, for purposes of this audit, which does not assess the underlying science of the EcoHealth grants, we use the terms interchangeably. Both terms refer generally to research involving the enhancement of a pathogen's transmissibility or virulence. The NIH is now using the ePPP research classification on place of the GOF research classification.

- Attractive to children;
- Manufactured in the shape of humans, cartoons, or animals;
- Manufactured in a form that bears any reasonable resemblance to products available for consumption as commercially available candy; or contain any color additives.

The bill prohibits an MMTC's logo, trade name, and advertisements from containing wording, images, or content that is attractive to children or promotes recreational use of marijuana.

The bill expands the DOH's rulemaking authority to authorize any "rules it deems necessary to protect the health and safety of qualified patients and minors, including, but not limited to, standards to ensure that medical marijuana treatment centers operate in a manner consistent with the provision of medical products and rules to discourage the diversion and illicit use of marijuana."

The bill amends ss. 381.986 and 381.988, F.S., to prohibit exemptions from disqualification due to a failed background screening from applying to these sections and to require that a caregiver, an MMTC, or a CMTL bear the costs of the background screening, as applicable. The bill also adds the requirement that all employees of a CMTL pass a level 2 background screening and makes the disqualifying offenses for CMTLs consistent with those for MMTCs. Specifically, the bill adds that disqualifying offense in s. 435.04, F.S., apply and adds that a person is disqualified if they have an arrest awaiting final disposition for an offense under chs. 837, 895, or 896, F.S.[68]

Sections 4 through 11 - Vital Statistics

CS/SB 1506 updates ch. 382, F.S., to make electronic filing mandatory, when possible, and amends:

- Section 382.005, F.S., to require each local registrar to electronically file all live birth, death, and fetal death records within their respective jurisdictions in the DOH's electronic registration system; but if the system is unavailable, the local registrar must file a paper record, and make blank paper forms available.
- Section 382.008, F.S., to require the funeral director to file certificates of death and fetal death electronically.
- Section 382.009, F.S., to require that if a patient's treating practitioner is an A-APRN, a determination of that patient's brain death must be made by that A-APRN practitioner and two physicians licensed under ch. 458 or 459, F.S., and the two physicians must each be a board-eligible or board certified neurologist, neurosurgeon, internist, pediatrician, surgeon, or anesthesiologist.
- Section 382.009, F.S., to no longer require two physicians to make a determination of brain death for a comatose patient. The bill instead requires such determinations be made by two licensed health care practitioners who must be physicians, PAs or A-APRNs, with one being the patient's treating health care practitioner.
- Section 382.013, F.S., clarifying that certificates of live birth occurring in this state must be filed within five days after the birth in the DOH's electronic registration system with the local registrar; and that a birth in a hospital, birth center, or other health care facility, or en

[68] Perjury, offenses concerning racketeering and illegal debts, offenses related to financial transactions, respectively.

route, must also be filed in the DOH's electronic registration system with the local registrar by the person in charge of the facility.
- Section 382.015, F.S., requiring court clerks in adoptions, annulment of an adoptions, affirmations of parental status, or determinations of paternity to forward electronically to the DOH a certified copy of the court order, or a report of the proceedings, upon a DOH form with sufficient information to identify the original birth certificate and to enable the preparation of a new birth certificate.
- Section 382.021, F.S., requiring the county judge or court clerk to electronically transfer to the DOH marriage licenses weekly, instead of monthly.
- Section 382.023, F.S., requiring the county judge or court clerk to electronically transfer to the DOH judgments of dissolution of marriage granted by the court weekly, instead of monthly.
- Section 382.025, F.S., to increase the age at which birth records will remain confidential and exempt, except to a specific list of persons, from 100 years of age to 125 years of age; and authorized persons appointed by the DOH, to the state registrar and local registrars, as individuals who my issue certified copy of a certificate of live birth, death, or fetal death.

Sections 12 through 16 - EMTs and Paramedics

CS/SB 1506 amends s. 401. 27, F.S., to remove the certification application requirement for EMTs and paramedics applying to the DOH that they do so "under oath;" and replaces the legal term with an attestation. The bill deletes obsolete language referring application filing deadlines before examination dates, certification examinations being offered monthly and the parameters for the DOH's grading process and administrative review.

The bill amends s. 401. 2701, F.S., to exempt Florida institutions desiring to conduct an approved program for the education of EMTs and paramedics, from the requirement that they have an affiliation agreement with a current licensed EMS provider which includes a commitment from the EMS provider to conduct the field experience portion of the education program, if the applicant is licensed as an ALS service under s. 401.25, F.S., with permitted transport vehicles under s. 401.26, F.S.

CS/SB 1506 amends s. 401.272, F.S., to eliminate an EMT's or paramedic's ability to partner with local county health departments and requires that EMTs and paramedics operate under the medical direction of a physician through two-way voice communication or pursuant to established standing orders or protocols and within the scope of their training when providing BLS, ALS, and health promotion and wellness activities in a nonemergency environment.

The bill deletes the required supervision of the EMT and paramedic by a medical director in the nonemergency environment. Medical directors are employed by, or have contracted with, a BLS transportation service or ALS transport service to provides medical supervision, including appropriate quality assurance including administrative and managerial functions, for daily operations and training of an EMS transport provider.[69]

[69] See ss. 401.23(16) and 401.265, F.S.

The bill eliminates blood pressure screening from the activities an EMT or paramedic may perform only under medical direction in a nonemergency environment.

The bill requires that EMTs and paramedics operate under the medical direction of a physician through two-way communication or pursuant to established standing orders or protocols and within the scope of their training when a patient is not transported to an emergency department or is transported to a facility other than a hospital.

Under current law, paramedics are authorized to administer immunizations in a nonemergency environment, within the scope of their training. The bill transfers their required supervision from the EMS medical director to a physician who will provide medical direction through two-way communication or pursuant to established standing orders or protocols and requires a written agreement between the physician providing the medical direction and the DOH or the county health department located in each county in which the paramedic administers immunizations. This agreement must establish the protocols, policies, and procedures under which the paramedic must operate. The physician providing direction to the paramedic administering immunizations must also verify and document that the paramedic has received sufficient training and experience to administer immunizations.

CS/SB 1506 amends s. 401.34, F.S., to delete same-day grading of EMT and paramedic examinations, walk-in eligibility determinations and examinations, and the fees for EMT and paramedic examination review. The DOH no longer offers any of these.[70]

CS/SB 1506 amends s. 401.435, F.S., to change the term "first responder" to "emergency medical responder." The change in terminology was done by the National Highway Traffic Safety Administration (NHTSA) in 2009. The term was also adopted by the National Registry of Emergency Medical Technicians (NREMT). The term "first responder" was commonly confused with other public safety professionals and not referenced as a medical certification level.[71]

Section 17 - CNAs

The bill amends s. 464.203, F.S., to exempt CNA applicants who have completed an approved training program from the licensure requirement of take the skills-demonstration portion of the licensure examination.

Sections 18 through 36 - Hearing Aids, Audiologists, Hearing Aid Specialists

CS/SB 1506 amends numerous sections of Part I, ch. 468 and Part II, ch. 484, F.S., in response to recent federal rules permitting the sale of OTC hearing aids, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the rule requirements for consumers with "perceived mild to moderate hearing impairment" who wish to

[70] Department of Health, *2023 Agency Legislative Bill Analysis, Senate Bill 1506* (on file with the Senate Committee on Health Policy).
[71] Department of Health, *2023 Agency Legislative Bill Analysis, Senate Bill 1506* (on file with the Senate Committee on Health Policy).

buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance.

Audiologists

CS/SB 1506 amends s. 468.1125, F.S., to define the following additional terms to align state law with the federal law permitting the sale of certain OTC hearing aids, and limiting an audiologists scope of practice to prescription hearing aids:

- "Air-conduction hearing aid" is a hearing aid that conducts sound to the ear through the air;
- "Hearing aid" is any wearable device designed for, offered for the purpose of, or represented as aiding persons with, or compensating for, impaired hearing, to be worn by a hearing-impaired person to improve hearing;
- "Over-the-counter hearing aid" is an air-conduction hearing aid that does not require implantation or other surgical intervention and is intended for use only by a person 18 years of age or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss. The device is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements of 21 C.F.R. parts 800, 801, and 874 (2022), which are specifically incorporated by reference herein; and
- "Prescription hearing aid" is a hearing aid or sound amplifying device that is not an over-the-counter hearing aid. Hearing aids intended for use by persons younger than 18 years of age must be prescription hearing aids.

CS/SB 1506 amends s. 468.1225, F.S., to narrow the scope of the regulatory requirements for audiologists to the dispensing of prescription hearing aid; and clarifies that any hearing aid provided to a person younger than 18 years of age must be a prescription hearing aid and may not be an over-the-counter hearing aid.

CS/SB 1506 amends s. 468.1115, F.S., to clarify that audiologists are not prohibited from fitting, selling, dispensing, servicing, marketing, providing customer support for, or distributing OTC hearing aids to persons 18 years of age or older.

The bill also amends ss. 468.1245, 468.1246, 468.1255, 468.1265, and 468.1275, F.S., adding the term "prescription" in front of the term "hearing aid" to make clear that Florida's regulation of hearing aids only applies to "prescription hearing aids" and does not conflict with federal law. The bill also makes other technical changes to those statutory sections.

This bill amends s. 468.1246, F.S., to remove an obsolete reference to rulemaking that was required to be completed during the year the original bill was passed.

Hearing Aid Specialists

CS/SB 1506 narrows the scope of the regulatory requirements for hearing aid specialists to the dispensing of prescription hearing aids to align with new federal rules on the sale of OTC hearing aids.

The bill amends s. 484.041, F.S., to redefines hearing aid and hearing aid establishment for hearing aid specialists as follows:

- "Hearing aid" is any wearable device designed for, offered for the purpose of, or represented as aiding persons with, or compensating for, impaired hearing.
- "Hearing aid establishment" is an establishment that offers, advertises, and performs hearing aid services for the general public, and the bill add the requirement that it must employ a licensed hearing aid specialist.

The bill further amends s. 484.041, F.S., to define air conduction hearing aids, OTC hearing aids and prescription hearing aids for hearing aid specialists:

- "Air-conduction hearing aid" is a hearing aid that conducts sound to the ear through the air;
- Over-the-counter hearing aid" means an air-conduction hearing aid that does not require implantation or other surgical intervention and is intended for use only by a person 18 years of age or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss. The device is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements of 21 C.F.R. parts 800, 801, and 874 (2022), which are specifically incorporated by reference herein;
- "Prescription hearing aid" means a hearing aid or sound amplifying device that is not an over-the-counter hearing aid. Hearing aids intended for use by persons younger than 18 years of age must be prescription hearing aids.

CS/SB 1506 amends s. 484.0501, F.S., to clarify that a licensed hearing aid specialist may fit, sell, dispense, service, market, provide customer support for, and distribute prescription and OTC hearing aids, but that OTC hearing aids may be provided only to persons 18 years of age or older.

The bill amends s. 484.059, F.S., to exempt from hearing aid specialist licensure requirements persons who services, markets, sells, dispenses, provides customer support for, or distributes exclusively OTC hearing aids, whether through in-person transactions, by mail, or online.

The bill amends s. 484.0501, F.S., to authorize a licensed hearing aid specialist to service, market, sell, dispense, provide customer support for, and distribute prescription and OTC hearing aids.

The bill amends s. 484.054, F.S., to removes restrictions and criminal penalties for the sale or distribution of hearing aids through the mail.

The bill amends ss. 484.0401, 484.041, 484.042, 484.044, 484.0445, 484.045, 484.0501, 484.051, 484.0512, 484.0513, 484.053, 484.054, and 484.059, F.S., adding the term "prescription" in front of the term "hearing aid" to make clear that Florida's regulation of hearing aids only applies to "prescription hearing aids" and does not conflict with federal law. The bill also makes other technical changes.

This bill also amends s. 484.512, F.S., to remove an obsolete reference to rulemaking that was required to be completed during the year the original bill was passed.

Section 37

The bill directs the Division of Law Revision to replace the phrase "the effective date of this act" with the date the act becomes law.

Section 38

The bill provides an effective date of July 1, 2023, unless otherwise indicated.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

Article II, s. 3, of the Florida Constitution states "the powers of the state government shall be divided into legislative, executive and judicial branches. No person belonging to one branch shall exercise any powers appertaining to either of the other branches unless expressly provided herein."

The Legislature is permitted to transfer subordinate functions "to permit administration of legislative policy by an agency with the expertise and flexibility to deal with complex and fluid conditions." However, the Legislature "may not delegate the power to enact a law or the right to exercise unrestricted discretion in applying the law."[72] The Florida Supreme Court has found that "statutes granting power to the executive branch 'must clearly announce adequate standards to guide ... in the execution of the powers delegated. The statute must so clearly define the power delegated that the [executive] is precluded from acting through whim, showing favoritism, or exercising unbridled discretion.'"[73]

[72] *Bush v. Schiavo*, 885 So. 2d 321 (Fla. 2004)
[73] *Id.*

Section 2 of CS/SB 1506 provides rulemaking language in s. 381.986(8)(k), F.S., which grants the DOH the authority to "adopt rules *it deems necessary* to protect the health and safety of qualified patients and minors." This grant of rulemaking authority places no boundaries on what rules the DOH may adopt to "protect the health and safety of qualified patients and minors" and grants the DOH unfettered authority to adopt such rules "it deems necessary." As such, it is possible that this rulemaking authority does not preclude the DOH from "acting through whim, showing favoritism, or exercising unbridled discretion" and may be found to be an unlawful delegation of authority violating Art. II, s. 3, of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Persons with mild to moderate hearing impairment will now be able to purchase OTC hearing aids without the supervision, prescription, involvement, or intervention of a licensed person through in-person transactions, by mail, or online which will presumably reduce their cost.

C. Government Sector Impact:

Multiple sections of the bill will require rule making by various DOH boards, but it is unclear whether DOH can absorb those costs, or if additional funding is required.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The rulemaking authority granted to the DOH on lines 518 through 524 of the bill may be an unlawful delegation of authority that violates Art. II, s. 3, of the Florida Constitution. See Section IV of this analysis.

VIII. Statutes Affected:

This bill creates section 381.875 of the Florida Statutes.

This bill substantially amends the following sections of the Florida Statutes: 381.986, 381.988, 382.005, 382.008, 382.009, 382.013, 382.015, 382.021, 382.023, 382.025, 401.27, 401.2701, 401.272, 401.34, 401.435, 464.203, 468.1115, 468.1225, 468.1245, 468.1246, 468.1255, 468.1265, 468.1275, 484.0401, 484.041, 484.042, 484.044, 484.0445, 484.045, 484.0501, 484.051, 484.0512, 484.0513, 484.053, 484.054, and 484.059.

IX. Additional Information:

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

CS by Health Policy on March 27, 2023:
The CS:

- Amended s 382.009, F.S., to update who may make a determination of brain death. The underlying bill authorized two health care practitioners who must be physicians, A-APRNs, or PAs to make the determination of brain death, with one being the treating practitioner. The CS updates s. 382.009, F.S., to account for cases in which an A-APRN is a patient's treating health care practitioner and requires the determination of that patient's brain death to be made by that practitioner and two physicians licensed under ch. 458 or 459, F.S. The two physicians must each be a board-eligible or board certified neurologist, neurosurgeon, internist, pediatrician, surgeon, or anesthesiologist.
- Amends s. 468.1125 and s. 484.041, F.S., with definitions of "air conduction hearing aid," "hearing aid," "OTC hearing aid" and "prescription hearing aid," and several other sections Part I, ch. 468 and Part II, ch. 484, F.S., to align state law with recent federal rules permitting the sale of OTC hearing aids, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, to persons 18 years of age and molder.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
03/28/2023	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete lines 659 - 672.

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

And the title is amended as follows:

Delete lines 35 - 38

and insert:

provisions to changes made by the act; amending ss. 382.013 and 382.015, F.S.;

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/28/2023	.	
	.	
	.	
	.	

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

Senate Amendment

Delete lines 665 - 672
and insert:
medical standards.

(a) If the patient's treating health care practitioner is a physician licensed under chapter 458 or chapter 459, the determination must be made by that physician and a second physician ~~two physicians~~ licensed under chapter 458 or chapter 459 who is~~. One physician shall be the treating physician, and~~

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~~the other physician shall be~~ a board-eligible or board-certified neurologist, neurosurgeon, internist, pediatrician, surgeon, or anesthesiologist.

(b) If the patient's treating health care practitioner is an autonomous advanced practice registered nurse registered under s. 464.0123, the determination must be made by that practitioner and two physicians licensed under chapter 458 or chapter 459. Each physician must be a board-eligible or board-certified neurologist, neurosurgeon, internist, pediatrician, surgeon, or anesthesiologist.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/28/2023	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete lines 1269 - 1890
and insert:

Section 18. Section 468.1115, Florida Statutes, is amended to read:

468.1115 Exemptions.—

(1) ~~No provision of~~ This part may not ~~shall~~ be construed to limit the practice of persons licensed in this state from engaging in the professions for which they are licensed, so long

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as they do not hold themselves out to the public as possessing a license or certificate issued pursuant to this part or use a title protected by this part.

(2) This part may not be construed to prohibit audiologists from fitting, selling, dispensing, servicing, marketing, providing customer support for, or distributing over-the-counter hearing aids to persons 18 years of age or older.

(3) ~~The provisions of~~ This part does ~~shall~~ not apply to:

(a) Students actively engaged in a training program, if such persons are acting under the direct supervision of a licensed speech-language pathologist or a licensed audiologist.

(b) Persons practicing a licensed profession or operating within the scope of their profession, such as doctors of medicine, clinical psychologists, nurses, or hearing aid specialists, who are properly licensed under the laws of this state.

(c) Persons certified in the areas of speech-language impairment or hearing impairment in this state under chapter 1012 when engaging in the profession for which they are certified, or any person under the direct supervision of such a certified person, or of a licensee under this chapter, when the person under such supervision is performing hearing screenings in a school setting for prekindergarten through grade 12.

(d) Laryngectomized individuals, rendering guidance and instruction to other laryngectomized individuals, who are under the supervision of a speech-language pathologist licensed under this part or of a physician licensed under chapter 458 or chapter 459 and qualified to perform this surgical procedure.

(e) Persons licensed by another state as speech-language

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pathologists or audiologists who provide services within the applicable scope of practice set forth in s. 468.1125(10) or (11) ~~s. 468.1125(6) or (7)~~ for no more than 5 calendar days per month or 15 calendar days per year under the direct supervision of a Florida-licensed speech-language pathologist or audiologist. A person whose state of residence does not license speech-language pathologists or audiologists may also qualify for this exemption, if the person holds a certificate of clinical competence from the American Speech-Language and Hearing Association and meets all other requirements of this paragraph. In either case, the board shall hold the supervising Florida licensee fully accountable for the services provided by the out-of-state licensee.

(f) Nonlicensed persons working in a hospital setting who provide newborn infant hearing screenings, so long as training, clinical interpretation of the screenings, and the protocol for followup of infants who fail in-hospital screenings are provided by a licensed audiologist.

(g) An audiologist while engaged in fitting, selling, dispensing, servicing, marketing, providing customer support for, or distributing over-the-counter hearing aids.

(h) Any person who fits, sells, dispenses, services, markets, provides customer support for, or distributes exclusively over-the-counter hearing aids.

Section 19. Section 468.1125, Florida Statutes, is reordered and amended to read:

468.1125 Definitions.—As used in this part, the term:

(1) "Air-conduction hearing aid" means a hearing aid that conducts sound to the ear through the air.

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(2) "Audiologist" means a person licensed under this part to practice audiology.

(3) ~~(2)~~ "Board" means the Board of Speech-Language Pathology and Audiology.

(4) ~~(3)~~ "Certified audiology assistant" means a person who is certified under this part to perform audiology services under the direct supervision of an audiologist.

(5) ~~(4)~~ "Certified speech-language pathology assistant" means a person who is certified under this part to perform speech pathology services under the direct supervision of a speech pathologist.

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

(8) "Hearing aid" means any wearable device designed for, offered for the purpose of, or represented as aiding persons with, or compensating for, impaired hearing, to be worn by a hearing-impaired person to improve hearing.

(9) "Over-the-counter hearing aid" means an air-conduction hearing aid that does not require implantation or other surgical intervention and is intended for use only by a person 18 years of age or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss. The device is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements of 21 C.F.R. parts 800, 801,

and 874 (2022), which are specifically incorporated by reference herein.

(10)(a) ~~(6)(a)~~ "Practice of audiology" means 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, and to related language and speech disorders. "Disorders" are defined to include any and all conditions, whether of organic or nonorganic origin, peripheral or central, that impede the normal process of human communication, including, but not limited to, disorders of auditory sensitivity, acuity, function, or processing, or damage to the integrity of the physiological system.

(b) Any audiologist who has complied with the provisions of this part may:

1. Offer, render, plan, direct, conduct, consult, or supervise services to individuals or groups of individuals who have or are suspected of having disorders of hearing, including prevention, identification, evaluation, treatment, consultation, habilitation, rehabilitation, instruction, and research.

2. Participate in hearing conservation, evaluation of noise environment, and noise control.

3. Conduct and interpret tests of vestibular function and nystagmus, electrophysiologic auditory-evoked potentials, central auditory function, and calibration of measurement equipment used for such purposes.

4. Habilitate and rehabilitate, including, but not limited to, prescription hearing aid evaluation, prescription, preparation, fitting and dispensing prescription hearing aids,

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assistive listening device selection and orientation, auditory training, aural habilitation, aural rehabilitation, speech conservation, and speechreading.

5. Fabricate earmolds.

6. Evaluate tinnitus.

7. Include speech and language screening, limited to a pass/fail determination for identifying individuals with disorders of communication.

(11)(a) ~~(7)(a)~~ "Practice of speech-language pathology" means the application of principles, methods, and procedures for the prevention, identification, evaluation, treatment, consultation, habilitation, rehabilitation, instruction, and research, relative to the development and disorders of human communication; to related oral and pharyngeal competencies; and to behavior related to disorders of human communication. "Disorders" are defined to include any and all conditions, whether of organic or nonorganic origin, that impede the normal process of human communication, including, but not limited to, disorders and related disorders of speech, phonology, articulation, fluency, voice, accent, verbal and written language and related nonoral/nonverbal forms of language, cognitive communication, auditory and visual processing, memory and comprehension, interactive communication, mastication, deglutition, and other oral, pharyngeal, and laryngeal sensorimotor competencies.

(b) Any speech-language pathologist who has complied with the provisions of this part may:

1. Offer, render, plan, direct, conduct, and supervise services to individuals or groups of individuals who have or are

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suspected of having disorders of human communication, including identification, evaluation, treatment, consultation, habilitation, rehabilitation, amelioration, instruction, and research.

2. Determine the need for personal alternatives or augmentative systems, and recommend and train for the utilization of such systems.

3. Perform a hearing screening, limited to a pass/fail determination, for the purpose of initial identification of communication disorders.

(12) "Prescription hearing aid" means a hearing aid or sound amplifying device that is not an over-the-counter hearing aid. Hearing aids intended for use by persons younger than 18 years of age must be prescription hearing aids.

(13) ~~(8)~~ "Speech-language pathologist" means a person licensed under this part to practice speech pathology.

(7) ~~(9)~~ "Direct supervision" means responsible supervision and control by a licensed speech-language pathologist who shall assume legal liability for the services rendered by any certified speech-language pathology assistant under the licensee's supervision, or responsible supervision and control by a licensed audiologist who shall assume legal liability for the services rendered by any certified audiology assistant under the licensee's supervision. Direct supervision shall require the physical presence of the licensed speech-language pathologist for consultation and direction of the actions of the certified speech-language pathology assistant, or the physical presence of the licensed audiologist for consultation and direction of the actions of the certified audiology assistant, unless the

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assistant is acting under protocols established by the board. The board shall establish rules further defining direct supervision of a certified speech-language pathology assistant or a certified audiology assistant.

Section 20. Section 468.1225, Florida Statutes, is amended to read:

468.1225 Procedures, equipment, and protocols.—

(1) The following minimal procedures shall be used when a licensed audiologist fits and sells a prescription hearing aid:

(a) Pure tone audiometric testing by air and bone to determine the type and degree of hearing deficiency when indicated.

(b) Effective masking when indicated.

(c) 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.

(2) The following equipment shall be used:

(a) A wide range audiometer that ~~which~~ meets the specifications of the American National Standards Institute for diagnostic audiometers when indicated.

(b) A speech audiometer or a master hearing aid in order to determine the most comfortable listening level and speech discrimination when indicated.

(3) A final fitting ensuring physical and operational comfort of the prescription hearing aid shall be made when indicated.

(4) A licensed audiologist who fits and sells prescription

hearing aids shall obtain the following medical clearance: If, upon inspection of the ear canal with an otoscope in the common procedure of fitting a prescription hearing aid and upon interrogation of the client, there is any recent history of infection or any observable anomaly, the client shall be instructed to see a physician, and a prescription hearing aid may ~~shall~~ not be fitted until medical clearance is obtained for the condition noted. If, upon return, the condition noted is no longer observable and the client signs a medical waiver, a prescription hearing aid may be fitted. Any person with a significant difference between bone conduction hearing and air conduction hearing must be informed of the possibility of medical or surgical correction.

(5)(a) A licensed audiologist's office must have available, or have access to, a selection of prescription hearing aid models, hearing aid supplies, and services complete enough to accommodate the various needs of the hearing aid wearers.

(b) At the time of the initial examination for fitting and sale of a prescription hearing aid, the attending audiologist must notify the prospective purchaser of the benefits of telecoil, also known as "t" coil or "t" switch, technology, including increased access to telephones and noninvasive access to assistive listening systems required under the Americans with Disabilities Act of 1990.

(6) Unless otherwise indicated, each audiometric test conducted by a licensee or a certified audiology assistant in the fitting and selling of prescription hearing aids must ~~shall~~ be made in a testing room that has been certified by the department, or by an agent approved by the department, not to

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exceed the following sound pressure levels at the specified frequencies: 250Hz-40dB, 500Hz-40dB, 750Hz-40dB, 1000Hz-40dB, 1500Hz-42dB, 2000Hz-47dB, 3000Hz-52dB, 4000Hz-57dB, 6000Hz-62dB, and 8000Hz-67dB. An exception to this requirement shall be made in the case of a client who, after being provided written notice of the benefits and advantages of having the test conducted in a certified testing room, requests that the test be conducted in a place other than the licensee's certified testing room. Such request must ~~shall~~ be documented by a waiver that ~~which~~ includes the written notice and is signed by the licensee and the client before ~~prior to~~ the testing. The waiver must ~~shall~~ be executed on a form provided by the department. The executed waiver must ~~shall~~ be attached to the client's copy of the contract, and a copy of the executed waiver must ~~shall~~ be retained in the licensee's file.

(7) The board may ~~shall have the power to~~ prescribe the minimum procedures and equipment used in the conducting of hearing assessments and for the fitting and selling of prescription hearing aids. The board shall adopt and enforce rules necessary to implement ~~carry out the provisions of~~ this subsection and subsection (6).

(8) Any duly authorized officer or employee of the department may ~~shall have the right to~~ make such inspections and investigations as ~~are~~ necessary ~~in order~~ to determine the state of compliance with ~~the provisions of~~ this section and the applicable rules and may enter the premises of a licensee and inspect the records of same upon reasonable belief that a violation of this law is being or has been committed or that the licensee has failed or is failing to comply with ~~the provisions~~

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~~of~~ this part.

(9) Any hearing aid provided to a person younger than 18 years of age must be a prescription hearing aid and may not be an over-the-counter hearing aid.

Section 21. Section 468.1245, Florida Statutes, is amended to read:

468.1245 Itemized listing of prices; delivery of prescription hearing aid; receipt; guarantee; packaging; disclaimer.—

(1) Before ~~Prior to~~ delivery of services or products to a prospective purchaser, a licensee must ~~shall~~ disclose, upon request by the prospective purchaser, an itemized listing of prices, which must ~~listing shall~~ include separate price estimates for each service component and each product. Provision of such itemized listing of prices may ~~shall~~ not be predicated on the prospective purchaser's payment of any charge or agreement to purchase any service or product.

(2) Any licensee who fits and sells a prescription hearing aid shall, at the time of delivery, provide the purchaser with a receipt containing the seller's signature, the address of his or her regular place of business, and his or her license or certification number, if applicable, together with the brand, model, manufacturer or manufacturer's identification code, and serial number of the prescription hearing aid furnished and the amount charged for the prescription hearing aid. The receipt must also ~~shall~~ specify whether the prescription hearing aid is new, used, or rebuilt, ~~and shall specify~~ the length of time and other terms of the guarantee, and by whom the prescription hearing aid is guaranteed. When the client has requested an

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itemized list of prices, the receipt must ~~shall~~ also provide an itemization of the total purchase price, including, but not limited to, the cost of the aid, ear mold, batteries, and other accessories, and the cost of any services. Notice of the availability of this service must be displayed in a conspicuous manner in the office. The receipt must also ~~shall~~ state that any complaint concerning the prescription hearing aid and its guarantee, if not reconciled with the licensee from whom the prescription hearing aid was purchased, should be directed by the purchaser to the department. The address and telephone number of such office must ~~shall~~ be stated on the receipt.

(3) A prescription ~~No~~ hearing aid may not be sold to any person unless both the packaging containing the prescription hearing aid and the contract provided pursuant to subsection (2) carry the following disclaimer in 10-point or larger type: "A hearing aid will not restore normal hearing, nor will it prevent further hearing loss."

Section 22. Section 468.1246, Florida Statutes, is amended to read:

468.1246 Thirty-day trial period; purchaser's right to cancel; notice; refund; cancellation fee.—

(1) A person selling a prescription hearing aid in this state must provide the buyer with written notice of a 30-day trial period and money-back guarantee. The guarantee must permit the purchaser to cancel the purchase for a valid reason as defined by rule of the board within 30 days after receiving the prescription hearing aid, by returning the prescription hearing aid or mailing written notice of cancellation to the seller. If the prescription hearing aid must be repaired, remade, or

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adjusted during the 30-day trial period, the running of the 30-day trial period is suspended 1 day for each 24-hour period that the prescription hearing aid is not in the purchaser's possession. A repaired, remade, or adjusted prescription hearing aid must be claimed by the purchaser within 3 working days after notification of availability. The running of the 30-day trial period resumes on the day the purchaser reclaims a repaired, remade, or adjusted prescription hearing aid or on the 4th day after notification of availability.

(2) The board, in consultation with the Board of Hearing Aid Specialists, shall prescribe by rule the terms and conditions to be contained in the money-back guarantee and any exceptions thereto. Such rule must ~~shall~~ provide, at a minimum, that the charges for earmolds and service provided to fit the prescription hearing aid may be retained by the licensee. The rules must ~~shall~~ also set forth any reasonable charges to be held by the licensee as a cancellation fee. ~~Such rule shall be effective on or before December 1, 1994. Should the board fail to adopt such rule, a licensee may not charge a cancellation fee which exceeds 5 percent of the total charge for a hearing aid alone.~~ The terms and conditions of the guarantee, including the total amount available for refund, must ~~shall~~ be provided in writing to the purchaser before ~~prior to~~ the signing of the contract.

Section 23. Section 468.1255, Florida Statutes, is amended to read:

468.1255 Cancellation by medical authorization; purchaser's right to return.—

(1) In addition to any other rights and remedies the


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purchaser of a prescription hearing aid may have, the purchaser has ~~shall have~~ the right to rescind the transaction if the purchaser for whatever reason consults a licensed physician with specialty board certification in otolaryngology or internal medicine or a licensed family practice physician, subsequent to purchasing a prescription hearing aid, and the physician certifies in writing that the purchaser has a hearing impairment for which a prescription hearing aid will not provide a benefit or that the purchaser has a medical condition which contraindicates the use of a prescription hearing aid.

(2) The purchaser of a prescription hearing aid has ~~shall have~~ the right to rescind as provided in subsection (1) only if the purchaser gives a written notice of the intent to rescind the transaction to the seller at the seller's place of business by certified mail, return receipt requested, which notice shall be posted not later than 60 days following the date of delivery of the prescription hearing aid to the purchaser, and the purchaser returns the prescription hearing aid to the seller in the original condition less normal wear and tear.

(3) If the conditions of subsections (1) and (2) are met, the seller must ~~shall~~, without request, refund to the purchaser, within 10 days after ~~of~~ the receipt of notice to rescind, a full and complete refund of all moneys received, less 5 percent. The purchaser does not ~~shall~~ incur any ~~no~~ additional liability for rescinding the transaction.

Section 24. Section 468.1265, Florida Statutes, is amended to read:

468.1265 Sale or distribution of prescription hearing aids through mail; penalty.—It is unlawful for any person to sell or

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distribute prescription hearing aids through the mail to the ultimate consumer. Any person who violates this section commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 25. Section 468.1275, Florida Statutes, is amended to read:

468.1275 Place of business; display of license.—Each licensee who fits and sells a prescription hearing aid shall declare and establish a regular place of business, at which his or her license shall be conspicuously displayed.

Section 26. Section 484.0401, Florida Statutes, is amended to read:

484.0401 Purpose.—The Legislature recognizes that the dispensing of prescription hearing aids requires particularized knowledge and skill to ensure that the interests of the hearing-impaired public will be adequately served and safely protected. It recognizes that a poorly selected or fitted prescription hearing aid not only will give little satisfaction but may interfere with hearing ability and, therefore, deems it necessary in the interest of the public health, safety, and welfare to regulate the dispensing of prescription hearing aids in this state. Restrictions on the fitting and selling of prescription hearing aids shall be imposed only to the extent necessary to protect the public from physical and economic harm, and restrictions shall not be imposed in a manner which will unreasonably affect the competitive market.

Section 27. Section 484.041, Florida Statutes, is reordered and amended to read:

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

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(1) "Air-conduction hearing aid" means a hearing aid that conducts sound to the ear through the air.

(2) "Board" means the Board of Hearing Aid Specialists.

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

(4) ~~(3)~~ "Dispensing prescription hearing aids" means and includes:

(a) Conducting and interpreting hearing tests for purposes of selecting suitable prescription hearing aids, making earmolds or ear impressions, and providing appropriate counseling.

(b) All acts pertaining to the selling, renting, leasing, pricing, delivery, and warranty of prescription hearing aids.

(7) ~~(4)~~ "Hearing aid specialist" means a person duly licensed in this state to practice the dispensing of prescription hearing aids.

(5) "Hearing aid" means any wearable ~~an amplifying~~ device designed for, offered for the purpose of, or represented as aiding persons with, or compensating for, impaired hearing ~~to be worn by a hearing-impaired person to improve hearing~~.

(11) ~~(6)~~ "Trainee" means a person studying prescription hearing aid dispensing under the direct supervision of an active licensed hearing aid specialist for the purpose of qualifying for certification to sit for the licensure examination.

(6) ~~(7)~~ "Hearing aid establishment" means any establishment in this ~~the~~ state which employs a licensed hearing aid specialist who offers, advertises, and performs hearing aid services for the general public.

(8) "Over-the-counter hearing aid" means an air-conduction hearing aid that does not require implantation or other surgical intervention and is intended for use only by a person 18 years

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of age or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss. The device is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements of 21 C.F.R. parts 800, 801, and 874 (2022), which are specifically incorporated by reference herein.

(9) "Prescription hearing aid" means a hearing aid or sound amplifying device that is not an over-the-counter hearing aid. Hearing aids intended for use by persons younger than 18 years of age must be prescription hearing aids.

(10) "Sponsor" means an active, licensed hearing aid specialist under whose direct supervision one or more trainees are studying prescription hearing aid dispensing for the purpose of qualifying for certification to sit for the licensure examination.

Section 28. Subsection (2) of section 484.042, Florida Statutes, is amended to read:

484.042 Board of Hearing Aid Specialists; membership, appointment, terms.—

(2) Five members of the board shall be hearing aid specialists who have been licensed and practicing the dispensing of prescription hearing aids in this state for at least the preceding 4 years. The remaining four members, none of whom

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shall derive economic benefit from the fitting or dispensing of hearing aids, shall be appointed from the resident lay public of this state. One of the lay members shall be a prescription hearing aid user but may not ~~neither~~ be nor have been a hearing aid specialist or a licensee of a closely related profession. One lay member shall be an individual age 65 or over. One lay member shall be an otolaryngologist licensed pursuant to chapter 458 or chapter 459.

Section 29. Subsection (2) of section 484.044, Florida Statutes, is amended to read:

484.044 Authority to make rules.—

(2) The board shall adopt rules requiring that each prospective purchaser of a prescription hearing aid be notified by the attending hearing aid specialist, at the time of the initial examination for fitting and sale of a hearing aid, of telecoil, "t" coil, or "t" switch technology. The rules shall further require that hearing aid specialists make available to prospective purchasers or clients information regarding telecoils, "t" coils, or "t" switches. ~~These rules shall be effective on or before October 1, 1994.~~

Section 30. Subsection (2) of section 484.0445, Florida Statutes, is amended to read:

484.0445 Training program.—

(2) A trainee shall perform the functions of a hearing aid specialist in accordance with board rules only under the direct supervision of a licensed hearing aid specialist. The term "direct supervision" means that the sponsor is responsible for all work being performed by the trainee. The sponsor or a hearing aid specialist designated by the sponsor shall give


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final approval to work performed by the trainee and shall be physically present at the time the prescription hearing aid is delivered to the client.

Section 31. Subsection (2) of section 484.045, Florida Statutes, is amended to read:

484.045 Licensure by examination.—

(2) The department shall license each applicant who the board certifies meets all of the following criteria:

(a) Has completed the application form and remitted the required fees.~~;~~

(b) Is of good moral character.~~;~~

(c) Is 18 years of age or older.~~;~~

(d) Is a graduate of an accredited high school or its equivalent.~~;~~

(e)1. Has met the requirements of the training program; or

2.a. Has a valid, current license as a hearing aid specialist or its equivalent from another state and has been actively practicing in such capacity for at least 12 months; or

b. Is currently certified by the National Board for Certification in Hearing Instrument Sciences and has been actively practicing for at least 12 months.~~;~~

(f) Has passed an examination, as prescribed by board rule.~~; and~~

(g) Has demonstrated, in a manner designated by rule of the board, knowledge of state laws and rules relating to the fitting and dispensing of prescription hearing aids.

Section 32. Section 484.0501, Florida Statutes, is amended to read:

484.0501 Minimal procedures and equipment.—

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(1) The following minimal procedures shall be used in the fitting and selling of prescription hearing aids:

(a) Pure tone audiometric testing by air and bone to determine the type and degree of hearing deficiency.

(b) Effective masking when indicated.

(c) 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.

(2) The following equipment shall be used:

(a) A wide range audiometer that ~~which~~ meets the specifications of the American National Standards Institute for diagnostic audiometers.

(b) A speech audiometer or a master hearing aid in order to determine the most comfortable listening level and speech discrimination.

(3) A final fitting ensuring physical and operational comfort of the prescription hearing aid shall be made.

(4) The following medical clearance shall be obtained: If, upon inspection of the ear canal with an otoscope in the common procedure of a prescription hearing aid fitter and upon interrogation of the client, there is any recent history of infection or any observable anomaly, the client must ~~shall~~ be instructed to see a physician, and a prescription hearing aid may ~~shall~~ not be fitted until medical clearance is obtained for the condition noted. If, upon return, the condition noted is no longer observable and the client signs a medical waiver, a prescription hearing aid may be fitted. Any person with a


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significant difference between bone conduction hearing and air conduction hearing must be informed of the possibility of medical correction.

(5)(a) A prescription hearing aid establishment ~~office~~ must have available, or have access to, a selection of prescription hearing aid models, hearing aid supplies, and services complete enough to accommodate the various needs of the prescription hearing aid wearers.

(b) At the time of the initial examination for fitting and sale of a prescription hearing aid, the attending hearing aid specialist shall ~~must~~ notify the prospective purchaser or client of the benefits of telecoil, "t" coil, or "t" switch technology, including increased access to telephones and noninvasive access to assistive listening systems required under the Americans with Disabilities Act of 1990.

(6) Each audiometric test conducted by a licensee or authorized trainee in the fitting and selling of prescription hearing aids must ~~shall~~ be made in a testing room that has been certified by the department, or by an agent approved by the department, not to exceed the following sound pressure levels at the specified frequencies: 250Hz-40dB, 500Hz-40dB, 750Hz-40dB, 1000Hz-40dB, 1500Hz-42dB, 2000Hz-47dB, 3000Hz-52dB, 4000Hz-57dB, 6000Hz-62dB, and 8000Hz-67dB. An exception to this requirement shall be made in the case of a client who, after being provided written notice of the benefits and advantages of having the test conducted in a certified testing room, requests that the test be conducted in a place other than the licensee's certified testing room. Such request must ~~shall~~ be documented by a waiver which includes the written notice and is signed by the licensee and


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the client before ~~prior to~~ the testing. The waiver must ~~shall~~ be executed on a form provided by the department. The executed waiver must ~~shall~~ be attached to the client's copy of the contract, and a copy of the executed waiver must ~~shall~~ be retained in the licensee's file.

(7) The board may ~~shall have the power to~~ prescribe the minimum procedures and equipment which must ~~shall~~ be used in the conducting of hearing assessments, and for the fitting and selling of prescription hearing aids, including equipment that will measure the prescription hearing aid's response curves to ensure that they meet the manufacturer's specifications. These procedures and equipment may differ from those provided in this section in order to take full advantage of devices and equipment which may hereafter become available and which are demonstrated to be of greater efficiency and accuracy. The board shall adopt and enforce rules necessary to implement ~~carry out the provisions of~~ this subsection and subsection (6).

(8) Any duly authorized officer or employee of the department may ~~shall have the right to~~ make such inspections and investigations as ~~are~~ necessary ~~in order~~ to determine the state of compliance with ~~the provisions of~~ this section and the applicable rules and may enter the premises of a licensee and inspect the records of same upon reasonable belief that a violation of this law is being or has been committed or that the licensee has failed or is failing to comply with ~~the provisions of~~ this part ~~act~~.

(9) A licensed hearing aid specialist may fit, sell, dispense, service, market, provide customer support for, and distribute prescription and over-the-counter hearing aids.

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However, over-the-counter hearing aids may be provided only to persons 18 years of age or older.

Section 33. Section 484.051, Florida Statutes, is amended to read:

484.051 Itemization of prices; delivery of prescription hearing aid; receipt, packaging, disclaimer, guarantee.—

(1) Before ~~Prior to~~ delivery of services or products to a prospective purchaser, any person who fits and sells prescription hearing aids must ~~shall~~ disclose on request by the prospective purchaser an itemized listing of prices, which must ~~listing shall~~ include separate price estimates for each service component and each product. Provision of such itemized listing of prices may ~~shall~~ not be predicated on the prospective purchaser's payment of any charge or agreement to purchase any service or product.

(2) Any person who fits and sells a prescription hearing aid must ~~shall~~, at the time of delivery, provide the purchaser with a receipt containing the seller's signature, the address of her or his regular place of business, and her or his license or trainee registration number, if applicable, together with the brand, model, manufacturer or manufacturer's identification code, and serial number of the prescription hearing aid furnished and the amount charged for the prescription hearing aid. The receipt must also ~~shall~~ specify whether the prescription hearing aid is new, used, or rebuilt, ~~and shall specify~~ the length of time and other terms of the guarantee, and by whom the prescription hearing aid is guaranteed. If ~~When~~ the client has requested an itemized list of prices, the receipt must ~~shall~~ also provide an itemization of the total purchase

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price, including, but not limited to, the cost of the aid, earmold, batteries and other accessories, and any services. Notice of the availability of this service shall be displayed in a conspicuous manner in the office. The receipt must also ~~shall~~ state that any complaint concerning the prescription hearing aid and guarantee therefor, if not reconciled with the licensee from whom the prescription hearing aid was purchased, should be directed by the purchaser to the Department of Health. The address and telephone number of such office must ~~shall~~ be stated on the receipt.

(3) A prescription ~~No~~ hearing aid may not be sold to any person unless both the packaging containing the prescription hearing aid and the itemized receipt provided pursuant to subsection (2) carry the following disclaimer in 10-point or larger type: "A hearing aid will not restore normal hearing, nor will it prevent further hearing loss."

Section 34. Section 484.0512, Florida Statutes, is amended to read:

484.0512 Thirty-day trial period; purchaser's right to cancel; notice; refund; cancellation fee; criminal penalty.—

(1) A person selling a prescription hearing aid in this state must provide the buyer with written notice of a 30-day trial period and money-back guarantee. The guarantee must permit the purchaser to cancel the purchase for a valid reason, as defined by ~~rule of the~~ board rule, within 30 days after receiving the prescription hearing aid, by returning the prescription hearing aid or mailing written notice of cancellation to the seller. If the prescription hearing aid must be repaired, remade, or adjusted during the 30-day trial period,

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the running of the 30-day trial period is suspended 1 day for each 24-hour period that the prescription hearing aid is not in the purchaser's possession. A repaired, remade, or adjusted prescription hearing aid must be claimed by the purchaser within 3 working days after notification of availability. The running of the 30-day trial period resumes on the day the purchaser reclaims the repaired, remade, or adjusted prescription hearing aid or on the fourth day after notification of availability, whichever occurs earlier.

(2) The board, in consultation with the Board of Speech-Language Pathology and Audiology, shall prescribe by rule the terms and conditions to be contained in the money-back guarantee and any exceptions thereto. Such rules must ~~rule shall~~ provide, at a minimum, that the charges for earmolds and service provided to fit the prescription hearing aid may be retained by the licensee. The rules must ~~shall~~ also set forth any reasonable charges to be held by the licensee as a cancellation fee. ~~Such rule shall be effective on or before December 1, 1994. Should the board fail to adopt such rule, a licensee may not charge a cancellation fee which exceeds 5 percent of the total charge for a hearing aid alone.~~ The terms and conditions of the guarantee, including the total amount available for refund, must ~~shall~~ be provided in writing to the purchaser before ~~prior to~~ the signing of the contract.

(3) Within 30 days after the return or attempted return of the prescription hearing aid, the seller shall refund all moneys that must be refunded to a purchaser pursuant to this section. A violation of this subsection is a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

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(4) For purposes of this section, the term "seller" or "person selling a prescription hearing aid" includes:

(a) Any ~~natural~~ person licensed under this part or any other ~~natural~~ person who signs a sales receipt required by s. 484.051(2) or s. 468.1245(2) or ~~who~~ otherwise fits, delivers, or dispenses a prescription hearing aid.

(b) Any business organization, whether a sole proprietorship, partnership, corporation, professional association, joint venture, business trust, or other legal entity, that ~~which~~ dispenses a prescription hearing aid or enters into an agreement to dispense a prescription hearing aid.

(c) Any person who controls, manages, or operates an establishment or business that dispenses a prescription hearing aid or enters into an agreement to dispense a prescription hearing aid.

Section 35. Section 484.0513, Florida Statutes, is amended to read:

484.0513 Cancellation by medical authorization; purchaser's right to return.—

(1) In addition to any other rights and remedies the purchaser of a prescription hearing aid may have, the purchaser has ~~shall have~~ the right to rescind the transaction if the purchaser for whatever reason consults a licensed physician with specialty board certification in otolaryngology or internal medicine or a licensed family practice physician, subsequent to purchasing a prescription hearing aid, and the physician certifies in writing that the purchaser has a hearing impairment for which a prescription hearing aid will not provide a benefit or that the purchaser has a medical condition which

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contraindicates the use of a prescription hearing aid.

(2) The purchaser of a prescription hearing aid has ~~shall have~~ the right to rescind as provided in subsection (1) only if the purchaser gives a written notice of the intent to rescind the transaction to the seller at the seller's place of business by certified mail, return receipt requested, which must ~~notice shall~~ be posted within ~~not later than~~ 60 days after ~~following~~ the date of delivery of the prescription hearing aid to the purchaser, and the purchaser returns the prescription hearing aid to the seller in the original condition less normal wear and tear.

(3) If the conditions of subsections (1) and (2) are met, the seller must ~~shall~~, without request, refund to the purchaser, within 10 days after ~~of the~~ receipt of the notice to rescind, a full and complete refund of all moneys received, less 5 percent. The purchaser does not ~~shall~~ incur any ~~no~~ additional liability for rescinding the transaction.

Section 36. Section 484.053, Florida Statutes, is amended to read:

484.053 Prohibitions; penalties.—

(1) A person may not:

(a) Practice dispensing prescription hearing aids unless the person is a licensed hearing aid specialist;

(b) Use the name or title "hearing aid specialist" when the person has not been licensed under this part;

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

(d) Give false, incomplete, or forged evidence to the board or a member thereof for the purposes of obtaining a license;

(e) Use or attempt to use a hearing aid specialist license


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that is delinquent or has been suspended, revoked, or placed on inactive status;

(f) Knowingly employ unlicensed persons in the practice of dispensing prescription hearing aids; or

(g) Knowingly conceal information relative to violations of this part.

(2) Any person who violates any provision ~~of the provisions~~ of this section is guilty of a felony of the third degree, punishable as provided in s. 775.082 or s. 775.083.

(3) If a person licensed under this part allows the sale of a prescription hearing aid by an unlicensed person not registered as a trainee or fails to comply with the requirements of s. 484.0445(2) relating to supervision of trainees, the board must ~~shall~~, upon determination of that violation, order the full refund of moneys paid by the purchaser upon return of the prescription hearing aid to the seller's place of business.

Section 37. Section 484.054, Florida Statutes, is amended to read:

484.054 Sale or distribution of prescription hearing aids through mail; penalty.—It is unlawful for any person to sell or distribute prescription hearing aids through the mail to the ultimate consumer. Any violation of this section constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 38. Section 484.059, Florida Statutes, is amended to read:

484.059 Exemptions.—

(1) The licensure requirements of this part do not apply to any person engaged in recommending prescription hearing aids as


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part of the academic curriculum of an accredited institution of higher education, or as part of a program conducted by a public charitable institution supported primarily by voluntary contribution, provided this organization does not dispense or sell prescription hearing aids or accessories.

(2) The licensure requirements of this part do not apply to any person licensed to practice medicine in this ~~the~~ state, except that such physician must ~~shall~~ comply with the requirement of periodic filing of the certificate of testing and calibration of audiometric equipment as provided in this part. A ~~No~~ person employed by or working under the supervision of a person licensed to practice medicine may not ~~shall~~ perform any services or acts which would constitute the dispensing of prescription hearing aids as defined in s. 484.041 ~~s. 484.041(3)~~, unless such person is a licensed hearing aid specialist.

(3) The licensure requirements of this part do not apply to an audiologist licensed under ~~pursuant to~~ part I of chapter 468.

(4) Section ~~The provisions of s.~~ 484.053(1)(a) does ~~shall~~ not apply to registered trainees operating in compliance with this part and board rules ~~of the board~~.

(5) The licensure requirements of this part do not apply to a person who fits, sells, dispenses, services, markets, provides customer support for, or distributes exclusively over-the-counter hearing aids.

Section 39. Paragraph (b) of subsection (4) of section 1002.394, Florida Statutes, is amended to read:

1002.394 The Family Empowerment Scholarship Program.—

(4) AUTHORIZED USES OF PROGRAM FUNDS.—


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(b) Program funds awarded to a student with a disability determined eligible pursuant to paragraph (3)(b) may be used for the following purposes:

1. Instructional materials, including digital devices, digital periphery devices, and assistive technology devices that allow a student to access instruction or instructional content and training on the use of and maintenance agreements for these devices.

2. Curriculum as defined in subsection (2).

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

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

b. Services provided by speech-language pathologists as defined in s. 468.1125 ~~s. 468.1125(8)~~.

c. Occupational therapy as defined in s. 468.203.

d. Services provided by physical therapists as defined in s. 486.021(8).

e. Services provided by listening and spoken language specialists and an appropriate acoustical environment for a child who has a hearing impairment, including deafness, and who has received an implant or assistive hearing device.

4. Tuition or fees associated with full-time or part-time enrollment in a home education program, an eligible private school, an eligible postsecondary educational institution or a program offered by the postsecondary educational institution, a private tutoring program authorized under s. 1002.43, a virtual program offered by a department-approved private online provider


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that meets the provider qualifications specified in s. 1002.45(2)(a), the Florida Virtual School as a private paying student, or an approved online course offered pursuant to s. 1003.499 or s. 1004.0961.

5. Fees for nationally standardized, norm-referenced achievement tests, Advanced Placement Examinations, industry certification examinations, assessments related to postsecondary education, or other assessments.

6. Contributions to the Stanley G. Tate Florida Prepaid College Program pursuant to s. 1009.98 or the Florida College Savings Program pursuant to s. 1009.981 for the benefit of the eligible student.

7. Contracted services provided by a public school or school district, including classes. A student who receives services under a contract under this paragraph is not considered enrolled in a public school for eligibility purposes as specified in subsection (6).

8. Tuition and fees for part-time tutoring services provided by a person who holds a valid Florida educator's certificate pursuant to s. 1012.56, a person who holds an adjunct teaching certificate pursuant to s. 1012.57, a person who has a bachelor's degree or a graduate degree in the subject area in which instruction is given, a person who has demonstrated a mastery of subject area knowledge pursuant to s. 1012.56(5), or a person certified by a nationally or internationally recognized research-based training program as approved by the department. As used in this paragraph, the term "part-time tutoring services" does not qualify as regular school attendance as defined in s. 1003.01(13)(e).

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9. Fees for specialized summer education programs.

10. Fees for specialized after-school education programs.

11. Transition services provided by job coaches.

12. Fees for an annual evaluation of educational progress by a state-certified teacher under s. 1002.41(1)(f), if this option is chosen for a home education student.

13. Tuition and fees associated with programs offered by Voluntary Prekindergarten Education Program providers approved pursuant to s. 1002.55 and school readiness providers approved pursuant to s. 1002.88.

14. Fees for services provided at a center that is a member of the Professional Association of Therapeutic Horsemanship International.

15. Fees for services provided by a therapist who is certified by the Certification Board for Music Therapists or credentialed by the Art Therapy Credentials Board, Inc.

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

And the title is amended as follows:

Delete lines 72 - 96

and insert:

examination; amending s. 468.1115, F.S.; providing construction and applicability; conforming a cross-reference; reordering and amending s. 468.1125, F.S.; providing and revising definitions; amending ss. 468.1225 and 468.1245, F.S.; revising the scope of practice for audiologists, as it relates to hearing aids to apply to prescription hearing aids only; requiring that hearing aids provided to persons


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younger than 18 years of age be prescription hearing aids and not over-the-counter hearing aids; amending s. 468.1246, F.S.; conforming provisions to changes made by the act; deleting obsolete language; amending ss. 468.1255, 468.1265, and 468.1275, F.S.; conforming provisions to changes made by the act; amending s. 484.0401, F.S.; revising legislative findings and intent to conform to changes made by the act; reordering and amending s. 484.041, F.S.; providing and revising definitions; amending s. 484.042, F.S.; revising membership requirements for members of the Board of Hearing Aid Specialists; amending s. 484.044, F.S.; revising the board's rulemaking authority; deleting obsolete language; amending ss. 484.0445, 484.045, 484.0501, and 484.051, F.S.; revising the scope of practice for hearing aid specialists and making conforming changes to licensure and practice requirements; amending s. 484.0512, F.S.; conforming provisions to changes made by the act; deleting obsolete language; amending ss. 484.0513, 484.053, and 484.054, F.S.; conforming provisions to changes made by the act; amending s. 484.059, F.S.; conforming provisions to changes made by the act; providing applicability; amending s. 1002.394, F.S.; conforming a cross-reference; providing a

By Senator Rodriguez

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A bill to be entitled

An act relating to the Department of Health; creating s. 381.875, F.S.; defining terms; prohibiting certain research in this state relating to enhanced potential pandemic pathogens; requiring researchers applying for state or local funding to disclose certain information; requiring the Department of Health to enjoin violations of specified provisions; providing construction; amending s. 381.986, F.S.; defining the term "attractive to children"; prohibiting medical marijuana treatment centers from producing marijuana products that are attractive to children or manufactured in specified manners; prohibiting marijuana packaging and labeling from including specified wording; prohibiting medical marijuana treatment centers from using certain content in their advertising which is attractive to children or promotes the recreational use of marijuana; requiring the department to adopt certain rules; revising background screening requirements for certain individuals; amending s. 381.988, F.S.; requiring medical marijuana testing laboratories to subject their employees to background screenings; revising background screening requirements for certain individuals; amending s. 382.005, F.S.; requiring local registrars to electronically file all live birth, death, and fetal death records in their respective jurisdictions in the department's electronic registration system; requiring the local

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registrars to file a paper record with the department if the electronic system is unavailable; requiring local registrars to make blank paper forms available in such instances; providing requirements for such paper records; amending s. 382.008, F.S.; conforming provisions to changes made by the act; amending s. 382.009, F.S.; revising the types of health care practitioners who may make certain determinations of death; amending ss. 382.013 and 382.015, F.S.; conforming provisions to changes made by the act; amending ss. 382.021 and 382.023, F.S.; revising the frequency with which circuit courts must transmit marriage licenses and certain dissolution-of-marriage records to the department; requiring that such records be transmitted electronically; amending s. 382.025, F.S.; extending the timeframe for the confidentiality of certain birth records; authorizing persons appointed by the department to issue certified copies of live birth, death, and fetal death certificates; amending s. 401.27, F.S.; revising requirements for applicants for certification or recertification as emergency medical technicians or paramedics; deleting a requirement that a certain certification examination be offered monthly; deleting related duties of the department; deleting a temporary certificate and related provisions; amending s. 401.2701, F.S.; exempting certain emergency medical services training program applicants from the requirement to have a certain affiliation agreement; amending s. 401.272,

F.S.; revising the purpose of certain provisions; specifying requirements for the provision of specified services by paramedics and emergency medical technicians under certain circumstances; revising the department's rulemaking authority; amending s. 401.34, F.S.; deleting certain provisions and fees related to the department's grading of a certain certification examination; amending s. 401.435, F.S.; revising provisions related to minimum standards for emergency medical responder training; amending s. 464.203, F.S.; exempting certain applicants for certification as a certified nursing assistant from the skills-demonstration portion of a certain competency examination; amending ss. 468.1225 and 468.1245, F.S.; revising the scope of practice for audiologists, as it relates to hearing aids to apply to prescription hearing aids only; amending s. 468.1246, F.S.; conforming provisions to changes made by the act; deleting obsolete language; amending ss. 468.1255, 468.1265, and 468.1275, F.S.; conforming provisions to changes made by the act; amending s. 484.0401, F.S.; revising legislative findings and intent to conform to changes made by the act; reordering and amending s. 484.041, F.S.; providing and revising definitions; amending s. 484.042, F.S.; revising membership requirements for members of the Board of Hearing Aid Specialists; amending s. 484.044, F.S.; revising the board's rulemaking authority; deleting obsolete language; amending ss. 484.0445, 484.045, 484.0501,

and 484.051, F.S.; revising the scope of practice for hearing aid specialists and making conforming changes to licensure and practice requirements; amending s. 484.0512, F.S.; conforming provisions to changes made by the act; deleting obsolete language; amending ss. 484.0513, 484.053, and 484.054, F.S.; conforming provisions to changes made by the act; amending s. 484.059, F.S.; conforming provisions to changes made by the act; providing applicability; providing a directive to the Division of Law Revision; providing effective dates.

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

Section 1. Effective upon this act becoming law, section 381.875, Florida Statutes, is created to read:

381.875 Enhanced potential pandemic pathogen research prohibited.—

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

(a) "Enhanced potential pandemic pathogen" means a potential pandemic pathogen that results from enhancing the transmissibility or virulence of a pathogen. The term does not include naturally occurring pathogens circulating in or recovered from nature, regardless of their pandemic potential.

(b) "Enhanced potential pandemic pathogen research" means research that may be reasonably anticipated to create, transfer, or use potential pandemic pathogens that result from enhancing a pathogen's transmissibility or virulence in humans.

(c) "Potential pandemic pathogen" means a bacterium, virus,

or other microorganism that is likely to be both:

1. Highly transmissible and capable of wide, uncontrollable spread in human populations; and

2. Highly virulent, making it likely to cause significant morbidity or mortality in humans.

(2) Any research that is reasonably likely to create an enhanced potential pandemic pathogen or that has been determined by the United States Department of Health and Human Services, another federal agency, or a state agency as defined in s. 11.45 to create such a pathogen is prohibited in this state.

(3) Any researcher applying for state or local funding to conduct research in this state must disclose in the application to the funding source whether the research meets the definition of enhanced potential pandemic pathogen research.

(4) The Department of Health shall exercise its authority under s. 381.0012 to enjoin violations of this section.

(5) This section does not affect research funded or conducted before the effective date of this act.

Section 2. Present paragraphs (a) through (o) of subsection (1) of section 381.986, Florida Statutes, are redesignated as paragraphs (b) through (p), respectively, a new paragraph (a) is added to that subsection, and paragraphs (a) and (c) of subsection (3), paragraphs (e), (h), and (k) of subsection (8), and subsection (9) of that section are amended, to read:

381.986 Medical use of marijuana.—

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

(a) "Attractive to children" means the use of any image or words designed or likely to appeal to persons younger than 18 years of age, including, but not limited to, cartoons, toys,

animals, food, or depictions of persons younger than 18 years of age; any other likeness to images, characters, or phrases that are popularly used to advertise to persons younger than 18 years of age; or any reasonable likeness to commercially available candy.

(3) QUALIFIED PHYSICIANS AND MEDICAL DIRECTORS.—

(a) Before being approved as a qualified physician~~, as defined in paragraph (1)(m),~~ and before each license renewal, a physician must successfully complete a 2-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association which encompass the requirements of this section and any rules adopted hereunder. The course and examination must ~~shall~~ be administered at least annually and may be offered in a distance learning format, including an electronic, online format that is available upon request. The price of the course may not exceed $500. A physician who has met the physician education requirements of former s. 381.986(4), Florida Statutes 2016, before June 23, 2017, shall be deemed to be in compliance with this paragraph from June 23, 2017, until 90 days after the course and examination required by this paragraph become available.

(c) Before being employed as a medical director~~, as defined in paragraph (1)(i),~~ and before each license renewal, a medical director must successfully complete a 2-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association which encompass the requirements of this section and any rules adopted hereunder. The course and examination must ~~shall~~ be administered at least annually and may be offered in a distance learning

format, including an electronic, online format that is available upon request. The price of the course may not exceed $500.

(8) MEDICAL MARIJUANA TREATMENT CENTERS.—

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

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

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

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

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

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

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

2. A medical marijuana treatment center, and any individual or entity who directly or indirectly owns, controls, or holds with power to vote 5 percent or more of the voting shares of a

medical marijuana treatment center, may not acquire direct or indirect ownership or control of any voting shares or other form of ownership of any other medical marijuana treatment center.

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

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

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

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

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

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

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

d. Must perform fumigation or treatment of plants, or

remove and destroy infested or infected plants, in accordance with chapter 581 and any rules adopted thereunder.

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

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

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

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

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

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

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

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

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

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

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

including all marijuana and marijuana products made from the same batch of marijuana, that fails to meet the potency requirements of this section, that is unsafe for human consumption, or for which the labeling of the tetrahydrocannabinol and cannabidiol concentration is inaccurate. The department shall adopt rules to establish marijuana potency variations of no greater than 15 percent using negotiated rulemaking pursuant to s. 120.54(2)(d) which accounts for, but is not limited to, time lapses between testing, testing methods, testing instruments, and types of marijuana sampled for testing. The department may not issue any recalls for product potency as it relates to product labeling before issuing a rule relating to potency variation standards. A medical marijuana treatment center must also recall all marijuana delivery devices determined to be unsafe for use by qualified patients. The medical marijuana treatment center must retain records of all testing and samples of each homogenous batch of marijuana for at least 9 months. The medical marijuana treatment center must contract with a marijuana testing laboratory to perform audits on the medical marijuana treatment center's standard operating procedures, testing records, and samples and provide the results to the department to confirm that the marijuana or low-THC cannabis meets the requirements of this section and that the marijuana or low-THC cannabis is safe for human consumption. A medical marijuana treatment center shall reserve two processed samples from each batch and retain such samples for at least 9 months for the purpose of such audits. A medical marijuana treatment center may use a laboratory that has not been certified by the department under s. 381.988 until such time as

at least one laboratory holds the required certification, but in no event later than July 1, 2018.

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

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

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

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

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

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

(V) The name of the patient.

(VI) The product name, if applicable, and dosage form, including concentration of tetrahydrocannabinol and cannabidiol. The product name may not contain wording commonly associated with products that are attractive to children or which promote the recreational use of marijuana ~~marketed by or to children~~.

(VII) The recommended dose.

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

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

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

a. Clinical pharmacology.

b. Indications and use.

c. Dosage and administration.

d. Dosage forms and strengths.

e. Contraindications.

f. Warnings and precautions.

g. Adverse reactions.

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

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

15. Each edible must ~~shall~~ be individually sealed in plain, opaque wrapping marked only with the marijuana universal symbol. Where practical, each edible must ~~shall~~ be marked with the marijuana universal symbol. In addition to the packaging and labeling requirements in subparagraphs 11. and 12., edible receptacles must be plain, opaque, and white without depictions of the product or images other than the medical marijuana

treatment center's department-approved logo and the marijuana universal symbol. The receptacle must also include a list of all the edible's ingredients, storage instructions, an expiration date, a legible and prominent warning to keep away from children and pets, and a warning that the edible has not been produced or inspected pursuant to federal food safety laws.

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

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

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

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

d. Must verify that the qualified patient and the caregiver, if applicable, each have an active registration in the medical marijuana use registry and an active and valid medical marijuana use registry identification card, the amount and type of marijuana dispensed matches the physician

certification in the medical marijuana use registry for that qualified patient, and the physician certification has not already been filled.

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

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

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

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

(h) A medical marijuana treatment center may not engage in advertising that is visible to members of the public from any street, sidewalk, park, or other public place, except:

1. The dispensing location of a medical marijuana treatment center may have a sign that is affixed to the outside or hanging in the window of the premises which identifies the dispensary by the licensee's business name, a department-approved trade name, or a department-approved logo. A medical marijuana treatment

center's trade name and logo may not contain wording or images that are attractive to children ~~commonly associated with marketing targeted toward children~~ or which promote recreational use of marijuana.

2. A medical marijuana treatment center may engage in Internet advertising and marketing under the following conditions:

a. All advertisements must be approved by the department.

b. An advertisement may not have any content that is attractive to children or which promotes the recreational use of marijuana ~~specifically targets individuals under the age of 18, including cartoon characters or similar images~~.

c. An advertisement may not be an unsolicited pop-up advertisement.

d. Opt-in marketing must include an easy and permanent opt-out feature.

(k) The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this subsection. The department shall adopt rules it deems necessary to protect the health and safety of qualified patients and minors, including, but not limited to, standards to ensure that medical marijuana treatment centers operate in a manner consistent with the provision of medical products and rules to discourage the diversion and illicit use of marijuana.

(9) BACKGROUND SCREENING.—An individual required to undergo a background screening pursuant to this section must pass a level 2 background screening as provided under chapter 435, which, in addition to the disqualifying offenses provided in s. 435.04, shall exclude an individual who has an arrest awaiting

final disposition for, has been found guilty of, regardless of adjudication, or has entered a plea of nolo contendere or guilty to an offense under chapter 837, chapter 895, or chapter 896 or similar law of another jurisdiction. Exemptions from disqualification as provided under s. 435.07 do not apply to this subsection.

(a) Such individual must submit a full set of fingerprints to the department or to a vendor, entity, or agency authorized by s. 943.053(13). The department, vendor, entity, or agency shall forward the fingerprints to the Department of Law Enforcement for state processing, and the Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for national processing.

(b) Fees for state and federal fingerprint processing and retention shall be borne by the medical marijuana treatment center or caregiver, as applicable ~~individual~~. The state cost for fingerprint processing shall be as provided in s. 943.053(3)(e) for records provided to persons or entities other than those specified as exceptions therein.

(c) Fingerprints submitted to the Department of Law Enforcement pursuant to this subsection shall be retained by the Department of Law Enforcement as provided in s. 943.05(2)(g) and (h) and, when the Department of Law Enforcement begins participation in the program, enrolled in the Federal Bureau of Investigation's national retained print arrest notification program. Any arrest record identified shall be reported to the department.

Section 3. Paragraph (d) of subsection (1) of section 381.988, Florida Statutes, is amended to read:

381.988 Medical marijuana testing laboratories; marijuana tests conducted by a certified laboratory.—

(1) A person or entity seeking to be a certified marijuana testing laboratory must:

(d) Require all employees, owners, and managers to submit to and pass a level 2 background screening pursuant to chapter 435. The department ~~s. 435.04 and~~ shall deny certification if the person or entity seeking certification has a disqualifying offense as provided in s. 435.04 or has an arrest awaiting final disposition for, has been found guilty of, or has entered a plea of guilty or nolo contendere to, regardless of adjudication, any offense listed in chapter 837, chapter 895, or chapter 896 or similar law of another jurisdiction. Exemptions from disqualification as provided under s. 435.07 do not apply to this paragraph.

1. Such employees, owners, and managers must submit a full set of fingerprints to the department or to a vendor, entity, or agency authorized by s. 943.053(13). The department, vendor, entity, or agency shall forward the fingerprints to the Department of Law Enforcement for state processing, and the Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for national processing.

2. Fees for state and federal fingerprint processing and retention shall be borne by the certified marijuana testing laboratory ~~such owners or managers~~. The state cost for fingerprint processing shall be as provided in s. 943.053(3)(e) for records provided to persons or entities other than those specified as exceptions therein.

3. Fingerprints submitted to the Department of Law

Enforcement pursuant to this paragraph shall be retained by the Department of Law Enforcement as provided in s. 943.05(2)(g) and (h) and, when the Department of Law Enforcement begins participation in the program, enrolled in the Federal Bureau of Investigation's national retained print arrest notification program. Any arrest record identified shall be reported to the department.

Section 4. Section 382.005, Florida Statutes, is amended to read:

382.005 Duties of local registrars.—

(1) Each local registrar is charged with the strict and thorough enforcement of the provisions of this chapter and rules adopted hereunder in his or her registration district, and shall make an immediate report to the department of any violation or apparent violation of this law or rules adopted hereunder.

(2) Each local registrar must electronically file all live birth, death, and fetal death records within their respective jurisdictions in the department's electronic registration system. If the department's electronic registration system is unavailable, the local registrar must file a paper record with the department.

(3) Each local registrar must ~~shall~~ make ~~available~~ blank forms available if the department's electronic registration system is unavailable, ~~as necessary~~ and must ~~shall~~ examine each paper certificate of live birth, death, or fetal death when presented for registration in order to ascertain whether ~~or not~~ it has been completed in accordance with ~~the provisions of~~ this chapter and adopted rules. All paper birth, death, and fetal death certificates must ~~shall~~ be typewritten in permanent black

ink, and a paper certificate is not complete and correct if it does not supply each item of information called for or satisfactorily account for its omission.

(4) ~~(3)~~ The local registrar or his or her deputy, if authorized by the department, shall sign as registrar in attestation of the date of registration of any paper records filed, and may also make and preserve a local paper record of each birth, death, and fetal death certificate registered by him or her, in such manner as directed by the department. The local registrar shall transmit daily to the department all original paper certificates registered. If no births, deaths, or fetal deaths occurred in any month, the local registrar or deputy shall, on the 7th day of the following month, report that fact to the department on a form provided for such purpose.

(5) ~~(4)~~ Each local registrar, immediately upon appointment, shall designate one or more deputy registrars to act on behalf of the local registrar.

Section 5. Subsection (2) of section 382.008, Florida Statutes, is amended to read:

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

(2)(a) The funeral director who first assumes custody of a dead body or fetus shall electronically file the certificate of death or fetal death. In the absence of the funeral director, the physician, physician assistant, advanced practice registered nurse registered under s. 464.0123, or other person in attendance at or after the death or the district medical examiner of the county in which the death occurred or the body was found shall electronically file the certificate of death or

fetal death. The person who files the certificate shall obtain personal data from a legally authorized person as described in s. 497.005 or the best qualified person or source available. The medical certification of cause of death must ~~shall~~ be furnished to the funeral director, either in person or via certified mail or electronic transfer, by the physician, physician assistant, advanced practice registered nurse registered under s. 464.0123, or medical examiner responsible for furnishing such information. For fetal deaths, the physician, physician assistant, advanced practice registered nurse registered under s. 464.0123, midwife, or hospital administrator shall provide any medical or health information to the funeral director within 72 hours after expulsion or extraction.

(b) The State Registrar shall ~~may~~ receive electronically a certificate of death, fetal death, or nonviable birth which is required to be filed with the registrar under this chapter through facsimile or other electronic transfer for the purpose of filing the certificate. The receipt of a certificate of death, fetal death, or nonviable birth by electronic transfer constitutes delivery to the State Registrar as required by law.

Section 6. Subsection (2) of section 382.009, Florida Statutes, is amended to read:

382.009 Recognition of brain death under certain circumstances.—

(2) Determination of death pursuant to this section must ~~shall~~ be made in accordance with currently accepted reasonable medical standards by two licensed health care practitioners who must be physicians or physician assistants licensed under chapter 458 or chapter 459 or advanced practice registered

nurses registered under s. 464.0123. One of the health care practitioners must ~~physician shall~~ be the treating health care practitioner ~~physician, and the other physician shall be a board-eligible or board-certified neurologist, neurosurgeon, internist, pediatrician, surgeon, or anesthesiologist~~.

Section 7. Section 382.013, Florida Statutes, is amended to read:

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

(1) FILING.—

(a) If a birth occurs in a hospital, birth center, or other health care facility, or en route thereto, the person in charge of the facility is ~~shall be~~ responsible for preparing the certificate, certifying the facts of the birth, and filing the certificate in the department's electronic registration system with the local registrar. Within 48 hours after the birth, the physician, midwife, or person in attendance during or immediately after the delivery shall provide the facility with the medical information required by the birth certificate.

(b) If a birth occurs outside a facility and a physician licensed in this state, a certified nurse midwife, a midwife licensed in this state, or a public health nurse employed by the

department was in attendance during or immediately after the delivery, that person shall prepare and file the certificate.

(c) If a birth occurs outside a facility and the delivery is not attended by one of the persons described in paragraph (b), the person in attendance, the mother, or the father shall report the birth to the registrar and provide proof of the facts of birth. The department may require such documents to be presented and such proof to be filed as it deems necessary and sufficient to establish the truth of the facts to be recorded by the certificate and may withhold registering the birth until its requirements are met.

(d) If a birth occurs in a moving conveyance and the child is first removed from the conveyance in this state, the birth shall be filed and registered in this state and the place to which the child is first removed shall be considered the place of birth.

(e) The mother or the father of the child shall attest to the accuracy of the personal data entered on the certificate in time to permit the timely registration of the certificate.

(f) If a certificate of live birth is incomplete, the local registrar shall immediately notify the health care facility or person filing the certificate and shall require the completion of the missing items of information if they can be obtained before ~~prior to~~ issuing certified copies of the birth certificate.

(g) Regardless of any plan to place a child for adoption after birth, the information on the birth certificate as required by this section must be as to the child's birth parents unless and until an application for a new birth record is made

under s. 63.152.

(h) The State Registrar may receive electronically a birth certificate for each live birth which is required to be filed with the registrar under this chapter through facsimile or other electronic transfer for the purpose of filing the birth certificate. The receipt of a birth certificate by electronic transfer constitutes delivery to the State Registrar as required by law.

(2) PATERNITY.—

(a) If the mother is married at the time of birth, the name of the husband shall be entered on the birth certificate as the father of the child, unless paternity has been determined otherwise by a court of competent jurisdiction.

(b) Notwithstanding paragraph (a), if the husband of the mother dies while the mother is pregnant but before the birth of the child, the name of the deceased husband shall be entered on the birth certificate as the father of the child, unless paternity has been determined otherwise by a court of competent jurisdiction.

(c) If the mother is not married at the time of the birth, the name of the father may not be entered on the birth certificate without the execution of an affidavit signed by both the mother and the person to be named as the father. The facility shall give notice orally or through the use of video or audio equipment, and in writing, of the alternatives to, the legal consequences of, and the rights, including, if one parent is a minor, any rights afforded due to minority status, and responsibilities that arise from signing an acknowledgment of paternity, as well as information provided by the Title IV-D

agency established pursuant to s. 409.2557, regarding the benefits of voluntary establishment of paternity. Upon request of the mother and the person to be named as the father, the facility shall assist in the execution of the affidavit, a notarized voluntary acknowledgment of paternity, or a voluntary acknowledgment of paternity that is witnessed by two individuals and signed under penalty of perjury as specified by s. 92.525(2).

(d) If the paternity of the child is determined by a court of competent jurisdiction as provided under s. 382.015 or there is a final judgment of dissolution of marriage which requires the former husband to pay child support for the child, the name of the father and the surname of the child shall be entered on the certificate in accordance with the finding and order of the court. If the court fails to specify a surname for the child, the surname shall be entered in accordance with subsection (3).

(e) If the paternity of the child is determined pursuant to s. 409.256, the name of the father and the surname of the child shall be entered on the certificate in accordance with the finding and order of the Department of Revenue.

(f) If the mother and father marry each other at any time after the child's birth, upon receipt of a marriage license that identifies any such child, the department shall amend the certificate with regard to the parents' marital status as though the parents were married at the time of birth.

(g) If the father is not named on the certificate, no other information about the father shall be entered on the certificate.

(3) NAME OF CHILD.—

(a) If the mother is married at the time of birth, the mother and father whose names are entered on the birth certificate shall select the given names and surname of the child if both parents have custody of the child, otherwise the parent who has custody shall select the child's name.

(b) If the mother and father whose names are entered on the birth certificate disagree on the surname of the child and both parents have custody of the child, the surname selected by the father and the surname selected by the mother shall both be entered on the birth certificate, separated by a hyphen, with the selected names entered in alphabetical order. If the parents disagree on the selection of a given name, the given name may not be entered on the certificate until a joint agreement that lists the agreed upon given name and is notarized by both parents is submitted to the department, or until a given name is selected by a court.

(c) If the mother is not married at the time of birth, the parent who will have custody of the child shall select the child's given name and surname.

(d) If multiple names of the child exceed the space provided on the face of the birth certificate they shall be listed on the back of the certificate. Names listed on the back of the certificate shall be part of the official record.

(4) UNDETERMINED PARENTAGE.—The person having custody of a child of undetermined parentage shall register a birth certificate showing all known or approximate facts relating to the birth. To assist in later determination, information concerning the place and circumstances under which the child was found shall be included on the portion of the birth certificate

relating to marital status and medical details. In the event the child is later identified, a new birth certificate shall be prepared which shall bear the same number as the original birth certificate, and the original certificate shall be sealed and filed, shall be confidential and exempt from the provisions of s. 119.07(1), and shall not be opened to inspection by, nor shall certified copies of the same be issued except by court order to, any person other than the registrant if of legal age.

(5) DISCLOSURE.—The original certificate of live birth shall contain all the information required by the department for legal, social, and health research purposes. However, all information concerning parentage, marital status, and medical details shall be confidential and exempt from the provisions of s. 119.07(1), except for health research purposes as approved by the department, nor shall copies of the same be issued except as provided in s. 382.025.

Section 8. Section 382.015, Florida Statutes, is amended to read:

382.015 New certificates of live birth; duty of clerks of court and department.—The clerk of the court in which any proceeding for adoption, annulment of an adoption, affirmation of parental status, or determination of paternity is to be registered, shall within 30 days after the final disposition, forward <u>electronically</u> to the department a certified copy of the court order, or a report of the proceedings upon a form to be furnished by the department, together with sufficient information to identify the original birth certificate and to enable the preparation of a new birth certificate. The clerk of the court shall implement a monitoring and quality control plan

to ensure that all judicial determinations of paternity are reported to the department in compliance with this section. The department shall track paternity determinations reported monthly by county, monitor compliance with the 30-day timeframe, and report the data to the clerks of the court quarterly.

(1) ADOPTION AND ANNULMENT OF ADOPTION.—

(a) Upon receipt of the report or certified copy of an adoption decree, together with the information necessary to identify the original certificate of live birth, and establish a new certificate, the department shall prepare and file a new birth certificate, absent objection by the court decreeing the adoption, the adoptive parents, or the adoptee if of legal age. The certificate shall bear the same file number as the original birth certificate. All names and identifying information relating to the adoptive parents entered on the new certificate shall refer to the adoptive parents, but nothing in the certificate shall refer to or designate the parents as being adoptive. All other items not affected by adoption shall be copied as on the original certificate, including the date of registration and filing.

(b) Upon receipt of the report or certified copy of an annulment-of-adoption decree, together with the sufficient information to identify the original certificate of live birth, the department shall, if a new certificate of birth was filed following an adoption report or decree, remove the new certificate and restore the original certificate to its original place in the files, and the certificate so removed shall be sealed by the department.

(c) Upon receipt of a report or certified copy of an

adoption decree or annulment-of-adoption decree for a person born in another state, the department shall forward the report or decree to the state of the registrant's birth. If the adoptee was born in Canada, the department shall send a copy of the report or decree to the appropriate birth registration authority in Canada.

(2) DETERMINATION OF PATERNITY.—Upon receipt of the report, a certified copy of a final decree of determination of paternity, or a certified copy of a final judgment of dissolution of marriage which requires the former husband to pay child support for the child, together with sufficient information to identify the original certificate of live birth, the department shall prepare and file a new birth certificate, which shall bear the same file number as the original birth certificate. The registrant's name shall be entered as decreed by the court or as reflected in the final judgment or support order. The names and identifying information of the parents shall be entered as of the date of the registrant's birth.

(3) AFFIRMATION OF PARENTAL STATUS.—Upon receipt of an order of affirmation of parental status issued pursuant to s. 742.16, together with sufficient information to identify the original certificate of live birth, the department shall prepare and file a new birth certificate which shall bear the same file number as the original birth certificate. The names and identifying information of the registrant's parents entered on the new certificate shall be the commissioning couple, but the new certificate may not make reference to or designate the parents as the commissioning couple.

(4) SUBSTITUTION OF NEW CERTIFICATE OF BIRTH FOR ORIGINAL.—

When a new certificate of birth is prepared, the department shall substitute the new certificate of birth for the original certificate on file. All copies of the original certificate of live birth in the custody of a local registrar or other state custodian of vital records shall be forwarded to the State Registrar. Thereafter, when a certified copy of the certificate of birth or portion thereof is issued, it shall be a copy of the new certificate of birth or portion thereof, except when a court order requires issuance of a certified copy of the original certificate of birth. In an adoption, change in paternity, affirmation of parental status, undetermined parentage, or court-ordered substitution, the department shall place the original certificate of birth and all papers pertaining thereto under seal, not to be broken except by order of a court of competent jurisdiction or as otherwise provided by law.

(5) FORM.—Except for certificates of foreign birth which are registered as provided in s. 382.017, and delayed certificates of birth which are registered as provided in ss. 382.019 and 382.0195, all original, new, or amended certificates of live birth shall be identical in form, regardless of the marital status of the parents or the fact that the registrant is adopted or of undetermined parentage.

(6) RULES.—The department shall adopt and enforce all rules necessary for carrying out the provisions of this section.

Section 9. Section 382.021, Florida Statutes, is amended to read:

382.021 Department to receive marriage licenses.—Weekly ~~On or before the 5th day of each month~~, the county court judge or clerk of the circuit court shall electronically transmit all

original marriage licenses, with endorsements, received during the preceding calendar week ~~month~~, to the department. Any marriage licenses issued and not returned or any marriage licenses returned but not recorded shall be reported by the issuing county court judge or clerk of the circuit court to the department at the time of transmitting the recorded licenses on the forms to be prescribed and furnished by the department. If during any month no marriage licenses are issued or returned, the county court judge or clerk of the circuit court shall report such fact to the department upon forms prescribed and furnished by the department.

Section 10. Section 382.023, Florida Statutes, is amended to read:

382.023 Department to receive dissolution-of-marriage records; fees.—Clerks of the circuit courts shall collect for their services at the time of the filing of a final judgment of dissolution of marriage a fee of up to $10.50, of which 43 percent shall be retained by the clerk of the circuit court as a part of the cost in the cause in which the judgment is granted. The remaining 57 percent shall be remitted to the Department of Revenue for deposit to the Department of Health to defray part of the cost of maintaining the dissolution-of-marriage records. A record of each and every judgment of dissolution of marriage granted by the court during the preceding calendar week ~~month~~, giving names of parties and such other data as required by forms prescribed by the department, shall be electronically transmitted to the department weekly, ~~on or before the 10th day of each month,~~ along with an accounting of the funds remitted to the Department of Revenue pursuant to this section.

Section 11. Subsections (1) and (4) of section 382.025, Florida Statutes, are amended to read:

382.025 Certified copies of vital records; confidentiality; research.—

(1) BIRTH RECORDS.—Except for birth records over 125 ~~100~~ years old which are not under seal pursuant to court order, all birth records of this state shall be confidential and are exempt from the provisions of s. 119.07(1).

(a) Certified copies of the original birth certificate or a new or amended certificate, or affidavits thereof, are confidential and exempt from the provisions of s. 119.07(1) and, upon receipt of a request and payment of the fee prescribed in s. 382.0255, shall be issued only as authorized by the department and in the form prescribed by the department, and only:

1. To the registrant, if the registrant is of legal age, is a certified homeless youth, or is a minor who has had the disabilities of nonage removed under s. 743.01 or s. 743.015;

2. To the registrant's parent or guardian or other legal representative;

3. Upon receipt of the registrant's death certificate, to the registrant's spouse or to the registrant's child, grandchild, or sibling, if of legal age, or to the legal representative of any ~~of~~ such person ~~persons~~;

4. To any person if the birth record is more than 125 ~~over 100~~ years old and not under seal pursuant to court order;

5. To a law enforcement agency for official purposes;

6. To any agency of the state or the United States for official purposes upon approval of the department; or

7. Upon order of any court of competent jurisdiction.

(b) To protect the integrity of vital records and prevent the fraudulent use of the birth certificates of deceased persons, the department shall match birth and death certificates and post the fact of death to the appropriate birth certificate. Except for a commemorative birth certificate, any certification of a birth certificate of a deceased registrant shall be marked "deceased." In the case of a commemorative birth certificate, such indication of death shall be made on the back of the certificate.

(c) The department shall issue, upon request and upon payment of an additional fee as prescribed under s. 382.0255, a commemorative birth certificate representing that the birth of the person named thereon is recorded in the office of the registrar. The certificate issued under this paragraph shall be in a form consistent with the need to protect the integrity of vital records but shall be suitable for display. It may bear the seal of the state printed thereon and may be signed by the Governor.

(4) CERTIFIED COPIES OF ORIGINAL CERTIFICATES.—Only the state registrar, ~~and~~ local registrars, and those persons appointed by the department are authorized to issue any certificate which purports to be a certified copy of an original certificate of live birth, death, or fetal death. Except as provided in this section, preparing or issuing certificates is exempt from the provisions of s. 119.07(1).

Section 12. Subsections (3), (4), and (5) of section 401.27, Florida Statutes, are amended to read:

401.27 Personnel; standards and certification.—

(3) Any person who desires to be certified or recertified as an emergency medical technician or paramedic must apply to the department ~~under oath~~ on forms provided by the department which shall contain such information as the department reasonably requires, which may include affirmative evidence of ability to comply with applicable laws and rules. The department shall determine whether the applicant meets the requirements specified in this section and in rules of the department and shall issue a certificate to any person who meets such requirements.

(4) An applicant for certification or recertification as an emergency medical technician or paramedic must:

(a) Have completed an appropriate training program as follows:

1. For an emergency medical technician, an emergency medical technician training program approved by the department as equivalent to the most recent EMT-Basic National Standard Curriculum or the National EMS Education Standards of the United States Department of Transportation;

2. For a paramedic, a paramedic training program approved by the department as equivalent to the most recent EMT-Paramedic National Standard Curriculum or the National EMS Education Standards of the United States Department of Transportation;

(b) Attest ~~Certify under oath~~ that he or she is not addicted to alcohol or any controlled substance;

(c) Attest ~~Certify under oath~~ that he or she is free from any physical or mental defect or disease that might impair the applicant's ability to perform his or her duties;

(d) Within 2 years after program completion have passed an

examination developed or required by the department;

(e)1. For an emergency medical technician, hold a current American Heart Association cardiopulmonary resuscitation course card or an American Red Cross cardiopulmonary resuscitation course card or its equivalent as defined by department rule;

2. For a paramedic, hold a certificate of successful course completion in advanced cardiac life support from the American Heart Association or its equivalent as defined by department rule;

(f) Submit the certification fee and the nonrefundable examination fee prescribed in s. 401.34, which examination fee will be required for each examination administered to an applicant; and

(g) Submit a completed application to the department, which application documents compliance with paragraphs (a), (b), (c), (e), (f), and this paragraph, and, if applicable, paragraph (d). ~~The application must be submitted so as to be received by the department at least 30 calendar days before the next regularly scheduled examination for which the applicant desires to be scheduled.~~

~~(5) The certification examination must be offered monthly. The department shall issue an examination admission notice to the applicant advising him or her of the time and place of the examination for which he or she is scheduled. Individuals achieving a passing score on the certification examination may be issued a temporary certificate with their examination grade report. The department must issue an original certification within 45 days after the examination. Examination questions and answers are not subject to discovery but may be introduced into~~

~~evidence and considered only in camera in any administrative proceeding under chapter 120. If an administrative hearing is held, the department shall provide challenged examination questions and answers to the administrative law judge. The department shall establish by rule the procedure by which an applicant, and the applicant's attorney, may review examination questions and answers in accordance with s. 119.071(1)(a).~~

Section 13. Paragraph (a) of subsection (1) of section 401.2701, Florida Statutes, is amended to read:

401.2701 Emergency medical services training programs.—

(1) Any private or public institution in Florida desiring to conduct an approved program for the education of emergency medical technicians and paramedics shall:

(a) Submit a completed application on a form provided by the department, which must include:

1. Evidence that the institution is in compliance with all applicable requirements of the Department of Education.

2. Evidence of an affiliation agreement with a hospital that has an emergency department staffed by at least one physician and one registered nurse.

3. Evidence of an affiliation agreement with a current emergency medical services provider that is licensed in this state. Such agreement shall include, at a minimum, a commitment by the provider to conduct the field experience portion of the education program. An applicant licensed as an advanced life support service under s. 401.25 with permitted transport vehicles pursuant to s. 401.26 is exempt from the requirements of this subparagraph and need not submit evidence of an affiliation agreement with a current emergency medical services

provider.

4. Documentation verifying faculty, including:

a. A medical director who is a licensed physician meeting the applicable requirements for emergency medical services medical directors as outlined in this chapter and rules of the department. The medical director shall have the duty and responsibility of certifying that graduates have successfully completed all phases of the education program and are proficient in basic or advanced life support techniques, as applicable.

b. A program director responsible for the operation, organization, periodic review, administration, development, and approval of the program.

5. Documentation verifying that the curriculum:

a. Meets the most recent Emergency Medical Technician-Basic National Standard Curriculum or the National EMS Education Standards approved by the department for emergency medical technician programs and Emergency Medical Technician-Paramedic National Standard Curriculum or the National EMS Education Standards approved by the department for paramedic programs.

b. Includes 2 hours of instruction on the trauma scorecard methodologies for assessment of adult trauma patients and pediatric trauma patients as specified by the department by rule.

6. Evidence of sufficient medical and educational equipment to meet emergency medical services training program needs.

Section 14. Section 401.272, Florida Statutes, is amended to read:

401.272 Emergency medical services community health care.—

(1) The purpose of this section is to encourage more

effective utilization of the skills of emergency medical technicians and paramedics by enabling them to perform~~, in partnership with local county health departments,~~ specific additional health care tasks that are consistent with the public health and welfare.

(2) Notwithstanding any other provision of law to the contrary:

(a) Paramedics or emergency medical technicians shall operate under the medical direction of a physician through two-way voice communication or pursuant to established standing orders or protocols and within the scope of their training when providing basic life support, advanced life support, and ~~may perform~~ health promotion and wellness activities ~~and blood pressure screenings~~ in a nonemergency environment~~, within the scope of their training, and under the direction of a medical director~~. As used in this paragraph, the term "health promotion and wellness" means the provision of public health programs pertaining to the prevention of illness and injury.

(b) Paramedics and emergency medical technicians shall operate under the medical direction of a physician through two-way communication or pursuant to established standing orders or protocols and within the scope of their training when a patient is not transported to an emergency department or is transported to a facility other than a hospital as defined in s. 395.002(12).

(c) Paramedics may administer immunizations in a nonemergency environment, within the scope of their training, and under the medical direction of a physician through two-way communication or pursuant to established standing orders or

protocols ~~medical director~~. There must be a written agreement between the physician providing medical direction ~~paramedic's medical director~~ and the department or the county health department located in each county in which the paramedic administers immunizations. This agreement must establish the protocols, policies, and procedures under which the paramedic must operate.

(d) ~~(c)~~ Paramedics may provide basic life support services and advanced life support services to patients receiving acute and postacute hospital care at home as specified in the paramedic's supervisory relationship with a physician or standing orders as described in s. 401.265, s. 458.348, or s. 459.025. A physician who supervises or provides medical direction to a paramedic who provides basic life support services or advanced life support services to patients receiving acute and postacute hospital care at home pursuant to a formal supervisory relationship or standing orders is liable for any act or omission of the paramedic acting under the physician's supervision or medical direction when providing such services. The department may adopt and enforce rules necessary to implement this paragraph.

(3) Each physician providing medical direction to ~~medical director under whose direction~~ a paramedic who administers immunizations must verify and document that the paramedic has received sufficient training and experience to administer immunizations. The verification must be documented on forms developed by the department, and the completed forms must be maintained at the service location of the licensee and made available to the department upon request.

(4) The department may adopt and enforce all rules necessary to enforce the provisions relating to a paramedic's administration of immunizations and the performance of health promotion and wellness activities ~~and blood pressure screenings~~ by a paramedic or emergency medical technician in a nonemergency environment.

Section 15. Subsections (5), (6), and (7) of section 401.34, Florida Statutes, are amended to read:

401.34 Fees.—

~~(5) The department may provide same-day grading of the examination for an applicant for emergency medical technician or paramedic certification.~~

~~(6) The department may offer walk-in eligibility determination and examination to applicants for emergency medical technician or paramedic certification who pay to the department a nonrefundable fee to be set by the department not to exceed $65. The fee is in addition to the certification fee and examination fee. The department must establish locations and times for eligibility determination and examination.~~

~~(7) The cost of emergency medical technician or paramedic certification examination review may not exceed $50.~~

Section 16. Section 401.435, Florida Statutes, is amended to read:

401.435 Emergency medical ~~First~~ responder agencies and training.—

(1) The department must adopt by rule the United States Department of Transportation National Emergency Medical Services Education Standards for the Emergency Medical ~~Services: First~~ Responder level ~~Training Course~~ as the minimum standard for

emergency medical ~~first~~ responder training. In addition, the department must adopt rules establishing minimum emergency medical ~~first~~ responder instructor qualifications. For purposes of this section, an emergency medical ~~a first~~ responder includes any individual who receives training to render initial care to an ill or injured person, other than an individual trained and certified pursuant to s. 943.1395(1), but who does not have the primary responsibility of treating and transporting ill or injured persons.

(2) Each emergency medical ~~first~~ responder agency must take all reasonable efforts to enter into a memorandum of understanding with the emergency medical services licensee within whose territory the agency operates in order to coordinate emergency services at an emergency scene. The department must provide a model memorandum of understanding for this purpose. The memorandum of understanding should include dispatch protocols, the roles and responsibilities of emergency medical ~~first~~ responder personnel at an emergency scene, and the documentation required for patient care rendered. For purposes of this section, the term "emergency medical ~~first~~ responder agency" includes a law enforcement agency, a fire service agency not licensed under this part, a lifeguard agency, and a volunteer organization that renders, as part of its routine functions, on-scene patient care before emergency medical technicians or paramedics arrive.

Section 17. Paragraph (a) of subsection (1) of section 464.203, Florida Statutes, is amended to read:

464.203 Certified nursing assistants; certification requirement.—

(1) The board shall issue a certificate to practice as a certified nursing assistant to any person who demonstrates a minimum competency to read and write and successfully passes the required background screening pursuant to s. 400.215. If the person has successfully passed the required background screening pursuant to s. 400.215 or s. 408.809 within 90 days before applying for a certificate to practice and the person's background screening results are not retained in the clearinghouse created under s. 435.12, the board shall waive the requirement that the applicant successfully pass an additional background screening pursuant to s. 400.215. The person must also meet one of the following requirements:

(a) Has successfully completed an approved training program and achieved a minimum score, established by rule of the board, on the nursing assistant competency examination, which consists of a written portion and skills-demonstration portion approved by the board and administered at a site and by personnel approved by the department. Any person who has successfully completed an approved training program within 6 months before filing an application for certification is not required to take the skills-demonstration portion of the competency examination.

Section 18. Section 468.1225, Florida Statutes, is amended to read:

468.1225 Procedures, equipment, and protocols.—

(1) The following minimal procedures shall be used when a licensed audiologist fits and sells a prescription hearing aid:

(a) Pure tone audiometric testing by air and bone to determine the type and degree of hearing deficiency when indicated.

(b) Effective masking when indicated.

(c) 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.

(2) The following equipment shall be used:

(a) A wide range audiometer that ~~which~~ meets the specifications of the American National Standards Institute for diagnostic audiometers when indicated.

(b) A speech audiometer or a master hearing aid in order to determine the most comfortable listening level and speech discrimination when indicated.

(3) A final fitting ensuring physical and operational comfort of the prescription hearing aid shall be made when indicated.

(4) A licensed audiologist who fits and sells prescription hearing aids shall obtain the following medical clearance: If, upon inspection of the ear canal with an otoscope in the common procedure of fitting a prescription hearing aid and upon interrogation of the client, there is any recent history of infection or any observable anomaly, the client shall be instructed to see a physician, and a prescription hearing aid may ~~shall~~ not be fitted until medical clearance is obtained for the condition noted. If, upon return, the condition noted is no longer observable and the client signs a medical waiver, a prescription hearing aid may be fitted. Any person with a significant difference between bone conduction hearing and air conduction hearing must be informed of the possibility of

medical or surgical correction.

(5)(a) A licensed audiologist's office must have available, or have access to, a selection of prescription hearing aid models, hearing aid supplies, and services complete enough to accommodate the various needs of the hearing aid wearers.

(b) At the time of the initial examination for fitting and sale of a prescription hearing aid, the attending audiologist must notify the prospective purchaser of the benefits of telecoil, also known as "t" coil or "t" switch, technology, including increased access to telephones and noninvasive access to assistive listening systems required under the Americans with Disabilities Act of 1990.

(6) Unless otherwise indicated, each audiometric test conducted by a licensee or a certified audiology assistant in the fitting and selling of prescription hearing aids must ~~shall~~ be made in a testing room that has been certified by the department, or by an agent approved by the department, not to exceed the following sound pressure levels at the specified frequencies: 250Hz-40dB, 500Hz-40dB, 750Hz-40dB, 1000Hz-40dB, 1500Hz-42dB, 2000Hz-47dB, 3000Hz-52dB, 4000Hz-57dB, 6000Hz-62dB, and 8000Hz-67dB. An exception to this requirement shall be made in the case of a client who, after being provided written notice of the benefits and advantages of having the test conducted in a certified testing room, requests that the test be conducted in a place other than the licensee's certified testing room. Such request must ~~shall~~ be documented by a waiver that ~~which~~ includes the written notice and is signed by the licensee and the client before ~~prior to~~ the testing. The waiver must ~~shall~~ be executed on a form provided by the department. The executed waiver must

~~shall~~ be attached to the client's copy of the contract, and a copy of the executed waiver must ~~shall~~ be retained in the licensee's file.

(7) The board may ~~shall have the power to~~ prescribe the minimum procedures and equipment used in the conducting of hearing assessments and for the fitting and selling of prescription hearing aids. The board shall adopt and enforce rules necessary to implement ~~carry out the provisions of~~ this subsection and subsection (6).

(8) Any duly authorized officer or employee of the department may ~~shall have the right to~~ make such inspections and investigations as ~~are~~ necessary ~~in order~~ to determine the state of compliance with ~~the provisions of~~ this section and the applicable rules and may enter the premises of a licensee and inspect the records of same upon reasonable belief that a violation of this law is being or has been committed or that the licensee has failed or is failing to comply with ~~the provisions of~~ this part.

Section 19. Section 468.1245, Florida Statutes, is amended to read:

468.1245 Itemized listing of prices; delivery of prescription hearing aid; receipt; guarantee; packaging; disclaimer.—

(1) Before ~~Prior to~~ delivery of services or products to a prospective purchaser, a licensee must ~~shall~~ disclose, upon request by the prospective purchaser, an itemized listing of prices, which must ~~listing shall~~ include separate price estimates for each service component and each product. Provision of such itemized listing of prices may ~~shall~~ not be predicated

on the prospective purchaser's payment of any charge or agreement to purchase any service or product.

(2) Any licensee who fits and sells a prescription hearing aid shall, at the time of delivery, provide the purchaser with a receipt containing the seller's signature, the address of his or her regular place of business, and his or her license or certification number, if applicable, together with the brand, model, manufacturer or manufacturer's identification code, and serial number of the prescription hearing aid furnished and the amount charged for the prescription hearing aid. The receipt must also ~~shall~~ specify whether the prescription hearing aid is new, used, or rebuilt, ~~and shall specify~~ the length of time and other terms of the guarantee, and by whom the prescription hearing aid is guaranteed. When the client has requested an itemized list of prices, the receipt must ~~shall~~ also provide an itemization of the total purchase price, including, but not limited to, the cost of the aid, ear mold, batteries, and other accessories, and the cost of any services. Notice of the availability of this service must be displayed in a conspicuous manner in the office. The receipt must also ~~shall~~ state that any complaint concerning the prescription hearing aid and its guarantee, if not reconciled with the licensee from whom the prescription hearing aid was purchased, should be directed by the purchaser to the department. The address and telephone number of such office must ~~shall~~ be stated on the receipt.

(3) A prescription ~~No~~ hearing aid may not be sold to any person unless both the packaging containing the prescription hearing aid and the contract provided pursuant to subsection (2) carry the following disclaimer in 10-point or larger type: "A

hearing aid will not restore normal hearing, nor will it prevent further hearing loss."

Section 20. Section 468.1246, Florida Statutes, is amended to read:

468.1246 Thirty-day trial period; purchaser's right to cancel; notice; refund; cancellation fee.—

(1) A person selling a prescription hearing aid in this state must provide the buyer with written notice of a 30-day trial period and money-back guarantee. The guarantee must permit the purchaser to cancel the purchase for a valid reason as defined by rule of the board within 30 days after receiving the prescription hearing aid, by returning the prescription hearing aid or mailing written notice of cancellation to the seller. If the prescription hearing aid must be repaired, remade, or adjusted during the 30-day trial period, the running of the 30-day trial period is suspended 1 day for each 24-hour period that the prescription hearing aid is not in the purchaser's possession. A repaired, remade, or adjusted prescription hearing aid must be claimed by the purchaser within 3 working days after notification of availability. The running of the 30-day trial period resumes on the day the purchaser reclaims a repaired, remade, or adjusted prescription hearing aid or on the 4th day after notification of availability.

(2) The board, in consultation with the Board of Hearing Aid Specialists, shall prescribe by rule the terms and conditions to be contained in the money-back guarantee and any exceptions thereto. Such rule must ~~shall~~ provide, at a minimum, that the charges for earmolds and service provided to fit the prescription hearing aid may be retained by the licensee. The

rules must ~~shall~~ also set forth any reasonable charges to be held by the licensee as a cancellation fee. ~~Such rule shall be effective on or before December 1, 1994. Should the board fail to adopt such rule, a licensee may not charge a cancellation fee which exceeds 5 percent of the total charge for a hearing aid alone.~~ The terms and conditions of the guarantee, including the total amount available for refund, must ~~shall~~ be provided in writing to the purchaser before ~~prior to~~ the signing of the contract.

Section 21. Section 468.1255, Florida Statutes, is amended to read:

468.1255 Cancellation by medical authorization; purchaser's right to return.—

(1) In addition to any other rights and remedies the purchaser of a prescription hearing aid may have, the purchaser has ~~shall have~~ the right to rescind the transaction if the purchaser for whatever reason consults a licensed physician with specialty board certification in otolaryngology or internal medicine or a licensed family practice physician, subsequent to purchasing a prescription hearing aid, and the physician certifies in writing that the purchaser has a hearing impairment for which a prescription hearing aid will not provide a benefit or that the purchaser has a medical condition which contraindicates the use of a prescription hearing aid.

(2) The purchaser of a prescription hearing aid has ~~shall have~~ the right to rescind as provided in subsection (1) only if the purchaser gives a written notice of the intent to rescind the transaction to the seller at the seller's place of business by certified mail, return receipt requested, which notice shall

be posted not later than 60 days following the date of delivery of the prescription hearing aid to the purchaser, and the purchaser returns the prescription hearing aid to the seller in the original condition less normal wear and tear.

(3) If the conditions of subsections (1) and (2) are met, the seller must ~~shall~~, without request, refund to the purchaser, within 10 days after ~~of~~ the receipt of notice to rescind, a full and complete refund of all moneys received, less 5 percent. The purchaser does not ~~shall~~ incur any ~~no~~ additional liability for rescinding the transaction.

Section 22. Section 468.1265, Florida Statutes, is amended to read:

468.1265 Sale or distribution of prescription hearing aids through mail; penalty.—It is unlawful for any person to sell or distribute prescription hearing aids through the mail to the ultimate consumer. Any person who violates this section commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 23. Section 468.1275, Florida Statutes, is amended to read:

468.1275 Place of business; display of license.—Each licensee who fits and sells a prescription hearing aid shall declare and establish a regular place of business, at which his or her license shall be conspicuously displayed.

Section 24. Section 484.0401, Florida Statutes, is amended to read:

484.0401 Purpose.—The Legislature recognizes that the dispensing of prescription hearing aids requires particularized knowledge and skill to ensure that the interests of the hearing-

impaired public will be adequately served and safely protected. It recognizes that a poorly selected or fitted prescription hearing aid not only will give little satisfaction but may interfere with hearing ability and, therefore, deems it necessary in the interest of the public health, safety, and welfare to regulate the dispensing of prescription hearing aids in this state. Restrictions on the fitting and selling of prescription hearing aids shall be imposed only to the extent necessary to protect the public from physical and economic harm, and restrictions shall not be imposed in a manner which will unreasonably affect the competitive market.

Section 25. Section 484.041, Florida Statutes, is reordered and amended to read:

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

(1) "Board" means the Board of Hearing Aid Specialists.

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

(3) "Dispensing prescription hearing aids" means and includes:

(a) Conducting and interpreting hearing tests for purposes of selecting suitable prescription hearing aids, making earmolds or ear impressions, and providing appropriate counseling.

(b) All acts pertaining to the selling, renting, leasing, pricing, delivery, and warranty of prescription hearing aids.

(6) ~~(4)~~ "Hearing aid specialist" means a person duly licensed in this state to practice the dispensing of prescription hearing aids.

(4) ~~(5)~~ "Hearing aid" means any wearable ~~an amplifying~~ device designed for, offered for the purpose of, or represented as aiding persons with, or compensating for, impaired hearing ~~to~~

~~be worn by a hearing-impaired person to improve hearing~~.

(10)~~(6)~~ "Trainee" means a person studying prescription hearing aid dispensing under the direct supervision of an active licensed hearing aid specialist for the purpose of qualifying for certification to sit for the licensure examination.

(5)~~(7)~~ "Hearing aid establishment" means any establishment in this ~~the~~ state which employs a licensed hearing aid specialist who offers, advertises, and performs hearing aid services for the general public.

(7) "Over-the-counter hearing aid" means an air-conduction hearing aid that does not require implantation or other surgical intervention and is intended for use by a person 18 years of age or older to compensate for perceived mild to moderate hearing impairment.

(8) "Prescription hearing aid" means a hearing aid that is not an over-the-counter hearing aid and that does not otherwise meet the criteria for a prescription hearing aid under this part.

(9) "Sponsor" means an active, licensed hearing aid specialist under whose direct supervision one or more trainees are studying prescription hearing aid dispensing for the purpose of qualifying for certification to sit for the licensure examination.

Section 26. Subsection (2) of section 484.042, Florida Statutes, is amended to read:

484.042 Board of Hearing Aid Specialists; membership, appointment, terms.—

(2) Five members of the board shall be hearing aid specialists who have been licensed and practicing the dispensing

of prescription hearing aids in this state for at least the preceding 4 years. The remaining four members, none of whom shall derive economic benefit from the fitting or dispensing of hearing aids, shall be appointed from the resident lay public of this state. One of the lay members shall be a prescription hearing aid user but may not ~~neither~~ be nor have been a hearing aid specialist or a licensee of a closely related profession. One lay member shall be an individual age 65 or over. One lay member shall be an otolaryngologist licensed pursuant to chapter 458 or chapter 459.

Section 27. Subsection (2) of section 484.044, Florida Statutes, is amended to read:

484.044 Authority to make rules.—

(2) The board shall adopt rules requiring that each prospective purchaser of a prescription hearing aid be notified by the attending hearing aid specialist, at the time of the initial examination for fitting and sale of a hearing aid, of telecoil, "t" coil, or "t" switch technology. The rules shall further require that hearing aid specialists make available to prospective purchasers or clients information regarding telecoils, "t" coils, or "t" switches. ~~These rules shall be effective on or before October 1, 1994.~~

Section 28. Subsection (2) of section 484.0445, Florida Statutes, is amended to read:

484.0445 Training program.—

(2) A trainee shall perform the functions of a hearing aid specialist in accordance with board rules only under the direct supervision of a licensed hearing aid specialist. The term "direct supervision" means that the sponsor is responsible for

all work being performed by the trainee. The sponsor or a hearing aid specialist designated by the sponsor shall give final approval to work performed by the trainee and shall be physically present at the time the prescription hearing aid is delivered to the client.

Section 29. Subsection (2) of section 484.045, Florida Statutes, is amended to read:

484.045 Licensure by examination.—

(2) The department shall license each applicant who the board certifies meets all of the following criteria:

(a) Has completed the application form and remitted the required fees.~~;~~

(b) Is of good moral character.~~;~~

(c) Is 18 years of age or older.~~;~~

(d) Is a graduate of an accredited high school or its equivalent.~~;~~

(e)1. Has met the requirements of the training program; or

2.a. Has a valid, current license as a hearing aid specialist or its equivalent from another state and has been actively practicing in such capacity for at least 12 months; or

b. Is currently certified by the National Board for Certification in Hearing Instrument Sciences and has been actively practicing for at least 12 months.~~;~~

(f) Has passed an examination, as prescribed by board rule.~~; and~~

(g) Has demonstrated, in a manner designated by rule of the board, knowledge of state laws and rules relating to the fitting and dispensing of prescription hearing aids.

Section 30. Section 484.0501, Florida Statutes, is amended

to read:

484.0501 Minimal procedures and equipment.—

(1) The following minimal procedures shall be used in the fitting and selling of prescription hearing aids:

(a) Pure tone audiometric testing by air and bone to determine the type and degree of hearing deficiency.

(b) Effective masking when indicated.

(c) 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.

(2) The following equipment shall be used:

(a) A wide range audiometer that ~~which~~ meets the specifications of the American National Standards Institute for diagnostic audiometers.

(b) A speech audiometer or a master hearing aid in order to determine the most comfortable listening level and speech discrimination.

(3) A final fitting ensuring physical and operational comfort of the prescription hearing aid shall be made.

(4) The following medical clearance shall be obtained: If, upon inspection of the ear canal with an otoscope in the common procedure of a prescription hearing aid fitter and upon interrogation of the client, there is any recent history of infection or any observable anomaly, the client must ~~shall~~ be instructed to see a physician, and a prescription hearing aid may ~~shall~~ not be fitted until medical clearance is obtained for the condition noted. If, upon return, the condition noted is no

longer observable and the client signs a medical waiver, a prescription hearing aid may be fitted. Any person with a significant difference between bone conduction hearing and air conduction hearing must be informed of the possibility of medical correction.

(5)(a) A prescription hearing aid establishment ~~office~~ must have available, or have access to, a selection of prescription hearing aid models, hearing aid supplies, and services complete enough to accommodate the various needs of the prescription hearing aid wearers.

(b) At the time of the initial examination for fitting and sale of a prescription hearing aid, the attending hearing aid specialist shall ~~must~~ notify the prospective purchaser or client of the benefits of telecoil, "t" coil, or "t" switch technology, including increased access to telephones and noninvasive access to assistive listening systems required under the Americans with Disabilities Act of 1990.

(6) Each audiometric test conducted by a licensee or authorized trainee in the fitting and selling of prescription hearing aids must ~~shall~~ be made in a testing room that has been certified by the department, or by an agent approved by the department, not to exceed the following sound pressure levels at the specified frequencies: 250Hz-40dB, 500Hz-40dB, 750Hz-40dB, 1000Hz-40dB, 1500Hz-42dB, 2000Hz-47dB, 3000Hz-52dB, 4000Hz-57dB, 6000Hz-62dB, and 8000Hz-67dB. An exception to this requirement shall be made in the case of a client who, after being provided written notice of the benefits and advantages of having the test conducted in a certified testing room, requests that the test be conducted in a place other than the licensee's certified testing

room. Such request must ~~shall~~ be documented by a waiver which includes the written notice and is signed by the licensee and the client before ~~prior to~~ the testing. The waiver must ~~shall~~ be executed on a form provided by the department. The executed waiver must ~~shall~~ be attached to the client's copy of the contract, and a copy of the executed waiver must ~~shall~~ be retained in the licensee's file.

(7) The board may ~~shall have the power to~~ prescribe the minimum procedures and equipment which must ~~shall~~ be used in the conducting of hearing assessments, and for the fitting and selling of prescription hearing aids, including equipment that will measure the prescription hearing aid's response curves to ensure that they meet the manufacturer's specifications. These procedures and equipment may differ from those provided in this section in order to take full advantage of devices and equipment which may hereafter become available and which are demonstrated to be of greater efficiency and accuracy. The board shall adopt and enforce rules necessary to implement ~~carry out the provisions of~~ this subsection and subsection (6).

(8) Any duly authorized officer or employee of the department may ~~shall have the right to~~ make such inspections and investigations as ~~are~~ necessary ~~in order~~ to determine the state of compliance with ~~the provisions of~~ this section and the applicable rules and may enter the premises of a licensee and inspect the records of same upon reasonable belief that a violation of this law is being or has been committed or that the licensee has failed or is failing to comply with ~~the provisions of~~ this part ~~act~~.

(9) A licensed hearing aid specialist may service, market,

sell, dispense, provide customer support for, and distribute prescription and over-the-counter hearing aids.

Section 31. Section 484.051, Florida Statutes, is amended to read:

484.051 Itemization of prices; delivery of prescription hearing aid; receipt, packaging, disclaimer, guarantee.—

(1) Before ~~Prior to~~ delivery of services or products to a prospective purchaser, any person who fits and sells prescription hearing aids must ~~shall~~ disclose on request by the prospective purchaser an itemized listing of prices, which must ~~listing shall~~ include separate price estimates for each service component and each product. Provision of such itemized listing of prices may ~~shall~~ not be predicated on the prospective purchaser's payment of any charge or agreement to purchase any service or product.

(2) Any person who fits and sells a prescription hearing aid must ~~shall~~, at the time of delivery, provide the purchaser with a receipt containing the seller's signature, the address of her or his regular place of business, and her or his license or trainee registration number, if applicable, together with the brand, model, manufacturer or manufacturer's identification code, and serial number of the prescription hearing aid furnished and the amount charged for the prescription hearing aid. The receipt must also ~~shall~~ specify whether the prescription hearing aid is new, used, or rebuilt, ~~and shall specify~~ the length of time and other terms of the guarantee, and by whom the prescription hearing aid is guaranteed. If ~~When~~ the client has requested an itemized list of prices, the receipt must ~~shall~~ also provide an itemization of the total purchase

price, including, but not limited to, the cost of the aid, earmold, batteries and other accessories, and any services. Notice of the availability of this service shall be displayed in a conspicuous manner in the office. The receipt must also ~~shall~~ state that any complaint concerning the prescription hearing aid and guarantee therefor, if not reconciled with the licensee from whom the prescription hearing aid was purchased, should be directed by the purchaser to the Department of Health. The address and telephone number of such office must ~~shall~~ be stated on the receipt.

(3) A prescription ~~No~~ hearing aid may not be sold to any person unless both the packaging containing the prescription hearing aid and the itemized receipt provided pursuant to subsection (2) carry the following disclaimer in 10-point or larger type: "A hearing aid will not restore normal hearing, nor will it prevent further hearing loss."

Section 32. Section 484.0512, Florida Statutes, is amended to read:

484.0512 Thirty-day trial period; purchaser's right to cancel; notice; refund; cancellation fee; criminal penalty.—

(1) A person selling a prescription hearing aid in this state must provide the buyer with written notice of a 30-day trial period and money-back guarantee. The guarantee must permit the purchaser to cancel the purchase for a valid reason, as defined by ~~rule of the~~ board rule, within 30 days after receiving the prescription hearing aid, by returning the prescription hearing aid or mailing written notice of cancellation to the seller. If the prescription hearing aid must be repaired, remade, or adjusted during the 30-day trial period,

the running of the 30-day trial period is suspended 1 day for each 24-hour period that the prescription hearing aid is not in the purchaser's possession. A repaired, remade, or adjusted prescription hearing aid must be claimed by the purchaser within 3 working days after notification of availability. The running of the 30-day trial period resumes on the day the purchaser reclaims the repaired, remade, or adjusted prescription hearing aid or on the fourth day after notification of availability, whichever occurs earlier.

(2) The board, in consultation with the Board of Speech-Language Pathology and Audiology, shall prescribe by rule the terms and conditions to be contained in the money-back guarantee and any exceptions thereto. Such rules must ~~rule shall~~ provide, at a minimum, that the charges for earmolds and service provided to fit the prescription hearing aid may be retained by the licensee. The rules must ~~shall~~ also set forth any reasonable charges to be held by the licensee as a cancellation fee. ~~Such rule shall be effective on or before December 1, 1994. Should the board fail to adopt such rule, a licensee may not charge a cancellation fee which exceeds 5 percent of the total charge for a hearing aid alone.~~ The terms and conditions of the guarantee, including the total amount available for refund, must ~~shall~~ be provided in writing to the purchaser before ~~prior to~~ the signing of the contract.

(3) Within 30 days after the return or attempted return of the prescription hearing aid, the seller shall refund all moneys that must be refunded to a purchaser pursuant to this section. A violation of this subsection is a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(4) For purposes of this section, the term "seller" or "person selling a prescription hearing aid" includes:

(a) Any ~~natural~~ person licensed under this part or any other ~~natural~~ person who signs a sales receipt required by s. 484.051(2) or s. 468.1245(2) or ~~who~~ otherwise fits, delivers, or dispenses a prescription hearing aid.

(b) Any business organization, whether a sole proprietorship, partnership, corporation, professional association, joint venture, business trust, or other legal entity, that ~~which~~ dispenses a prescription hearing aid or enters into an agreement to dispense a prescription hearing aid.

(c) Any person who controls, manages, or operates an establishment or business that dispenses a prescription hearing aid or enters into an agreement to dispense a prescription hearing aid.

Section 33. Section 484.0513, Florida Statutes, is amended to read:

484.0513 Cancellation by medical authorization; purchaser's right to return.—

(1) In addition to any other rights and remedies the purchaser of a prescription hearing aid may have, the purchaser has ~~shall have~~ the right to rescind the transaction if the purchaser for whatever reason consults a licensed physician with specialty board certification in otolaryngology or internal medicine or a licensed family practice physician, subsequent to purchasing a prescription hearing aid, and the physician certifies in writing that the purchaser has a hearing impairment for which a prescription hearing aid will not provide a benefit or that the purchaser has a medical condition which

contraindicates the use of a prescription hearing aid.

(2) The purchaser of a prescription hearing aid has ~~shall have~~ the right to rescind as provided in subsection (1) only if the purchaser gives a written notice of the intent to rescind the transaction to the seller at the seller's place of business by certified mail, return receipt requested, which must ~~notice shall~~ be posted within ~~not later than~~ 60 days after ~~following~~ the date of delivery of the prescription hearing aid to the purchaser, and the purchaser returns the prescription hearing aid to the seller in the original condition less normal wear and tear.

(3) If the conditions of subsections (1) and (2) are met, the seller must ~~shall~~, without request, refund to the purchaser, within 10 days after ~~of the~~ receipt of the notice to rescind, a full and complete refund of all moneys received, less 5 percent. The purchaser does not ~~shall~~ incur any ~~no~~ additional liability for rescinding the transaction.

Section 34. Section 484.053, Florida Statutes, is amended to read:

484.053 Prohibitions; penalties.—

(1) A person may not:

(a) Practice dispensing prescription hearing aids unless the person is a licensed hearing aid specialist;

(b) Use the name or title "hearing aid specialist" when the person has not been licensed under this part;

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

(d) Give false, incomplete, or forged evidence to the board or a member thereof for the purposes of obtaining a license;

(e) Use or attempt to use a hearing aid specialist license

that is delinquent or has been suspended, revoked, or placed on inactive status;

(f) Knowingly employ unlicensed persons in the practice of dispensing prescription hearing aids; or

(g) Knowingly conceal information relative to violations of this part.

(2) Any person who violates any provision ~~of the provisions~~ of this section is guilty of a felony of the third degree, punishable as provided in s. 775.082 or s. 775.083.

(3) If a person licensed under this part allows the sale of a prescription hearing aid by an unlicensed person not registered as a trainee or fails to comply with the requirements of s. 484.0445(2) relating to supervision of trainees, the board must ~~shall~~, upon determination of that violation, order the full refund of moneys paid by the purchaser upon return of the prescription hearing aid to the seller's place of business.

Section 35. Section 484.054, Florida Statutes, is amended to read:

484.054 Sale or distribution of prescription hearing aids through mail; penalty.—It is unlawful for any person to sell or distribute prescription hearing aids through the mail to the ultimate consumer. Any violation of this section constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 36. Section 484.059, Florida Statutes, is amended to read:

484.059 Exemptions.—

(1) The licensure requirements of this part do not apply to any person engaged in recommending prescription hearing aids as

part of the academic curriculum of an accredited institution of higher education, or as part of a program conducted by a public charitable institution supported primarily by voluntary contribution, provided this organization does not dispense or sell prescription hearing aids or accessories.

(2) The licensure requirements of this part do not apply to any person licensed to practice medicine in this ~~the~~ state, except that such physician must ~~shall~~ comply with the requirement of periodic filing of the certificate of testing and calibration of audiometric equipment as provided in this part. A ~~No~~ person employed by or working under the supervision of a person licensed to practice medicine may not ~~shall~~ perform any services or acts which would constitute the dispensing of prescription hearing aids as defined in s. 484.041 ~~s. 484.041(3)~~, unless such person is a licensed hearing aid specialist.

(3) The licensure requirements of this part do not apply to an audiologist licensed under ~~pursuant to~~ part I of chapter 468.

(4) Section ~~The provisions of s.~~ 484.053(1)(a) does ~~shall~~ not apply to registered trainees operating in compliance with this part and board rules ~~of the board~~.

(5) The licensure requirements of this part do not apply to a person who services, markets, sells, dispenses, provides customer support for, or distributes exclusively over-the-counter hearing aids, whether through in-person transactions, by mail, or online. For purposes of this subsection, over-the-counter hearing aids are those that are available without the supervision, prescription, or other order, involvement, or intervention of a licensed person to consumers through in-person

transactions, by mail, or online. These devices allow the user to control the device and customize it to the user's hearing needs through the use of tools, tests, or software, including, but not limited to, wireless technology or tests for self-assessment of hearing loss.

Section 37. The Division of Law Revision is directed to replace the phrase "the effective date of this act" wherever it occurs in this act with the date the act becomes a law.

Section 38. Except as otherwise expressly provided in this act and except for this section, which shall take effect upon this act becoming a law, this act shall take effect July 1, 2023.

The Florida Senate

Committee Agenda Request

To: Senator Colleen Burton, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: March 9, 2023

I respectfully request that **Senate Bill #1506**, relating to Department of Health, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Ana Maria Rodriguez
Florida Senate, District 40

File signed original with committee office

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3/27/23
Meeting Date

Health Policy
Committee

1506
Bill Number or Topic

974128
Amendment Barcode (if applicable)

Name Theresa Bulger (pronounced Bull-jar) Phone 904 880 9063

Address 253 Hayden
Street

Tallahassee, FL 32303
City State Zip

Email th@deafkidscan.org

Speaking: [X] For [ ] Against [ ] Information **OR** Waive Speaking: [ ] In Support [ ] Against

PLEASE CHECK ONE OF THE FOLLOWING:

[ ] I am appearing without compensation or sponsorship.

[X] I am a registered lobbyist, representing:
1.) Florida Academy of Audiologists
2.) Sertoma Speech and Hearing Foundation 3.- Deaf Kids Can

[ ] I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

THE FLORIDA SENATE

APPEARANCE RECORD

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3/27/23
Meeting Date

1506
Bill Number (if applicable)

974128
Amendment Barcode (if applicable)

Topic

Name Stephen Winn

Job Title Lobbyist

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Tall. Fla. 32312
City State Zip

Phone 850-878-3056

Email winnsr@earthlink.net

Speaking: [ ] For [ ] Against [ ] Information

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

Representing FLA. Hearing Society

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

Lobbyist registered with Legislature: [X] Yes [ ] No

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

S-001 (10/14/14)

The Florida Senate

APPEARANCE RECORD

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3/27/23
Meeting Date

Health Policy
Committee

1506
Bill Number or Topic

Amendment Barcode (if applicable)

Name THERESA BULGER (pronounced Bol-JAR) Phone 904 880 9063

Address 253 Hayden
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Tallahassee, FL 32308
City State Zip

Email tb@deafkidscan.org

Speaking: ☒ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☒ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

1.) Florida Academy of Audiologists 2.) Sertoma Speech and Hearing 3.) Deaf Kids Can

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 612
INTRODUCER:	Health Policy Committee and Senator Yarborough, and others.
SUBJECT:	Prevention of Blood Clots
DATE:	March 29, 2023 REVISED:

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 612 creates the "Emily Adkins Prevention Act" in s. 408.0621, F.S., to establish a blood clot and pulmonary embolism policy workgroup. The Secretary of Health Care Administration (Secretary), in conjunction with the State Surgeon General are required to establish the policy workgroup. The workgroup will be composed of health care providers, patients who have experienced blood clots, family members of patients who have died from blood clots, advocates, and other interested parties and associations.

The workgroup is tasked with identifying specific background information pertaining to the prevalence, data collection, impacts, standards of care, and emerging treatments of blood clots and pulmonary embolisms. The workgroup is further tasked with developing a risk surveillance system for various health care providers and facilities and policy recommendations to improve patient awareness, including written materials and guidelines that affect the standard of care for patients at risk of forming blood clots.

The Secretary is directed to submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 31, 2024, and a final report to these officials by January 4, 2025.

The bill provides an effective date of July 1, 2023.

II. Present Situation:

A pulmonary embolism (PE) is a sudden blockage in a pulmonary artery resulting from a blood clot that develops in a blood vessel (often in the leg) that travels through the circulatory system to a lung, creating the blockage in blood flow.[1]

The heart, arteries, capillaries, and veins make up the body's circulatory system. Blood is pumped with great force from the heart into the arteries. From there blood flows into the capillaries (tiny blood vessels in the tissues). Blood returns to the heart through the veins. As it moves through the veins back to the heart, blood flow slows. Sometimes this slower blood flow may lead to clot formation.

Blood clotting is a normal process to prevent bleeding. The body makes blood clots and then breaks them down. Under certain circumstances, the body may be unable to break down a clot. When blood clots in a vein, it may be due to the slowed blood flow, an abnormality in clot forming, or from an injury to the blood vessel wall.

Blood clots can form in arteries and veins. Clots formed in veins are called venous clots. Veins of the legs can be superficial veins (close to the surface of the skin) or deep veins (located near the bone and surrounded by muscle).

Venous clots most often happen in the deep veins of the legs. This is called deep vein thrombosis (DVT). Once a clot has formed in the deep veins of the leg, there is a potential for part of the clot to break off and travel through the blood to another area of the body, often the lung. DVT is the most common cause of a pulmonary embolism.

Other less frequent sources of pulmonary embolism are a fat embolus (often linked to the breaking of a large bone), amniotic fluid embolus, air bubbles, and a deep vein thrombosis in the upper body. Clots may also form on the end of an indwelling intravenous (IV) catheter, break off, and travel to the lungs.

Risk factors[2]

Although anyone can develop blood clots that result in a pulmonary embolism, certain factors can increase the risk.

- History of blood clots**.**
- Medical conditions and treatments. Some medical conditions and treatments create higher risk, such as:
  - Heart disease. Heart and blood vessel disease, specifically heart failure, makes clot formation more likely.
  - Cancer. Certain cancers, especially brain, ovary, pancreas, colon, stomach, lung and kidney cancers, and cancers that have spread, can increase the risk of blood clots. Chemotherapy further increases the risk.

[1] Johns Hopkins Medicine: Pulmonary Embolism, available at: https://www.hopkinsmedicine.org/health/conditions-and-diseases/pulmonary-embolism (last visited Mar. 22, 2023).
[2] Mayo Clinic: Pulmonary embolism, available at: https://www.mayoclinic.org/diseases-conditions/pulmonary-embolism/symptoms-causes/syc-20354647 (last visited Mar 22, 2023.

  - Surgery. Surgery is one of the leading causes of problem blood clots. For this reason, medicine to prevent clots may be given before and after major surgery, such as joint replacement.
  - Disorders that affect clotting. Some inherited disorders affect blood, making it more likely to clot. Other medical disorders such as kidney disease also can increase the risk of blood clots.
  - COVID-19. People who have severe symptoms of COVID-19 have an increased risk of pulmonary embolism.
- Extended periods of inactivity. Blood clots are more likely to form during longer than usual periods of inactivity, such as:
  - Bed rest. Being confined to bed for an extended period after surgery, a heart attack, leg fracture, trauma, or any serious illness creates higher risk of blood clots.
  - Long trips. Sitting in a cramped position during lengthy plane or car trips slows blood flow in the legs, which increases the risk of blood clots.

Other risk factors
- **Smoking.** For reasons that aren't well understood, tobacco use increases the risk of blood clots in some people, especially those who have other risk factors.
- **Being overweight.** Excess weight increases the risk of blood clots – particularly in people with other risk factors.
- **Supplemental estrogen.** The estrogen in birth control pills and in hormone replacement therapy can increase clotting factors in the blood, especially in those who smoke or are overweight.
- **Pregnancy.** The weight of a baby pressing on veins in the pelvis can slow blood return from the legs. Clots are more likely to form when blood slows or pools.

Symptoms

Pulmonary embolism symptoms can vary greatly, depending on how much of the lung is involved, the size of the clots, and the existence of underlying lung or heart disease.

Common symptoms include:
- **Shortness of breath.** This symptom usually appears suddenly. Trouble catching one’s breath happens even when resting and gets worse with physical activity.
- **Chest pain.** Afflicted persons might feel like they are having a heart attack. The pain is often sharp and felt when taking deep breaths.
- **Fainting.** An afflicted person may pass out if his or her heart rate or blood pressure drops suddenly. This is called syncope.

Other symptoms that can occur with pulmonary embolism include:
- A cough that may include bloody or blood-streaked mucus.
- Rapid or irregular heartbeat.
- Lightheadedness or dizziness.
- Excessive sweating.
- Fever.
- Leg pain or swelling, or both, usually in the back of the lower leg.

- Clammy or discolored skin, called cyanosis.

Treatment for pulmonary embolism[3]

Treatment choices for pulmonary embolism (PE) include:

- **Anticoagulants.** Also described as blood thinners, these medicines decrease the ability of the blood to clot. This helps stop a clot from getting bigger and keep new clots from forming.
- **Fibrinolytic therapy.** Also called clot busters, these medicines are given intravenously (IV or into a vein) to break down the clot. These medicines are only used in life-threatening situations.
- **Vena cava filter.** A small metal device placed in the vena cava (the large blood vessel that returns blood from the body to the heart) may be used to keep clots from traveling to the lungs. These filters are generally used when a person cannot tolerate anticoagulation treatment (for medical reasons), develops more clots even with anticoagulation treatment, or has bleeding problems from anticoagulation medicines.
- **Pulmonary embolectomy.** Rarely used, this is surgery is performed to remove a PE. It is generally done only in severe cases when a PE is very large, the patient cannot get anticoagulation and/or thrombolytic therapy due to other medical problems or he or she has not responded well to those treatments, or the patient's condition is unstable.
- **Percutaneous thrombectomy.** A long, thin, hollow tube (catheter) can be threaded through the blood vessel to the site of the embolism guided by X-ray. Once the catheter is in place, it is used to break up the embolism, pull it out, or dissolve it using thrombolytic medicine.

An important aspect of treating a PE is treatment to prevent formation of additional embolisms.

Task Force

A "workgroup" is not defined in the Florida Statutes. However, s. 20.03, F.S., includes definitions related to the required organizational structure of task forces. In part, it defines a "task force" as an advisory body created without specific statutory enactment for a time not to exceed one year or created by specific statutory enactment for a time not to exceed three years and appointed to study a specific problem and recommend a solution or policy alternative with respect to that problem. Its existence terminates upon the completion of its assignment.[4]

III. Effect of Proposed Changes:

Section 1 creates a non-statutory section of law citing the bill as the "Emily Adkins Prevention Act."

Section 2 creates s. 408.0621, F.S., to establish the blood clot and pulmonary embolism policy workgroup. The Secretary, in conjunction with the State Surgeon General, are required to establish the workgroup, that is tasked with:

[3] *Supra* n 1.
[4] Section 20.30(8). F.S.

- Identifying the aggregate number of people who experience blood clots and pulmonary embolisms each year in this state.
- Identifying how data is collected regarding blood clots, pulmonary embolisms, and adverse health outcomes associated with these conditions.
- Identifying how blood clots and pulmonary embolisms impact the lives of people in this state.
- Identifying the standards of care for blood clot surveillance, detection, and treatment.
- Identifying emerging treatments, therapies, and research relating to blood clots.
- Developing a risk surveillance system to help health care providers identify patients who may be at higher risk of forming blood clots and pulmonary embolisms.
- Developing policy recommendations to help improve patient awareness of blood clot risks.
- Developing policy recommendations to help improve surveillance and detection of patients who may be at a higher risk of forming blood clots in licensed health care facilities, including, hospitals, nursing homes, assisted living facilities, residential treatment facilities, and ambulatory surgical centers.
- Developing policy recommendations relating to guidelines used that affect the standard of care for patients at risk of forming blood clots.
- Developing policy recommendations relating to providing patients and their families with written notice of increased risks of forming blood clots.

The President of the Senate and the Speaker of the House of Representative shall each appoint two members to the workgroup and the State Surgeon General shall appoint the chair of the workgroup

Members of the workgroup are not entitled to receive compensation. Meetings of the workgroup may be health through teleconference or other electronic means.

The chair may create subcommittees to help with research, scheduling speakers on important subjects, and drafting a workgroup report and policy recommendations.

The Secretary is required to submit an annual report detailing the findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 31, 2024. The Secretary must submit a final report detailing the findings and recommendations to these officials by January 4, 2025.

The bill provides an effective date of July 1, 2023.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The AHCA and the DOH will incur insignificant costs to coordinate and manage the workgroup and for preparing the annual and final reports.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 408.0621 of the Florida Statutes.

This bill creates one non-statutory section of the Laws of Florida.

IX. Additional Information:

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

CS by Health Policy on March 27, 2023:
The CS changes the citation for the Act to the "Emily Adkins Prevention Act" and establishes the workgroup in a newly created statute. The number of appointed members on the workgroup is reduced from 17 to five. The amendment is silent on reimbursement

for per diem or travel expenses. The CS streamlines the responsibilities of the workgroup and focuses the policy recommendations on the risks of forming blood clots and early detection and prevention. The CS requires an annual report that includes detailed findings and recommendations rather than an update on the workgroup's activities, findings, and recommendations. Submission of the final report is moved up from January 31, 2025, to January 4, 2025. The CS eliminates the sunset date for the workgroup included in the underlying bill.

B. Amendments:

None.

558772

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/28/2023	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. This act may be cited as the "Emily Adkins Prevention Act."

Section 2. Section 408.0621, Florida Statutes, is created to read:

408.0621 Blood clot and pulmonary embolism policy workgroup.—

558772

(1) The Secretary of Health Care Administration, in conjunction with the State Surgeon General, shall establish a blood clot and pulmonary embolism policy workgroup.

(2) The workgroup shall:

(a) Identify the aggregate number of people who experience blood clots and pulmonary embolisms each year in this state.

(b) Identify how data is collected regarding blood clots, pulmonary embolisms, and adverse health outcomes associated with these conditions.

(c) Identify how blood clots and pulmonary embolisms impact the lives of people in this state.

(d) Identify the standards of care for blood clot surveillance, detection, and treatment.

(e) Identify emerging treatments, therapies, and research relating to blood clots.

(f) Develop a risk surveillance system to help health care providers identify patients who may be at a higher risk of forming blood clots and pulmonary embolisms.

(g) Develop policy recommendations to help improve patient awareness of blood clot risks.

(h) Develop policy recommendations to help improve surveillance and detection of patients who may be at a higher risk of forming blood clots in licensed health care facilities, including, hospitals, nursing homes, assisted living facilities, residential treatment facilities, and ambulatory surgical centers.

(i) Develop policy recommendations relating to guidelines used that affect the standard of care for patients at risk of forming blood clots.

(j) Develop policy recommendations relating to providing patients and their families with written notice of increased risks of forming blood clots.

(3)(a) The workgroup shall be composed of health care providers, patients who have experienced blood clots, family members of patients who have died from blood clots, advocates, and other interested parties and associations.

(b) The President of the Senate and the Speaker of the House of Representatives shall each appoint two members to the workgroup.

(c) Members of the workgroup shall serve without compensation.

(d) The State Surgeon General shall appoint the chair of the workgroup.

(e) The chair is authorized to create subcommittees to help with research, scheduling speakers on important subjects, and drafting a workgroup report and policy recommendations.

(f) Meetings of the workgroup may be held through teleconference or other electronic means.

(4)(a) The Secretary of Health Care Administration shall submit an annual report detailing his or her findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

(b) The Secretary of Health Care Administration shall submit a final report detailing his or her findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 4, 2025.

Section 3. This act shall take effect July 1, 2023.

558772

69
70 ================ T I T L E A M E N D M E N T ================
71 And the title is amended as follows:
72 Delete everything before the enacting clause
73 and insert:
74 A bill to be entitled
75 An act relating to the blood clot and pulmonary
76 embolism policy workgroup; providing a short title;
77 creating s. 408.0621, F.S.; requiring the Secretary of
78 Health Care Administration, in conjunction with the
79 State Surgeon General, to establish a blood clot and
80 pulmonary embolism policy workgroup; providing for the
81 duties, membership, and meetings of the workgroup;
82 requiring the secretary to submit annual reports to
83 the Governor and the Legislature; requiring the
84 secretary to submit a final report to the Governor and
85 the Legislature by a specified date; providing an
86 effective date.

By Senator Yarborough

4-00814-23 2023612__

A bill to be entitled

An act relating to the prevention of blood clots; providing a short title; requiring the Agency for Health Care Administration, in conjunction with the Department of Health, to establish a blood clot and pulmonary embolism prevention policy workgroup; providing for membership, meetings, and duties of the workgroup; requiring the agency to submit a certain report to the Governor and the Legislature by a specified date; requiring the agency to submit a final report on the workgroup's findings and recommendations by a specified date; providing for expiration of the workgroup; providing an effective date.

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

Section 1. This act may be cited as the "Emily Adkins Blood Clot Prevention Act."

Section 2. (1) The Agency for Health Care Administration, in conjunction with the Department of Health, shall establish a blood clot and pulmonary embolism prevention policy workgroup.

(2)(a) The workgroup shall be composed of the following members:

1. Four members representing state-licensed health care facilities, appointed by the Secretary of Health Care Administration.

2. Four members representing state-licensed health care providers, appointed by the State Surgeon General. The Surgeon General shall select one of his or her appointees to serve as

4-00814-23 2023612__

chair of the workgroup.

3. Five members representing patients who have experienced blood clots, family members of patients who have died from blood clots, advocates for blood clot and pulmonary embolism prevention policies, health care associations, and other interested parties or associations, appointed by the Governor.

4. Two members appointed by the President of the Senate.

5. Two members appointed by the Speaker of the House of Representatives.

(b) Members of the workgroup shall serve at their own expense and are not entitled to receive compensation or reimbursement for per diem or travel expenses.

(c) The workgroup shall meet at the call of the chair and may conduct its meetings through teleconference or other electronic means.

(d) The chair may create subcommittees to help with gathering research, scheduling speakers on relevant subjects, and drafting workgroup reports and policy recommendations.

(3) The workgroup shall do all of the following, at a minimum:

(a) Identify the aggregate number of people who experience blood clots and pulmonary embolisms each year in this state.

(b) Identify how data is collected in this state regarding blood clots, pulmonary embolisms, and adverse health outcomes associated with these conditions.

(c) Identify how blood clots and pulmonary embolisms impact the lives of residents in this state.

(d) Identify the best practices and standards of care for blood clot surveillance, detection, and treatment.

(e) Identify emerging treatments, therapies, and research relating to blood clots and pulmonary embolisms.

(f) Develop a risk surveillance system to help health care providers identify patients who may be at higher risk for blood clots or pulmonary embolisms.

(g) Develop policy recommendations to help improve patient awareness of blood clot risks.

(h) Develop policy recommendations to help health care facilities, including, but not limited to, hospitals, ambulatory surgical centers, nursing homes, assisted living facilities, and residential treatment facilities, improve surveillance and detection of patients who may be at a higher risk for blood clots or pulmonary embolisms.

(i) Develop recommended guidelines for the standard of care for patients at risk for blood clots or pulmonary embolisms.

(j) Develop recommended literature relating to increased risks of blood clots which health care facilities and health care providers can provide to patients and their families.

(4) By January 31, 2024, the Agency for Health Care Administration shall submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives which provides an update on the workgroup's activities, findings, and recommendations. The agency shall submit a final report on all of the workgroup's findings and recommendations by January 31, 2025.

(5) This section expires February 1, 2025.

Section 3. This act shall take effect upon becoming a law.

The Florida Senate

Committee Agenda Request

To: Senator Colleen Burton, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: March 13, 2023

I respectfully request that **Senate Bill #612**, relating to Prevention of Blood Clots, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Clay Yarborough

Senator Clay Yarborough
Florida Senate, District 4

File signed original with committee office

S-020 (03/2004)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
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3/22/23
Meeting Date

Health Policy
Committee

SB 612
Bill Number or Topic

Amendment Barcode (if applicable)

Name Douglas Adams

Phone 904-583-0134

Address 963 Laguna
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Fernandina Bch, FL
City State Zip

Email doug@dayspring.church

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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S-001 (08/10/2021)

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3-27-23
Meeting Date

Health Policy
Committee

612
Bill Number or Topic

Amendment Barcode (if applicable)

Name Janet Adkins

Phone 904-316-2008

Address 863 Laguna Drive
Street

Email janethadking@bellsouth.net

Fernandina Beach FL 32034
City State Zip

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

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3/27/23
Meeting Date

Health Policy
Committee

612
Bill Number or Topic

Amendment Barcode (if applicable)

Name Chris Nuland

Phone 904-233-3051

Address 4427 Herschel St
Street

Email nulandlawe aol.com

Jacksonville, FL 32210
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

Florida Society of Thoracic & Cardiovascular Surgeons

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

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3/27/23
Meeting Date

HP
Committee

612
Bill Number or Topic

Amendment Barcode (if applicable)

Name Theresa Bulger

Phone 904 880 9063

Address 253 Hayden
Street

Email bulger12@yahoo.com

Tallahassee, FL 32303
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☒ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☒ I am a registered lobbyist, representing: Deaf Kids Can

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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

S-001 (08/10/2021)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 514
INTRODUCER:	Senator Hooper
SUBJECT:	Private Instructional Personnel
DATE:	March 24, 2023
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Sagues	Bouck	ED	**Favorable**
2.	Brown	Brown	HP	**Favorable**
3.			RC	

I. Summary:

SB 514 modifies the requirements of a Registered Behavior Technician (RBT). Under the bill, the RBT is no longer be required to be employed by an enrolled Medicaid provider to provide Applied Behavior Analyst services in a K-12 public school, and instead, must be employed by a certified behavior analyst or a professional licensed under chapter 490, the "Psychological Services Act" or chapter 491, Clinical, Counseling, and Psychotherapy Services, of the Florida Statutes.

The bill has no fiscal impact.

The bill provides an effective date of July 1, 2023.

II. Present Situation:

Applied Behavior Analysis Services

Behavior Analysis measures outcomes through data collection and the direct observation of behavior.[1] Applied Behavior Analysis (ABA) is the use of principles and methods of behavior analysis to bring about meaningful changes in socially important behaviors.[2] ABA is best known

[1] Florida Association for Behavior Analysis, *What is Behavior Analysis?*, https://www.fabaworld.org/what-is-behavior-analysis (last visited Mar 22, 2023).
[2] Association of Professional Behavior Analysts, *Identifying Applied Behavior Analysis Interventions white paper, (2017), available at* https://cdn.ymaws.com/www.apbahome.net/resource/collection/1FDDBDD2-5CAF-4B2A-AB3F-DAE5E72111BF/APBAwhitepaperABAinterventions.pdf, at 16 (last visited Mar 22, 2023).

for its success in treating individuals with autism spectrum disorder (ASD)[3] and other developmental disabilities.[4]

Florida law defines ABA as "the design, implementation, and evaluation of environmental modifications, using behavioral stimuli and consequences, to produce socially significant improvement in human behavior, including but not limited to, the use of direct observation, measurement, and functional analysis of the relations between environment and behavior."[5]

Autism Spectrum Disorder Prevalence

In 2019 and 2020, 410 out of the 12,554 children aged 3 to 17 years included in the National Health Interview Survey[6] were diagnosed with ASD. The prevalence of ASD increased from 2.79 percent in 2019 to 3.49 percent in 2020.[7]

By 2030, the need for substance abuse, behavioral disorder, and mental health counselors is expected to grow by 19 percent in Florida.[8] Currently, Florida employs 17,710 individuals in such positions and has 17,598 job openings.[9] Specifically, for certified ABA providers, Florida supplies approximately four ABA providers per 100 children with ASD, when approximately six to eight are needed, depending on the level of treatment required.[10]

ABA Service Providers and Certification

Florida's Agency for Persons with Disabilities (APD) is required to recognize a non-profit corporation for the certification of behavior analysts. The non-profit corporation is required to:[11]

- Adhere to the national standards of boards that determine professional credentials; and
- Have a mission to meet professional credentialing needs identified by behavior analysts, state governments, and consumers of behavior analysis services.

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[3] ASD means any of the following disorders as defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association: Autistic disorder, Asperger's syndrome, and Pervasive developmental disorder not otherwise specified. Section 627.6686(2), F.S.

[4] Behavior Analyst Certification Board, *Autism & Intellectual/Development Disabilities*, https://www.bacb.com/wp-content/uploads/2020/05/Behavioral-Treatment-of-Autism-and-Other-Developmental-Disabilities-Fact-Sheet_210108.pdf (last visited Mar. 22, 2023).

[5] Sections 627.6686(2)(a), F.S. and 641.31098(2)(a), F.S.

[6] Centers for Disease Control and Prevention, National Health Interview Survey, https://www.cdc.gov/nchs/nhis/data-questionnaires-documentation.htm (last visited Mar. 22, 2023).

[7] Neurology Advisor, Prevalence of Autism Spectrum Disorder Up Among Youths, https://www.neurologyadvisor.com/topics/autism-spectrum-disorder/prevalence-autism-spectrum-disorder-youths-us/#:~:text=The%20estimated%20prevalence%20of%20autism%20spectrum%20disorder%20%28ASD%29,Pediatrics.%20The%20prevalence%20of%20ASD%20is%20globally%20increasing. (last visited Mar., 22, 2023).

[8] Department of Economic *Opportunity, Florida Insight Occupational Data Search*, https://floridajobs.org/economic-data/employment-projections/occupational-data-search (last visited Mar. 22, 2023).

[9] *Id.*

[10] Yidan Xue Zhang and Janet R. Cummings, *Supply of Certified Applied Behavior Analysts in the United States; Implications for Service Delivery for Children with Autism*, Psychiatric Services, Volume 71, Issue 4 April 01, 2020, available at https://ps.psychiatryonline.org/doi/epdf/10.1176/appi.ps.201900058 at 387. (last visited Mar. 22, 2023).

[11] Section 393.17(2), F.S.

Further, the certification procedure recognized by the APD must undergo regular psychometric review and validation, pursuant to a job analysis survey of the profession and standards established by content experts in the field.[12] The APD recognizes the certification awarded by the Behavior Analyst Certification Board, Inc.,[13] which certifies the three provider types: Board Certified Behavior Analysts, Board Certified Assistant Behavior Analysts, and Registered Behavior Technicians.

The Behavior Analyst Certification Board's requirements for certification are outlined below:

- Board Certified Behavior Analyst (BCBAs):[14]
  - At least a master's degree in applied behavior analysis or a closely-related field;
  - Completion of 270 hours of graduate-level instruction in specified behavior analysis topics;
  - Completion of specified hours of supervised experiential training in ABA; and,
  - Passage of the BCBA examination.
- Board Certified Assistant Behavior Analyst (BCaBAs):[15]
  - At least a bachelor's degree;
  - Completion of 180 classroom hours of instruction in specified behavior analysis topics;
  - Completion of specified hours of supervised experiential training in ABA; and,
  - Passage of the BCaBA examination.
- Registered Behavior Technician (RBTs):[16]
  - At least a high school diploma;
  - Be at least 18 years old;
  - Completion of 40 hours of training in specified behavior analysis topics;
  - Completion of the RBT competency assessment; and
  - Passage of the RBT examination.

The RBT is a paraprofessional certified in behavior analysis. RBTs may assist in delivering ABA services under the direction and supervision of a BCBA or a BCaBA.[17]

Medicaid Coverage of ABA Services

Florida Medicaid has covered ABA services since 2012.[18] In 2017, the Agency for Health Care Administration (AHCA) adopted a provider reimbursement rule, setting a formal classification for ABA providers that closely follows the certification hierarchy of the BCBA. The rule established "lead analysts" as those professionals either holding a BCBA certification or professionals licensed by the state under chapters 490 or 491, F.S. The rule also recognizes other

[12] *Id.*
[13] Rule 65G-4.0011, F.A.C.
[14] Behavior Analyst Certification Board, *Board Certified Behavior Analyst Handbook* (2022), *available at* https://www.bacb.com/wp-content/uploads/2021/09/BCBAHandbook_210915-2.pdf . (last visited Mar. 22, 2023).
[15] Behavior Analyst Certification Board, *Board Certified Assistant Behavior Analyst Handbook* (2022), *available at* https://www.bacb.com/wp-content/uploads/2021/09/BCaBAHandbook_210915-2.pdf. (last visited Mar. 22, 2023).
[16] Behavior Analyst Certification Board, *Registered Behavior Technician Handbook* (2022), *available at* https://www.bacb.com/wp-content/uploads/2021/09/RBTHandbook_210915-3.pdf . (last visited Mar. 22, 2023).
[17] *Id.*
[18] *See* The Florida Bar Foundation, *Federal judge orders state of Florida to cover applied behavioral analysis therapy for autism*, (July 1, 2012), https://thefloridabarfoundation.org/federal-judge-orders-state-of-florida-to-cover-applied-behavioral-analysis-therapy-for-autism/ (last visited Mar. 22, 2023).

personnel who are permitted to provide ABA services, such as those holding BCaBA credentials and RBT credentials.[19]

To enroll as a behavior analysis provider in Florida's Medicaid Program, a provider must submit an enrollment application along with documentation of proof of certification, which is then evaluated and verified by the AHCA.[20] Depending on the type of BCBA certification, a provider may apply as a sole proprietor or a sole proprietor enrolling as a member of a group.[21] An RBT may only apply as a sole proprietor enrolling as a member of a Medicaid-enrolled behavior analysis group, and the AHCA requires a behavior analysis group to have at least one lead analyst as a group member.[22]

ABA Services in Florida's Public Schools

In an educational setting, behavior analysis provides a scientific approach to designing, implementing, and evaluating instruction based on analyzing interactions between what the teacher does and student learning.[23]

Section 1003.572, F.S., was created in 2013[24] to encourage cooperation and coordination of services for students with disabilities through public and private instructional collaboration. Private instructional personnel who are hired by or contracted by parents to collaborate with public instructional personnel must be permitted to observe the student in the educational setting, act as a team with instructional personnel in the educational setting, and provide services in the educational setting.[25] Private instructional personnel must undergo a background screening, and the student's public instructional personnel and principal must consent to the time and place.[26]

Section 1003.572, F.S., defines term "private instructional personnel" to include:[27]

- Individuals certified under s. 393.17, F.S., (a Board Certified Behavior Analyst) or individuals licensed under ch. 490, F.S.,[28] or ch. 491, F.S.,[29] for applied behavior analysis services.

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[19] Rule 59G-4.125, F.A.C.
[20] Agency for Health Care Administration, *Enrolling as a Florida Medicaid Behavior Analysis Provider* (April 25, 2019), at 9, *available at* https://ahca.myflorida.com/medicaid/Policy_and_Quality/Policy/behavioral_health_coverage/bhfu/pdf/Enrolling_as_a_Florida_Medicaid_Behavior_Analysis_Provider.pdf.; A Medicaid Provider Enrollment Level 2 background screening is also required.(last visited Mar. 22, 2023).
[21] *Id.* at 13.
[22] *Id.* at 12-21.
[23] Behavior Analyst Certification Board, *Behavior Analysis in Education*, https://www.bacb.com/wp-content/uploads/2020/05/Behavior-Analysis-in-Education-Fact-Sheet_210108.pdf (last visited Mar. 22, 2023).
[24] Section 5, ch. 2013-236, Laws of Fla.
[25] Section 1003.572(3), F.S.
[26] *Id.*
[27] Section 1003.572(1), F.S.
[28] Chapter 490, "Psychological Services Act" regulates psychological services in the state of Florida, including but not limited to, the process and requirements to become a Florida Department of Health licensed psychologist, defining the scope of practice of psychology, and the continuing education requirements of a licensed psychologist.
[29] Chapter 491, regulates mental health counseling, clinical social work, and marriage and family therapy, including but not limited to the process and requirements to become a Florida Department of Health licensed marriage and family therapist, clinical social worker, and mental health counselor.

- Speech-language pathologists licensed under s. 468.1185, F.S.
- Occupational therapists licensed under part III of ch. 468, F.S.
- Physical therapists licensed under ch. 486, F.S.
- Psychologists licensed under ch. 490, F.S.
- Clinical social workers licensed under ch. 491, F.S.

III. Effect of Proposed Changes:

SB 514 modifies the requirements of a Registered Behavior Technician (RBT). Under the bill, the RBT would no longer be required to be employed by an enrolled Medicaid provider to provide Applied Behavior Analyst (ABA) services in a K-12 public school, and instead, must be employed by a certified behavior analyst or professional licensed under chapter 490 or chapter 491, F.S.

Given the increasing prevalence of Autism Spectrum Disorder (ASD) among school-aged children, the bill may help to increase the supply of ABA providers to meet the needs of this population.

The bill provides an effective date of July 1, 2023.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 1003.572 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Hooper

21-00635A-23 2023514__

A bill to be entitled

An act relating to private instructional personnel; amending s. 1003.572, F.S.; revising the definition of the term "private instructional personnel" to include registered behavioral technicians employed by certain providers; providing an effective date.

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

Section 1. Paragraph (b) of subsection (1) of section 1003.572, Florida Statutes, is amended to read:

1003.572 Collaboration of public and private instructional personnel.—

(1) As used in this section, the term "private instructional personnel" means:

(b) Registered behavior technicians who have a nationally recognized paraprofessional certification in behavior analysis and who practice under the supervision of individuals described in paragraph (a) by assisting and supporting such individuals in the provision of applied behavior analysis services. To provide services under this section, a registered behavior technician must be employed by a provider described in paragraph (a) ~~an enrolled Medicaid provider~~.

Section 2. This act shall take effect July 1, 2023.

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

The Florida Senate

Committee Agenda Request

To: Chair Burton
Committee on Health Policy

Subject: Committee Agenda Request

Date: March 20, 2023

I respectfully request that **Senate Bill #514**, relating to Private Instructional Personnel, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Senator Ed Hooper
Florida Senate, District 21

File signed original with committee office

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 1596
INTRODUCER:	Health Policy Committee and Senator Garcia
SUBJECT:	Provider Accountability
DATE:	March 29, 2023
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1596 amends ss. 408.809[1] and 435.04[2], F.S., to add additional crimes to the list of offenses that will disqualify a person from employment after undergoing a background screening. The bill also amends nursing home residents' rights to specify that a nursing home resident has the right to be free from sexual abuse, neglect, and exploitation. The bill amends s. 408.812, F.S., to create a new cause of action to pursue an injunction against unlicensed activity by persons or entities who are providing services for which a license is required under ch. 408, F.S.

The bill also creates registration requirements and standards of practice for physician offices registered with the Department of Health (DOH) for the performance of office surgeries.

The bill provides an effective date of July 1, 2023.

[1] Background screening specific to health care providers regulated by the Agency for Health Care Administration under ch. 408, F.S.

[2] General provisions for level 2 background screening.

II. Present Situation:

Unlicensed Activity

Section 408.812, F.S., prohibits any person or entity from offering or advertising services that require a license under Part II of ch. 408, F.S., authorizing statutes, or applicable rules to the public without obtaining a valid license from the Agency for Health Care Administration (AHCA). The section allows the AHCA, or any state attorney, to bring action for an injunction to halt the unlicensed activity or enjoin further operation or maintenance of the unlicensed provider until compliance with laws and rules has been demonstrated to the satisfaction of the AHCA. If a person or entity fails to cease operation after receiving notice from the AHCA, the person or entity is subject to penalties including a fine of up to $1,000 per each day of noncompliance, the revocation of other licenses if the unlicensed entity has an interest in other licensed providers, and the imposition of the same licensure violations that a regularly licensed provider would incur if a condition exists that poses a threat to the health, safety, or welfare of a client.

Limitations of the Current Statutory Scheme

Under the current regulatory scheme, where the unlicensed operation of a health care provider regulated by the AHCA is asserted, the AHCA may inspect the identified location to determine if the operators are providing services therein that meet the definition of a facility requiring licensure. Should the operator not provide consent for the inspection, the circuit court is empowered to issue an inspection warrant.

If the AHCA determines, during an inspection of an unlicensed provider, that the operator is in fact engaging in unlicensed activity, the AHCA's sole immediate action is to issue a notice directed to the operator indicating that the operator is engaging in unlicensed activity. Thereafter, the AHCA may conduct a subsequent inspection to determine if the unlicensed activity has ceased or continues. Should the operator be found to have continued the unlicensed activity on this second inspection, the AHCA may proceed to impose administrative fines of $1,000 per day.

Though the statutory scheme authorizes the AHCA to seek injunctive relief, the principal of exhaustion of administrative remedies prior to seeking judicial relief essentially renders this provision ineffective. The imposition of administrative fines invokes the Administrative Procedure Act in ch. 120, F.S., and its inherent time delays, which does not result in an order, administrative or otherwise, directing the operator to cease the unlicensed activity.

Thus, under the current legislative scheme, the AHCA has no statutory path to assure that unlicensed activity by an operator ceases in a timely manner to protect citizens from the health and safety risks presented by such unlicensed activity.[3]

Examples of Unlicensed Activity

In addition to other instances of unlicensed activity identified by the AHCA, individuals currently may travel to the state to receive cheaper surgical and recovery options. Lower-cost cosmetic surgeries have created a market for similarly priced post-operative care. "Recovery

[3] AHCA bill analysis for SB 1596, March 21, 2023, on file with Senate Health Policy Committee staff.

homes" charge persons to stay and receive care post-surgery. Most recovery homes offer transportation services following surgery, provide beds, and some have nurses on site that can check vital signs.

The AHCA oversees assisted living facilities (ALF), defined as any home or building where housing, meals, and nonmedical services are provided for more than 24 hours to one or more people who are not related to the homeowner or facility manager. The AHCA is typically only made aware of the existence of recovery homes if a complaint is submitted. Since January 2017, the AHCA has cited unlicensed activity a total of 289 times, including 17 times in the first six months of 2022. The AHCA does not currently have the authority to specifically regulate or license post-operative recovery homes.

Since 2017, the number of recovery care home complaints has increased yearly. The recovery home complaints slowly began to escalate in 2018, and into 2019. Various law enforcement agencies, fire department, and code enforcement personnel also began to alert the AHCA of potential unlicensed ALF/recovery home activity.

In 2019 and early 2020, prior to the COVID-19 pandemic, recovery home complaints were approximately three or fewer per month. In 2020, there were 14 unlicensed recovery home investigations with 12 being substantiated as unlicensed ALF's during the pandemic. In 2021, there were 30 unlicensed recovery home investigations with 20 being substantiated as unlicensed ALF's, and in 2022, there were 22 unlicensed recovery home investigations with 17 being substantiated.

As of March 3, 2023, four unlicensed recovery care home investigations have been conducted with three substantiated as unlicensed ALFs. Currently the AHCA has 10 ongoing and/or pending investigations.[4]

Level 2 Background Screening

Section 435.04, F.S., establishes the standards for level 2 background screenings. The section specifies that a background screening under its provisions must include fingerprinting for statewide criminal history records checks through the FDLE and a national criminal history records checks through the FBI, and may include local criminal records checks through local law enforcement agencies. Fingerprints submitted must be submitted electronically to the FDLE, and agencies may contract with one or more vendors to perform all or part of the electronic fingerprinting.

In order to pass a level 2 background screening, an individual being screened may not have been arrested for and awaiting final disposition of, have been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to, or have been adjudicated delinquent and the record has not been sealed or expunged, for any of the offenses listed in the section or similar provisions in other jurisdictions. The section provides additional disqualifying offenses applicable to participation in the Medicaid program.

[4] *Supra* n. 3

Section 408.809, F.S., requires that the following persons who are associated with a licensee under Part II of ch. 408, F.S., must pass a level 2 background screening and be rescreened every five years:

- The licensee, if an individual;
- The administrator or a similarly titled person who is responsible for the day-to-day operation of the provider;
- The financial officer or similarly titled individual who is responsible for the financial operation of the licensee or provider;
- Any person who has a controlling interest;
- Any person, as required by authorizing statutes, seeking employment with a licensee or provider who is expected to, or whose responsibilities may require him or her to, provide personal care or services directly to clients or have access to client funds, personal property, or living areas; and
- Any person, as required by authorizing statutes, contracting with a licensee or provider whose responsibilities require him or her to provide personal care or personal services directly to clients, or contracting with a licensee or provider, to work 20 hours a week or more who will have access to client funds, personal property, or living areas.

The section also provides a list of disqualifying offenses which will prevent a person from passing the background screening and which is in addition to the disqualifying offenses listed in s. 435.04, F.S.

Exemptions

Section 435.07, F.S., allows heads of agencies to grant an exemption from disqualification for an employee who would be disqualified under s. 435.04, F.S., or other background screening provisions. These exemptions may be granted for:

- Felonies for which at least three years have elapsed since the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court for the disqualifying felony;
- Misdemeanors prohibited under any of the statutes cited in this chapter or under similar statutes of other jurisdictions for which the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court;
- Offenses that were felonies when committed but that are now misdemeanors and for which the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court; or
- Findings of delinquency. For offenses that would be felonies if committed by an adult and the record has not been sealed or expunged, the exemption may not be granted until at least three years have elapsed since the applicant for the exemption has completed or been lawfully released from confinement, supervision, or nonmonetary condition imposed by the court for the disqualifying offense.

In order to be granted an exemption, the employee seeking the exemption must provide clear and convincing evidence that he or she should not be disqualified from employment. The employing, or potentially employing, agency may consider crimes committed or that he or she has been arrested for after the disqualifying offense, even if the crime is not itself a disqualifying offense.

The decision regarding whether to grant an exemption is subject to the due process provisions in ch. 120, F.S. Additionally, the section specifies that disqualification cannot be removed if the employee is seeking a child care position, if the employee is a sex offender, or if the disqualifying offense is one of a list of specified offenses.

Nursing Home Residents' Rights

Section 400.022, F.S., enumerates a number of rights for residents in a nursing home. The section requires each nursing home to adopt and make public a statement of the rights and responsibilities of residents in the facility. The facility is required to inform a resident of his or her rights and provide a copy of the statement to the resident and each staff member of the facility. The section specifies that a violation of residents' rights is grounds for AHCA licensure action and that a licensure inspection of the facility must include private informal conversations with a sample of residents to discuss their experiences with respect to residents' rights.

The section specifies that the statement of rights adopted by each facility must include the right for all residents to:

- Civil and religious liberties.
- Private and uncensored communication.
- Present grievances on behalf of themselves or others to the staff or administrator of the facility, to governmental officials, or to any other person; to recommend changes in policies and services to facility personnel; and to join with other residents or individuals within or outside the facility to work for improvements in resident care, free from restraint, interference, coercion, discrimination, or reprisal.
- Organize and participate in resident groups in the facility and the right to have their families meet in the facility with the families of other residents.
- Participate in social, religious, and community activities that do not interfere with the rights of other residents.
- Examine, upon reasonable request, the results of the most recent inspection of the facility conducted by a federal or state agency and any plan of correction in effect with respect to the facility.
- Manage their own financial affairs or to delegate such responsibility to the licensee, but only to the extent of the funds held in trust by the licensee for a resident.
- Be fully informed, in writing and orally, prior to or at the time of admission and during their stay, of services available in the facility and of related charges for such services.
- Be adequately informed of their medical condition and proposed treatment, unless they are determined to be unable to provide informed consent under Florida law, or the right to be fully informed in advance of any nonemergency changes in care or treatment that may affect their well-being.
- Participate in the planning of all medical treatment, including the right to refuse medication and treatment, unless otherwise indicated by their physician, and to know the consequences of such actions.
- Refuse medication or treatment and to be informed of the consequences of such decisions, unless determined unable to provide informed consent under state law.
- Receive adequate and appropriate health care and protective and support services, including social services; mental health services, if available; planned recreational activities; and

therapeutic and rehabilitative services consistent with their resident care plan, with established and recognized practice standards within the community, and with rules as adopted by the AHCA.
- Have privacy in treatment and in caring for personal needs; to close room doors and to have facility personnel knock before entering the room, except in the case of an emergency or unless medically contraindicated; and to security in storing and using personal possessions.
- Be treated courteously, fairly, and with the fullest measure of dignity and to receive a written statement and an oral explanation of the services provided by the licensee, including those required to be offered on an as-needed basis.
- Be free from mental and physical abuse, corporal punishment, extended involuntary seclusion, and from physical and chemical restraints, except those restraints authorized in writing by a physician for a specified and limited period of time or as are necessitated by an emergency.
- Be transferred only for specified reasons and to have no less than 30 days' notice of a transfer.
- Freedom of choice in selecting a personal physician and other related health care choices.
- Retain and use personal clothing and possessions as space permits, unless to do so would infringe upon the rights of other residents or unless medically contraindicated as documented by a physician in their medical records.
- Have copies of the rules and regulations of the facility and an explanation of the responsibility of all residents to obey all reasonable rules and regulations of the facility and to respect the personal rights and private property of the other residents.
- Receive notice before their room in the facility is changed.
- Be informed of the bed reservation policy for a hospitalization.
- Challenge a decision by the facility to discharge or transfer, for Medicaid or Medicare certified facilities.

Regulation of Office Surgeries

The Board of Medicine and the Board of Osteopathic Medicine (boards) have authority to adopt rules to regulate practice of medicine and osteopathic medicine, respectively.[5] The boards have authority to establish, by rule, standards of practice for particular settings.[6] Such standards may include education and training; medications, including anesthetics; assistance of and delegation to other personnel; sterilization; performance of complex or multiple procedures; records; informed consent; and policy and procedures manuals.[7]

The boards set forth the standards of practice that must be met for office surgeries. An office surgery is any surgery that is performed outside a facility licensed under ch. 390, F.S., or ch. 395, F.S.[8] There are several levels of office surgeries governed by rules adopted by the boards, which

[5] Chapter 458, F.S., regulates the practice of allopathic medicine, and ch. 459, F.S., regulates the practice of osteopathic medicine.
[6] Sections 458.331(v) and 459.015(z), F.S.
[7] *Id.*
[8] Rules 64B8-9.009(1)(d) and 64B15-14.007(1)(d), F.A.C. Abortion clinics are licensed under ch. 390, F.S., and facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgery centers, mobile surgical facilities, and certain intensive residential treatment programs.

set forth the scope of each level of office surgeries, the equipment and medications that must be available, and the training requirements for personnel present during the surgery.

Registration

The boards require a licensed physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, Level II procedures planned to last more than five minutes, and Level III procedures, to register the office with the DOH.[9] A physician who performs surgery in an office setting must ensure that the office is registered with DOH, regardless of whether other physicians practice in the office or the office is not owned by a physician.[10] The registration requires a physician to document compliance with transfer agreement[11] and training requirements. DOH must annually inspect registered offices or the office must be accredited by a national accreditation organization approved by the respective board. Currently, there are 719 offices registered with DOH.[12]

Standards of Practice

Prior to performing any surgery, a physician must evaluate the risk of anesthesia and of the surgical procedure to be performed.[13] A physician must maintain a complete record of each surgical procedure, including the anesthesia record, if applicable, and written informed consent.[14] The written consent must reflect the patient's knowledge of identified risks, consent to the procedure, type of anesthesia and anesthesia provider, and that a choice of anesthesia provider exists.[15]

Physicians performing office surgeries must maintain a log of all liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed and Level II and Level III surgical procedures performed, which includes:[16]

- A confidential patient identifier;
- The time the patient arrives in the operating suite;
- The name of the physician who provided medical clearance;
- The surgeon's name;
- The diagnosis;
- The CPT codes for the procedures performed;
- The patient's ASA classification;
- The type of procedure performed;
- The level of surgery;

[9] Sections 458.309(3) and 459.005(2), F.S., see also Rules 64B8-9.0091 and 64B15-14.0076, F.A.C.
[10] Rule 64B8-9.0091(1) and 64B15-14.0076(1), F.A.C.
[11] A physician or the facility where a surgical procedure is being performed must have a transfer agreement with a licensed hospital within a reasonable proximity or within 30 minutes transport time to the hospital. Rules 64B8-9.009 and 64B15-14.007, F.A.C.
[12] Department of Health, *License Verification – Office Surgery Registration, Practicing Statuses Only*, March 21, 2023, available at https://mqa-internet.doh.state.fl.us/MQASearchServices/HealthCareProviders.
[13] Rules 64B8-9.009(2) and 64B15-14.007(2), F.A.C.
[14] *Id.* A physician does not need to obtain written informed consent for minor Level I procedures limited to the skin and mucosa.
[15] *Id.* A patient may use an anesthesiologist, anesthesiologist assistant, another appropriately trained physician, certified registered nurse anesthetist, or physician assistant.
[16] Rules 64B8-9.009(2)(a) and 64B15-14.007(2)(a), F.A.C.

- The anesthesia provider;
- The type of anesthesia used;
- The duration of the procedure;
- The type of post-operative care;
- The duration of recovery;
- The disposition of the patient upon discharge;
- A list of medications used during surgery and recovery; and
- Any adverse incidents.

Such log must be maintained for at least six years from the last patient contact and must be provided to DOH investigators upon request.[17]

For elective cosmetic and plastic surgery procedures performed in a physician's office:[18]

- The maximum planned duration of all planned procedures cannot exceed eight hours.
- A physician must discharge the patient within 24 hours, and overnight stay may not exceed 23 hours and 59 minutes.
- The overnight stay is strictly limited to the physician's office.
- If the patient has not sufficiently recovered to be safely discharged within the 24-hour period, the patient must be transferred to a hospital for continued post-operative care.

Levels of Office Surgeries

Level I

Level I involves the most minor of surgeries, which require minimal sedation[19] or local or topical anesthesia, and have a remote chance of complications requiring hospitalization.[20] Level I procedures include:[21]

- Minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas and repair of lacerations, or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient;
- Liposuction involving the removal of less than 4000cc supernatant fat; and
- Incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cystoscopic procedures, and closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints).

[17] *Id.*
[18] Rules 64B8-9.009(2)(f) and 64B15-14.007(2)(f), F.A.C.
[19] Minimal sedation is a drug-induced state during which the patient responds normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilator and cardiovascular functions are not impaired. Controlled substances are limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.
[20] Rules 64B8-9.009(3) and 64B15-14.007(3), F.A.C.
[21] *Id.*

Level II

Level II office surgeries involve moderate sedation[22] and require the physician office to have a transfer agreement with a licensed hospital that is no more than 30 minutes from the office.[23] Level II office surgeries, include but are not limited to:[24]

- Hemorrhoidectomy, hernia repair, large joint dislocations, colonoscopy, and liposuction involving the removal of up to 4,000cc supernatant fat; and
- Any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation.

A physician performing a Level II office surgery must:[25]

- Have staff privileges at a licensed hospital to perform the same procedure in that hospital as the surgery being performed in the office setting;
- Demonstrate to the appropriate board that he or she has successfully completed training directly related to and include the procedure being performed, such as board certification or eligibility to become board-certified; or
- Demonstrate comparable background, training or experience.

A physician, or a facility where the procedure is being performed, must have a transfer agreement with a licensed hospital within a reasonable proximity[26] if the physician performing the procedure does not have staff privileges to perform the same procedure at a licensed hospital within a reasonable proximity.

Anesthesiology must be performed by an anesthesiologist, a certified registered nurse anesthetist (CRNA), or a qualified physician assistant (PA). An appropriately-trained physician, PA, or registered nurse with experience in post-anesthesia care, must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia.[27]

Level IIA

Level IIA office surgeries are those Level II surgeries with a maximum planned duration of five minutes or less and in which chances of complications requiring hospitalization are remote.[28] A physician, physician assistant, registered nurse, or licensed practical nurse must assist the surgeon during the procedure and monitor the patient in the recovery room until the patient is recovered from anesthesia.[29] The assisting health care practitioner must be appropriately certified

[22] Moderate sedation or conscious sedation is a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulations. No interventions are needed to manage the patient's airway and spontaneous ventilation is adequate. Cardiovascular function is maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response.
[23] Rules 64B8-9.009(4) and 64B15-14.007(4), F.A.C.
[24] *Id.*
[25] *Id.*
[26] Transport time to the hospital must be 30 minutes of less.
[27] *Id.* The assisting practitioner must be trained in advanced cardiovascular life support, or for pediatric patients, pediatric advanced life support.
[28] Rules 64B-9.009(5) and 64B15-14.007(5), F.A.C.
[29] *Id.*

in advanced cardiac life support, or in the case of pediatric patients, pediatric advanced life support.[30]

Level III

Level III office surgeries are the most complex and require deep sedation or general anesthesia.[31] A physician performing the surgery must have staff privileges to perform the same procedure in a hospital.[32] The physician must also have knowledge of the principles of general anesthesia.

Only patients classified under the American Society of Anesthesiologist's (ASA) risk classification criteria as Class I or II[33] are appropriate candidates for Level III office surgery. For all ASA Class II patients above the age of 50, the surgeon must obtain a complete workup performed prior to the performance of Level III surgery in a physician office setting.[34] If the patient has a cardiac history or is deemed to be a complicated medical patient, the patient must have a preoperative EKG and be referred to an appropriate consultant for medical optimization. The referral to a consultant may be waived after evaluation by the patient's anesthesiologist.[35] All Level III surgeries on patients classified as ASA III[36] and higher must be performed in a hospital or an ambulatory surgery center.

During the procedure, the physician must have one assistant who has current certification in advanced cardiac life support. Additionally, the physician must have emergency policies and procedures related to serious anesthesia complications, which address:

- Airway blockage (foreign body obstruction);
- Allergic reactions;
- Bradycardia;
- Bronchospasm;
- Cardiac arrest;

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[30] *Id.*

[31] Deep sedation is a drug-induced depression of consciousness during which a patient cannot be easily aroused but responds purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. A patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. General anesthesia is a drug-induced loss of consciousness during which a patient is not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. The use of spinal or epidural anesthesia is considered Level III.

[32] Rules 64B8-9.009(6) and 64B15-14.007(6), F.A.C. The physician may also document satisfactory completion of training directly related to and include the procedure being performed.

[33] An ASA Class I patient is a normal, healthy, non-smoking patient, with no or minimal alcohol use. An ASA Class II patient is a patient with mild systemic disease without substantive functional limitations. Examples include current smoker, social alcohol drinker, pregnancy, obesity, well-controlled hypertension with diabetes, or mild lung disease. *See* American Society of Anesthesiologists, *ASA Physical Status Classification System*, (Oct. 15, 2014, last amended Dec. 13, 2020), available at https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system (last visited on March 21, 2023).

[34] *Id.*

[35] *Id.*

[36] An ASA Class III patient is a patient with severe systemic disease who has substantive functional limitations and/or one or more moderate to severe diseases. This may include poorly controlled diabetes or hypertension, chronic obstructive pulmonary disease, morbid obesity, active hepatitis, alcohol dependence or abuse, implanted pacemaker, premature infant, recent history of myocardial infarction, cerebrovascular disease, transient ischemic attack, or coronary artery disease.

- Chest pain;
- Hypoglycemia;
- Hypotension;
- Hypoventilation;
- Laryngospasm;
- Local anesthetic toxicity reaction; and
- Malignant hypothermia.

Adverse Incident Reporting

A physician must report any adverse incident that occurs in an office practice setting to DOH within 15 days after the occurrence any adverse incident.[37] An adverse incident in an office setting is defined as an event over which the physician or licensee could exercise control and which is associated with a medical intervention and results in one of the following patient injuries:[38]

- The death of a patient;
- Brain or spinal damage to a patient;
- The performance of a surgical procedure on the wrong patient;
- If the procedure results in death; brain or spinal damage; permanent disfigurement; the fracture or dislocation of bones or joints; a limitation of neurological, physical, or sensory functions; or any condition that required the transfer of a patient, the performance of:
  - A wrong-site surgical procedure;
  - A wrong surgical procedure; or
  - A surgical repair of damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented through the informed consent process;
- A procedure to remove unplanned foreign objects remaining from a surgical procedure; or
- Any condition that required the transfer of a patient to a hospital from an ambulatory surgical center or any facility or any office maintained by a physician for the practice of medicine which is not licensed under ch. 395, F.S.

The DOH must review each adverse incident report to determine if discipline against the practitioner's license is warranted.[39]

III. Effect of Proposed Changes:

Background Screening

CS/SB 1596 amends ss. 408.809 and 435.04, F.S., to add to the lists of disqualifying offenses in those sections. The following offenses are added to s. 408.809, F.S., for violations of:

- Section 414.39, F.S., relating to fraud, if the offense was a felony.
- Section 815.04, F.S., relating to offenses against intellectual property.

[37] Sections 458.351 and 459.026, F.S.
[38] Sections 458.351(4) and 459.026(4), F.S.
[39] Sections 458.351(5) and 459.026(5), F.S.

- Section 815.06, F.S., relating to offenses against users of computers, computer systems, computer networks, and electronic devices.
- Section 831.29, F.S., relating to making or having instruments and material for counterfeiting driver licenses or identification cards.
- Section 831.311, F.S., relating to unlawful sale, manufacture, alteration, delivery, uttering, or possession of counterfeit-resistant prescription blanks for controlled substances.
- Section 836.05, F.S., relating to threats and extortion.
- Section 836.10, F.S., relating to written or electronic threats to kill or do bodily injury or conduct a mass shooting or an act of terrorism.
- Section 873.01, F.S., relating to the prohibited purchase or sale of human organs and tissue.

The following offenses are added to s. 435.04, F.S., for violations of:
- Section 39.205, F.S., relating to failure to report child abuse, abandonment, or neglect.
- Section 316.193(3)(c)3., F.S., relating to DUI manslaughter.
- Section 787.06, F.S., relating to human trafficking.
- Section 787.07, F.S., relating to human smuggling.
- Section 790.166, F.S., relating to the manufacture, possession, sale, delivery, display, use, or attempted or threatened use of weapons of mass destruction or hoax weapons of mass destruction.
- Section 838.015, F.S., relating to bribery.
- Section 859.01, F.S., relating to poisoning food or water.
- Section 873.01, F.S., relating to the prohibited purchase or sale of human organs and tissue.
- Section 876.32, F.S., relating to treason.
- Section 951.22, F.S., relating to county detention facilities and contraband articles.

Unlicensed Activity

The bill amends s. 408.812, F.S., to add a new cause of action for an ex parte injunction against continued unlicensed activity. The bill specifies that the AHCA may petition the circuit court for an ex parte injunction against continued unlicensed activity when AHCA personnel have verified, through an onsite inspection, that a person or entity is advertising, offering, or providing services for which licensure is required under this part and applicable statutes and such person or entity has previously received notification from the AHCA to discontinue such activity.

A sworn petition seeking the issuance of an ex parte injunction against continued unlicensed activity must include:
- The location of the unlicensed activity;
- The ownership and operators of the unlicensed provider;
- Identification of the service provider type for which licensure is required under the applicable statutes;
- Specific facts supporting the conclusion that the respondent engaged in unlicensed activity, specifying the date, time, and location at which the unlicensed provider was notified to discontinue such activity;
- Whether the respondent prohibited the agency from conducting a subsequent investigation to determine compliance;
- Any previous injunctive relief granted against the respondent; and

- Any previous AHCA determinations that the respondent was previously identified as engaging in unlicensed activity.

The bill prohibits a bond from being required by the court for the issuance of the injunction and also prohibits, except as provided in s. 90.204,[40] F.S., evidence being used at the hearing other than verified pleadings or affidavits by AHCA personnel or others with first-hand knowledge of the alleged unlicensed activity, unless the respondent appears at the hearing. Any denial of a petition must be by written order noting the legal grounds for denial. The bill specifies that nothing in the subsection affects the AHCA's right to promptly amend any petition or otherwise be heard in person consistent with the Florida Rules of Civil Procedure.

Should the court find that the respondent is engaged in unlicensed activity, the bill allows the court to grant an ex parte temporary injunction, pending a full hearing, and other relief the court deems appropriate such as an injunction restraining the respondent from advertising, offering, or providing services for which licensure is required under this part and applicable statutes, and requiring the respondent to provide agency personnel full access to facility personnel, records, and clients for a future inspection of the premises. An ex parte injunction must be effective for a fixed period not to exceed 30 days and must be served by the sheriff of the county in which the respondent's activities are conducted.

The AHCA is required to inspect the premises within 20 days after the injunction is issued to verify the respondent's compliance with the injunction. If the respondent is found to have complied with the temporary injunction, the AHCA must voluntarily dismiss its injunction action. If the AHCA finds that unlicensed activity has continued in apparent violation of the temporary injunction, the AHCA may file a petition for permanent injunction within 10 days after such discovery, at which time a full hearing must be set as soon as practicable. Contemporaneous with the filing of a petition for permanent injunction, the AHCA may move for an extension of the ex parte injunction until disposition of the permanent injunction proceedings.

The bill specifies that:
- Remedies provided in the bill are not exclusive but a supplement to any other administrative or criminal remedies for unlicensed activity;
- The AHCA is not required to exhaust its administrative remedies before seeking the injunctive relief provided by this subsection; and
- The AHCA may provide any records of its inspections to local law enforcement agencies or state attorney offices upon request and without redaction.

Residents' Rights in Nursing Homes

The bill amends s. 400.022, F.S., to add that a resident in a nursing home has the right to be free from sexual abuse, neglect, and exploitation.

[40] Relating to the determination of propriety of judicial notice and nature of matter noticed.

Office Surgeries

The bill amends ss. 458.328 and 459.0138, F.S., which regulate office surgeries under the Medical Practice Act and the Osteopathic Medicine Practice Act, respectively. The bill provides that:

- A physician office seeking registration must be inspected by the DOH before the office may be registered.
- If a registered office refuses any subsequent inspection required by the DOH, the office's registration must be immediately suspended and may not be reinstated before completion of an inspection by the DOH.
- Physicians performing gluteal fat grafting procedures in an office surgery setting must adhere to standards of practice provided under the bill, including:
    - An office in which a physician performs gluteal fat grafting procedures must at all times maintain a ratio of one physician to one patient during all phases of the procedure, beginning with the administration of anesthesia to the patient and concluding with the extubation of the patient.
    - A physician is not limited in the number of gluteal fat grafting procedures that he or she may safely perform in accordance with the applicable standard of care and as prescribed in the bill; however, after a physician has commenced, and while he or she is engaged in, a gluteal fat grafting procedure, the physician may not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.
    - Before a physician may delegate any duties during a gluteal fat grafting procedure, the patient must provide written, informed consent to such delegation.
    - Any duties delegated during a gluteal fat grafting procedure must be performed under the direct supervision of the physician performing the procedure.
    - Gluteal fat extractions and injections must be performed by the physician performing the procedure and may not be delegated.
    - Gluteal fat may be injected only into the subcutaneous space of the patient and may not cross the fascia overlying the gluteal muscle. Intramuscular and submuscular fat injections are prohibited.
    - When the physician performing a gluteal fat grafting procedure injects gluteal fat into the subcutaneous space of the patient, the physician must use ultrasound guidance during the placement and navigation of a cannula to ensure that the fat is placed into the subcutaneous space of the patient above the fascia overlying the gluteal muscle. Ultrasound guidance is not required for other portions of the procedure.

The bill authorizes the boards to adopt rules to prescribe additional requirements for the safe performance of gluteal fat grafting procedures, provided such rules do not conflict with the standards created under the bill.

The bill also provides standards of practice that apply to all surgeries performed in a registered office. Under the bill, surgeries performed in an office registered by the DOH may not:

- Result in blood loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin level;
- Require major or prolonged intracranial, intrathoracic, abdominal, or joint replacement procedures, except for laparoscopic procedures;

- Involve major blood vessels performed with direct visualization by open exposure of the major blood vessel, except for percutaneous endovascular intervention; or
- Be emergent or life threatening.

Effective date

The bill provides an effective date of July 1, 2023.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 1596 may have a negative fiscal impact on a person who is employed, or is seeking employment, with a provider and who would fail a background screening based on one of the added disqualifying offenses if the person would not have failed such background screening otherwise.

Physician offices registered with the DOH for the performance of office surgeries may incur indeterminate costs to comply with the standards of practice created by the bill.

C. Government Sector Impact:

The AHCA's analysis of SB 1596 does not indicate that the bill will have a fiscal impact on the AHCA.[41]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 400.022, 408.809, 408.812, 435.04, 458.328, and 459.0138.

IX. Additional Information:

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

CS by Health Policy on March 27, 2023:
The CS adds to the bill new requirements for physician offices registered with the DOH for the performance of office surgeries and new standards of practice for surgeries performed in such settings.

B. Amendments:

None.

[41] *Supra* n. 3

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/28/2023	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Between lines 374 and 375
insert:

Section 5. Present subsection (2) of section 458.328, Florida Statutes, is redesignated as subsection (4), a new subsection (2) and subsection (3) are added to that section, and paragraph (e) of subsection (1) of that section is amended, to read:

458.328 Office surgeries.—

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(1) REGISTRATION.—

(e)1. An office seeking registration under this section must be inspected by the department before the office may be registered. If a registered office refuses any subsequent inspection under subparagraph 2., the office's registration must be immediately suspended and may not be reinstated before completion of an inspection by the department. Completion of an inspection under this subparagraph does not guarantee a registration or reinstatement of a registration.

2. The department shall inspect a registered office at least annually, including a review of patient records, to ensure that the office is in compliance with this section and rules adopted hereunder unless the office is accredited by a nationally recognized accrediting agency approved by the board. The inspection may be unannounced, except for the inspection of an office that meets the description of a clinic specified in s. 458.3265(1)(a)3.h., and those wholly owned and operated physician offices described in s. 458.3265(1)(a)3.g. which perform procedures referenced in s. 458.3265(1)(a)3.h., which must be announced.

(2) GLUTEAL FAT GRAFTING PROCEDURES.—

(a) Physicians performing gluteal fat grafting procedures in an office surgery setting must adhere to standards of practice prescribed under this subsection. The board may adopt rules to prescribe additional requirements for the safe performance of gluteal fat grafting procedures, provided such rules do not conflict with this subsection.

(b) An office in which a physician performs gluteal fat grafting procedures must at all times maintain a ratio of one

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physician to one patient during all phases of the procedure, beginning with the administration of anesthesia to the patient and concluding with the extubation of the patient. A physician is not limited in the number of gluteal fat grafting procedures that he or she may safely perform in accordance with the applicable standard of care and as prescribed in this subsection. However, after a physician has commenced, and while he or she is engaged in, a gluteal fat grafting procedure, the physician may not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.

(c) Before a physician may delegate any duties during a gluteal fat grafting procedure, the patient must provide written, informed consent to such delegation. Any duties delegated during a gluteal fat grafting procedure must be performed under the direct supervision of the physician performing the procedure. Gluteal fat extractions and injections must be performed by the physician performing the procedure and may not be delegated.

(d) Only the physician performing the gluteal fat grafting procedure may extract gluteal fat from, or inject gluteal fat into, the patient. The gluteal fat may be injected only into the subcutaneous space of the patient and may not cross the fascia overlying the gluteal muscle. Intramuscular and submuscular fat injections are prohibited.

(e) When the physician performing a gluteal fat grafting procedure injects gluteal fat into the subcutaneous space of the patient, the physician must use ultrasound guidance during the placement and navigation of a cannula to ensure that the fat is

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placed into the subcutaneous space of the patient above the fascia overlying the gluteal muscle. Ultrasound guidance is not required for other portions of the procedure.

(3) STANDARDS OF PRACTICE.—Surgeries performed in an office registered under this section may not:

(a) Result in blood loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin level;

(b) Require major or prolonged intracranial, intrathoracic, abdominal, or joint replacement procedures, except for laparoscopic procedures;

(c) Involve major blood vessels performed with direct visualization by open exposure of the major blood vessel, except for percutaneous endovascular intervention; or

(d) Be emergent or life threatening.

Section 6. Present subsection (2) of section 459.0138, Florida Statutes, is redesignated as subsection (4), a new subsection (2) and subsection (3) are added to that section, and paragraph (e) of subsection (1) of that section is amended, to read:

459.0138 Office surgeries.—

(1) REGISTRATION.—

(e)1. An office seeking registration under this section must be inspected by the department before the office may be registered. If a registered office refuses any subsequent inspection under subparagraph 2., the office's registration must be immediately suspended and may not be reinstated before completion of an inspection by the department. Completion of an inspection under this subparagraph does not guarantee a

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registration or reinstatement of a registration.

2. The department shall inspect a registered office at least annually, including a review of patient records, to ensure that the office is in compliance with this section and rules adopted hereunder unless the office is accredited by a nationally recognized accrediting agency approved by the board. The inspection may be unannounced, except for the inspection of an office that meets the description of clinic specified in s. 459.0137(1)(a)3.h., and those wholly owned and operated physician offices described in s. 459.0137(1)(a)3.g. which perform procedures referenced in s. 459.0137(1)(a)3.h., which must be announced.

(2) GLUTEAL FAT GRAFTING PROCEDURES.—

(a) Physicians performing gluteal fat grafting procedures in an office surgery setting must adhere to standards of practice prescribed under this subsection. The board may adopt rules to prescribe additional requirements for the safe performance of gluteal fat grafting procedures, provided such rules do not conflict with this subsection.

(b) An office in which a physician performs gluteal fat grafting procedures must at all times maintain a ratio of one physician to one patient during all phases of the procedure, beginning with the administration of anesthesia to the patient and concluding with the extubation of the patient. A physician is not limited in the number of gluteal fat grafting procedures that he or she may safely perform in accordance with the applicable standard of care and as prescribed in this subsection. However, after a physician has commenced, and while he or she is engaged in, a gluteal fat grafting procedure, the

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physician may not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.

(c) Before a physician may delegate any duties during a gluteal fat grafting procedure, the patient must provide written, informed consent to such delegation. Any duties delegated during a gluteal fat grafting procedure must be performed under the direct supervision of the physician performing the procedure. Gluteal fat extractions and injections must be performed by the physician performing the procedure and may not be delegated.

(d) Only the physician performing the gluteal fat grafting procedure may extract gluteal fat from, or inject gluteal fat into, the patient. The gluteal fat may be injected only into the subcutaneous space of the patient and may not cross the fascia overlying the gluteal muscle. Intramuscular and submuscular fat injections are prohibited.

(e) When the physician performing a gluteal fat grafting procedure injects gluteal fat into the subcutaneous space of the patient, the physician must use ultrasound guidance during the placement and navigation of a cannula to ensure that the fat is placed into the subcutaneous space of the patient above the fascia overlying the gluteal muscle. Ultrasound guidance is not required for other portions of the procedure.

(3) STANDARDS OF PRACTICE.—Surgeries performed in an office registered under this section may not:

(a) Result in blood loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin level;

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(b) Require major or prolonged intracranial, intrathoracic, abdominal, or joint replacement procedures, except for laparoscopic procedures;

(c) Involve major blood vessels performed with direct visualization by open exposure of the major blood vessel, except for percutaneous endovascular intervention; or

(d) Be emergent or life threatening.

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

And the title is amended as follows:

Delete line 40

and insert:

screening requirements; amending ss. 458.328 and 459.0138, F.S.; requiring that a physician's office seeking registration to perform office surgeries must be inspected by the Department of Health before it may be registered; providing for immediate suspension of a registration under specified circumstances; providing construction; requiring physicians performing gluteal fat grafting procedures in an office surgery setting to adhere to specified standards of practice; authorizing the Board of Medicine and the Board of Osteopathic Medicine, respectively, to adopt certain rules; providing an effective date.

By Senator Garcia

36-01801-23 20231596__

A bill to be entitled

An act relating to provider accountability; amending s. 400.022, F.S.; revising the rights of residents of nursing home facilities; amending s. 408.809, F.S.; providing additional disqualifying offenses for purposes of background screening of employees of certain health care providers; amending s. 408.812, F.S.; creating a cause of action for ex parte injunctive relief against continued unlicensed activity relating to health care provider facilities; authorizing the Agency for Health Care Administration to petition the court for such injunctive relief; providing requirements for the petition; prohibiting courts from requiring bond in such proceedings; limiting the types of evidence that may be presented in such proceedings; providing that a denial of such injunctive relief must be by written order of the court noting the legal grounds for the denial; providing construction; providing for ex parte temporary injunctive relief under certain circumstances; requiring that temporary injunctions be effective for a fixed period not exceeding 30 days; requiring the agency to conduct an inspection of the identified premises of unlicensed activity within a specified timeframe after such temporary injunction is issued; requiring the agency to dismiss its petition if the respondent complies with the injunction; providing for a permanent injunction within a specified timeframe if the unlicensed activity

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continues; requiring that a full hearing be set as soon as practicable thereafter; authorizing the agency to move for an extension of the injunction until disposition of the proceedings; providing for service of an ex parte injunction; providing construction; authorizing the agency to provide any inspection records to local law enforcement agencies and state attorney offices upon request and without redaction; amending s. 435.04, F.S.; providing additional disqualifying offenses for employment background screening requirements; providing an effective date.

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

Section 1. Paragraph (o) of subsection (1) of section 400.022, Florida Statutes, is amended to read:

400.022 Residents' rights.—

(1) All licensees of nursing home facilities shall adopt and make public a statement of the rights and responsibilities of the residents of such facilities and shall treat such residents in accordance with the provisions of that statement. The statement shall assure each resident the following:

(o) The right to be free from mental and physical abuse, sexual abuse, neglect, exploitation, corporal punishment, extended involuntary seclusion, and from physical and chemical restraints, except those restraints authorized in writing by a physician for a specified and limited period of time or as are necessitated by an emergency. In case of an emergency, restraint may be applied only by a qualified licensed nurse who shall set

forth in writing the circumstances requiring the use of restraint, and, in the case of use of a chemical restraint, a physician shall be consulted immediately thereafter. Restraints may not be used in lieu of staff supervision or merely for staff convenience, for punishment, or for reasons other than resident protection or safety.

Section 2. Subsection (4) of section 408.809, Florida Statutes, is amended to read:

408.809 Background screening; prohibited offenses.—

(4) In addition to the offenses listed in s. 435.04, all persons required to undergo background screening pursuant to this part or authorizing statutes must not have an arrest awaiting final disposition for, must not have been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to, and must not have been adjudicated delinquent and the record not have been sealed or expunged for any of the following offenses or any similar offense of another jurisdiction:

(a) Any authorizing statutes, if the offense was a felony.

(b) This chapter, if the offense was a felony.

(c) Section 409.920, relating to Medicaid provider fraud.

(d) Section 409.9201, relating to Medicaid fraud.

(e) Section 414.39, relating to fraud, if the offense was a felony.

(f) Section 741.28, relating to domestic violence.

(g) ~~(f)~~ Section 777.04, relating to attempts, solicitation, and conspiracy to commit an offense listed in this subsection.

(h) ~~(g)~~ Section 784.03, relating to battery, if the victim is a vulnerable adult as defined in s. 415.102 or a patient or

resident of a facility licensed under chapter 395, chapter 400, or chapter 429.

(i) Section 815.04, relating to offenses against intellectual property.

(j) Section 815.06, relating to offenses against users of computers, computer systems, computer networks, and electronic devices.

(k) ~~(h)~~ Section 817.034, relating to fraudulent acts through mail, wire, radio, electromagnetic, photoelectronic, or photooptical systems.

(l) ~~(i)~~ Section 817.234, relating to false and fraudulent insurance claims.

(m) ~~(j)~~ Section 817.481, relating to obtaining goods by using a false or expired credit card or other credit device, if the offense was a felony.

(n) ~~(k)~~ Section 817.50, relating to fraudulently obtaining goods or services from a health care provider.

(o) ~~(l)~~ Section 817.505, relating to patient brokering.

(p) ~~(m)~~ Section 817.568, relating to criminal use of personal identification information.

(q) ~~(n)~~ Section 817.60, relating to obtaining a credit card through fraudulent means.

(r) ~~(o)~~ Section 817.61, relating to fraudulent use of credit cards, if the offense was a felony.

(s) ~~(p)~~ Section 831.01, relating to forgery.

(t) ~~(q)~~ Section 831.02, relating to uttering forged instruments.

(u) ~~(r)~~ Section 831.07, relating to forging bank bills, checks, drafts, or promissory notes.

(v) ~~(s)~~ Section 831.09, relating to uttering forged bank bills, checks, drafts, or promissory notes.

(w) Section 831.29, relating to making or having instruments and material for counterfeiting driver licenses or identification cards.

(x) ~~(t)~~ Section 831.30, relating to fraud in obtaining medicinal drugs.

(y) ~~(u)~~ Section 831.31, relating to the sale, manufacture, delivery, or possession with the intent to sell, manufacture, or deliver any counterfeit controlled substance, if the offense was a felony.

(z) Section 831.311, relating to unlawful sale, manufacture, alteration, delivery, uttering, or possession of counterfeit-resistant prescription blanks for controlled substances.

(aa) Section 836.05, relating to threats and extortion.

(bb) Section 836.10, relating to written or electronic threats to kill or do bodily injury or conduct a mass shooting or an act of terrorism.

(cc) Section 873.01, relating to the prohibited purchase or sale of human organs and tissue.

(dd) ~~(v)~~ Section 895.03, relating to racketeering and collection of unlawful debts.

(ee) ~~(w)~~ Section 896.101, relating to the Florida Money Laundering Act.

If, upon rescreening, a person who is currently employed or contracted with a licensee and was screened and qualified under s. 435.04 has a disqualifying offense that was not a

disqualifying offense at the time of the last screening, but is a current disqualifying offense and was committed before the last screening, he or she may apply for an exemption from the appropriate licensing agency and, if agreed to by the employer, may continue to perform his or her duties until the licensing agency renders a decision on the application for exemption if the person is eligible to apply for an exemption and the exemption request is received by the agency no later than 30 days after receipt of the rescreening results by the person.

Section 3. Subsection (6) of section 408.812, Florida Statutes, is amended to read:

408.812 Unlicensed activity.—

(6) In addition to granting injunctive relief pursuant to subsection (2), if the agency determines that a person or entity is operating or maintaining a provider without obtaining a license and determines that a condition exists that poses a threat to the health, safety, or welfare of a client of the provider, the person or entity is subject to the same actions and fines imposed against a licensee as specified in this part, authorizing statutes, and agency rules.

(a) There is created a cause of action for an ex parte injunction against continued unlicensed activity.

(b) The agency may petition the circuit court for an ex parte injunction against continued unlicensed activity when agency personnel have verified, through an onsite inspection, that a person or entity is advertising, offering, or providing services for which licensure is required under this part and applicable statutes and such person or entity has previously received notification from the agency to discontinue such

activity.

(c) A sworn petition seeking the issuance of an ex parte injunction against continued unlicensed activity must include the location of the unlicensed activity; the ownership and operators of the unlicensed provider; identification of the service provider type for which licensure is required under the applicable statutes; specific facts supporting the conclusion that the respondent engaged in unlicensed activity, specifying the date, time, and location at which the unlicensed provider was notified to discontinue such activity; whether the respondent prohibited the agency from conducting a subsequent investigation to determine compliance; any previous injunctive relief granted against the respondent; and any previous agency determinations that the respondent was previously identified as engaging in unlicensed activity.

(d) Bond may not be required by the court for the entry of an injunction under this subsection.

(e) Except as provided in s. 90.204, in an ex parte hearing for the purpose of obtaining such ex parte temporary injunction, no evidence other than verified pleadings or affidavits by agency personnel or others with first-hand knowledge of the alleged unlicensed activity may be used as evidence, unless the respondent appears at the hearing. A denial of a petition for an ex parte injunction must be by written order noting the legal grounds for denial. Nothing herein affects the agency's right to promptly amend any petition or otherwise be heard in person on any petition consistent with the Florida Rules of Civil Procedure.

(f) If it appears to the court that the respondent is

engaged in unlicensed activity and has not discontinued that activity after notification by the agency, the court may grant an ex parte temporary injunction, pending a full hearing, and may grant any relief the court deems appropriate, including an injunction restraining the respondent from advertising, offering, or providing services for which licensure is required under this part and applicable statutes, and requiring the respondent to provide agency personnel full access to facility personnel, records, and clients for a future inspection of the premises within 20 days after the injunction is issued to verify respondent's compliance with the temporary injunction.

(g) An ex parte temporary injunction issued under this subsection must be effective for a fixed period not to exceed 30 days.

(h) The agency must conduct an inspection of the identified premises within 20 days after the injunction is issued to verify the respondent's compliance with the temporary injunction. If the respondent is found to have complied with the temporary injunction, the agency must voluntarily dismiss its injunction action. If the agency finds that unlicensed activity has continued in apparent violation of the temporary injunction, the agency may file a petition for permanent injunction within 10 days after such discovery, at which time a full hearing must be set as soon as practicable. Contemporaneous with the filing of a petition for permanent injunction, the agency may move for an extension of the ex parte injunction until disposition of the permanent injunction proceedings.

(i) Any ex parte injunction against continued unlicensed activity must be served by the sheriff of the county in which

the respondent's activities are conducted.

(j) Remedies in this subsection are not exclusive but a supplement to any other administrative or criminal remedies for unlicensed activity.

(k) The agency is not required to exhaust its administrative remedies before seeking the injunctive relief provided by this subsection.

(l) The agency may provide any records of its inspections to local law enforcement agencies or state attorney offices upon request and without redaction.

Section 4. Subsection (2) of section 435.04, Florida Statutes, is amended to read:

435.04 Level 2 screening standards.—

(2) The security background investigations under this section must ensure that no persons subject to the provisions of this section have been arrested for and are awaiting final disposition of, have been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to, or have been adjudicated delinquent and the record has not been sealed or expunged for, any offense prohibited under any of the following provisions of state law or similar law of another jurisdiction:

(a) Section 39.205, relating to failure to report child abuse, abandonment, or neglect.

(b) Section 316.193(3)(c)3., relating to DUI manslaughter.

(c) Section 393.135, relating to sexual misconduct with certain developmentally disabled clients and reporting of such sexual misconduct.

(d) ~~(b)~~ Section 394.4593, relating to sexual misconduct with

certain mental health patients and reporting of such sexual misconduct.

(e) ~~(c)~~ Section 415.111, relating to adult abuse, neglect, or exploitation of aged persons or disabled adults.

(f) ~~(d)~~ Section 777.04, relating to attempts, solicitation, and conspiracy to commit an offense listed in this subsection.

(g) ~~(e)~~ Section 782.04, relating to murder.

(h) ~~(f)~~ Section 782.07, relating to manslaughter, aggravated manslaughter of an elderly person or disabled adult, or aggravated manslaughter of a child.

(i) ~~(g)~~ Section 782.071, relating to vehicular homicide.

(j) ~~(h)~~ Section 782.09, relating to killing of an unborn child by injury to the mother.

(k) ~~(i)~~ Chapter 784, relating to assault, battery, and culpable negligence, if the offense was a felony.

(l) ~~(j)~~ Section 784.011, relating to assault, if the victim of the offense was a minor.

(m) ~~(k)~~ Section 784.03, relating to battery, if the victim of the offense was a minor.

(n) ~~(l)~~ Section 787.01, relating to kidnapping.

(o) ~~(m)~~ Section 787.02, relating to false imprisonment.

(p) ~~(n)~~ Section 787.025, relating to luring or enticing a child.

(q) ~~(o)~~ Section 787.04(2), relating to taking, enticing, or removing a child beyond the state limits with criminal intent pending custody proceedings.

(r) ~~(p)~~ Section 787.04(3), relating to carrying a child beyond the state lines with criminal intent to avoid producing a child at a custody hearing or delivering the child to the

designated person.

(s) Section 787.06, relating to human trafficking.

(t) Section 787.07, relating to human smuggling.

(u) ~~(q)~~ Section 790.115(1), relating to exhibiting firearms or weapons within 1,000 feet of a school.

(v) ~~(r)~~ Section 790.115(2)(b), relating to possessing an electric weapon or device, destructive device, or other weapon on school property.

(w) Section 790.166, relating to the manufacture, possession, sale, delivery, display, use, or attempted or threatened use of weapons of mass destruction or hoax weapons of mass destruction.

(x) ~~(s)~~ Section 794.011, relating to sexual battery.

(y) ~~(t)~~ Former s. 794.041, relating to prohibited acts of persons in familial or custodial authority.

(z) ~~(u)~~ Section 794.05, relating to unlawful sexual activity with certain minors.

(aa) ~~(v)~~ Chapter 796, relating to prostitution.

(bb) ~~(w)~~ Section 798.02, relating to lewd and lascivious behavior.

(cc) ~~(x)~~ Chapter 800, relating to lewdness and indecent exposure.

(dd) ~~(y)~~ Section 806.01, relating to arson.

(ee) ~~(z)~~ Section 810.02, relating to burglary.

(ff) ~~(aa)~~ Section 810.14, relating to voyeurism, if the offense is a felony.

(gg)(bb) Section 810.145, relating to video voyeurism, if the offense is a felony.

(hh) ~~(cc)~~ Chapter 812, relating to theft, robbery, and

related crimes, if the offense is a felony.

(ii) ~~(dd)~~ Section 817.563, relating to fraudulent sale of controlled substances, only if the offense was a felony.

(jj) ~~(ee)~~ Section 825.102, relating to abuse, aggravated abuse, or neglect of an elderly person or disabled adult.

(kk) ~~(ff)~~ Section 825.1025, relating to lewd or lascivious offenses committed upon or in the presence of an elderly person or disabled adult.

(ll) ~~(gg)~~ Section 825.103, relating to exploitation of an elderly person or disabled adult, if the offense was a felony.

(mm) ~~(hh)~~ Section 826.04, relating to incest.

(nn) ~~(ii)~~ Section 827.03, relating to child abuse, aggravated child abuse, or neglect of a child.

(oo) ~~(jj)~~ Section 827.04, relating to contributing to the delinquency or dependency of a child.

(pp) ~~(kk)~~ Former s. 827.05, relating to negligent treatment of children.

(qq) ~~(ll)~~ Section 827.071, relating to sexual performance by a child.

(rr) Section 838.015, relating to bribery.

(ss) ~~(mm)~~ Section 843.01, relating to resisting arrest with violence.

(tt) ~~(nn)~~ Section 843.025, relating to depriving a law enforcement, correctional, or correctional probation officer means of protection or communication.

(uu) ~~(oo)~~ Section 843.12, relating to aiding in an escape.

(vv) ~~(pp)~~ Section 843.13, relating to aiding in the escape of juvenile inmates in correctional institutions.

(ww) ~~(qq)~~ Chapter 847, relating to obscene literature.

(xx) Section 859.01, relating to poisoning food or water.

(yy) Section 873.01, relating to the prohibited purchase or sale of human organs and tissue.

(zz) ~~(rr)~~ Section 874.05, relating to encouraging or recruiting another to join a criminal gang.

(aaa) Section 876.32, relating to treason.

(bbb) ~~(ss)~~ Chapter 893, relating to drug abuse prevention and control, only if the offense was a felony or if any other person involved in the offense was a minor.

(ccc) ~~(tt)~~ Section 916.1075, relating to sexual misconduct with certain forensic clients and reporting of such sexual misconduct.

(ddd) ~~(uu)~~ Section 944.35(3), relating to inflicting cruel or inhuman treatment on an inmate resulting in great bodily harm.

(eee) ~~(vv)~~ Section 944.40, relating to escape.

(fff) ~~(ww)~~ Section 944.46, relating to harboring, concealing, or aiding an escaped prisoner.

(ggg) ~~(xx)~~ Section 944.47, relating to introduction of contraband into a correctional facility.

(hhh) Section 951.22, relating to county detention facilities and contraband articles.

(iii) ~~(yy)~~ Section 985.701, relating to sexual misconduct in juvenile justice programs.

(jjj) ~~(zz)~~ Section 985.711, relating to contraband introduced into detention facilities.

Section 5. This act shall take effect July 1, 2023.

2023 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

BILL INFORMATION	
BILL NUMBER:	SB 1596
BILL TITLE:	Provider Accountability
BILL SPONSOR:	Senator Garcia
EFFECTIVE DATE:	July 1, 2023

COMMITTEES OF REFERENCE
1) Healthcare Regulation Subcommittee
2) Health Care Appropriations Subcommittee
3) Health & Human Services Committee
4) N/A
5) N/A

CURRENT COMMITTEE
Healthcare Regulation Subcommittee

SIMILAR BILLS	
BILL NUMBER:	SB 1596
SPONSOR:	Representative Busatta Cabrera

PREVIOUS LEGISLATION	
BILL NUMBER:	N/A
SPONSOR:	N/A
YEAR:	N/A
LAST ACTION:	N/A

IDENTICAL BILLS	
BILL NUMBER:	N/A
SPONSOR:	N/A

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

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	3/21/23
LEAD AGENCY ANALYST:	N/A
ADDITIONAL ANALYST(S):	N/A
LEGAL ANALYST:	N/A
FISCAL ANALYST:	N/A

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

The proposed language would strengthen the Agency's authority to regulate unlicensed activity, including the requirement for law enforcement to investigate complaints referred by the Agency. Additionally, the proposed legislation attempts to further strengthen the list of disqualifying criminal offenses in sections 435.04(2) and 408.809, F.S., by including similar offenses to the current disqualifying offenses to ensure that all like offenses are fully covered. Finally, the proposed changes would add a specific prohibition of sexual abuse, neglect, and exploitation of nursing home residents to s. 400.022, F.S.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

Prohibiting Nursing Home Resident Abuse and Neglect at the State Level

Current law does not specifically mention a prohibition of sexual abuse, neglect, or exploitation of nursing home residents. Without mention of these offenses in state statute, the Agency can only cite these offenses through federal regulations.

Unlicensed Activity

Under the current regulatory scheme, where the unlicensed operation of a health care provider regulated by the Agency is asserted, the Agency may inspect the identified location to determine if the operators are providing services therein that meet the definition of a facility requiring licensure. Should the operator not provide consent for the inspection, the Circuit Court is empowered to issue an inspection warrant.

If the Agency determines during an inspection of an unlicensed provider that the operator is in fact engaging in unlicensed activity, the Agency's sole immediate action is to issue a notice directed to the operator indicating that the operator is engaging in unlicensed activity. Thereafter, the Agency may conduct a subsequent inspection to determine if the unlicensed activity has ceased or continues. Should the operator be found to have continued in engaging in unlicensed activity on this second inspection, the Agency may proceed to impose administrative fines of one thousand dollars ($1,000.0) per day.

Though the statutory scheme authorizes the Agency to seek injunctive relief, the principal of exhaustion of administrative remedies prior to seeking judicial relief essentially renders this provision ineffective. The imposition of administrative fines invokes the Administrative Procedure Act and the inherent time delays therein and does not result in an order, administrative or otherwise, directing the operator to cease the unlicensed activity.

Thus, under the current legislative scheme, the Agency has no statutory path to assure that unlicensed activity by an operator ceases in a timely manner to protect citizens from the health and safety risks presented by such unlicensed activity. Florida law defines unlicensed activity as harm that materially affects the health, safety, and welfare of clients, and constitutes abuse and neglect. *See*, Section 408.812(2), Fla. Stat.

In addition to other instances of unlicensed activity the Agency identifies, currently, individuals are traveling to the state, primarily to South Florida, to receive cheaper surgical and recovery options. Lower-cost cosmetic surgeries have created a market for similarly priced post-operative care. Recovery homes charge for persons to stay and receive care post-surgery. Most recovery homes offer transportation services following surgery, provide beds, and some have nurses on site that can check vitals.

The Agency for Health Care Administration oversees assisted-living facilities, defined as any home or building where housing, meals, and nonmedical services are provided for more than 24 hours to one or more people who are not related to the homeowner or facility manager. The Agency is typically only made aware of the existence of recovery homes if a complaint is submitted. Since January 2017, the Agency has cited unlicensed activity a total of 289 times, including 17 times in the first six months of 2022. The Agency does not currently have the authority to specifically regulate or license post-operative recovery homes.

Since 2017, the number of recovery care home complaints has increased yearly. The recovery care home complaints slowly began to escalate in 2018, and into 2019. Various law enforcement agencies, fire department and code enforcement personnel also began to alert the Agency of potential unlicensed ALF/recovery home activity.

In 2019 and early 2020, prior to the pandemic, recovery home complaints were approximately 1-3 month. In 2020, there were 14 unlicensed recovery care home investigations with 12 being substantiated as unlicensed ALF's during the

pandemic. In 2021 there were 30 unlicensed recovery care home investigations with 20 being substantiated as unlicensed ALF's and in 2022 there were 22 unlicensed recovery home investigations with 17 being substantiated.

As of March 3, 2023, 4 unlicensed recovery care home investigations have been conducted with 3 substantiated as unlicensed ALF's. Currently the Agency has 10 ongoing and/or pending investigations.

Background Screening Disqualifying Offenses
Currently, the list of disqualifying offenses in sections 408.809 and 435.04(2), F.S. has been efficient in preventing those with certain crimes from working with Florida's vulnerable population. However, there have been numerous examples of individuals being charged with very similar offenses that are cleared for employment due to the fact that these offenses are not disqualifying. There are currently over 200 employees in the Clearinghouse that are eligible to work with one or more of the offenses listed on their record. There are 50 employees that currently work in facilities AHCA regulates.

2. EFFECT OF THE BILL:

Prohibiting Nursing Home Resident Abuse and Neglect at the State Level
The proposed legislation would strengthen AHCA's ability to consistently cite providers for sexual abuse, neglect, or exploitation of nursing home residents under a single statute.

Unlicensed Activity
As drafted, the proposed language would strengthen the Agency's authority to regulate unlicensed activity, including the requirement for law enforcement to investigate complaints referred by the Agency. The proposal creates a cause of action for an ex parte injunction against continued unlicensed activity. This newly created cause of action will create enhanced authority for law enforcement to shut down unlicensed activity when identified.

The bill would empower the Agency to undertake action enjoining unlicensed activity upon a determination by the Agency that despite a prior notification by the Agency to the operator that the operator is engaging in unlicensed activity, such activity continues.

The ex parte injunction provisions would in a relatively prompt time period judicially enjoin the operator from continuing in engaging in unlicensed activity. The violation of an injunction could result in the remedy of contempt of court.

The bill further removes delays hampering law enforcement's investigation of and pursuit of criminal charges against unlicensed operators chiefly by authorizing the Agency to release its investigatory records to law enforcement upon request, eliminating the necessity for the issuance of investigative subpoenas by law enforcement to the Agency.

Background Screening Disqualifying Offenses
As drafted, the proposal amends sections 408.809 and 435.04(2), F.S. to include the following disqualifying offenses in the background screening clearinghouse process:

- s. 39.205, relating to failure to report child abuse, abandonment, or neglect
- s. 414.39 relating to Fraud, if the offense was a felony
- s. 787.06, relating to human trafficking
- s. 787.07, relating to human smuggling
- s. 790.166, relating to weapons of mass destruction or hoax weapons of mass destruction
- s. 815.04, relating to offenses against intellectual property; public records exemption.
- s. 815.06; relating to offenses against users of computers, computer systems, computer networks, and electronic devices
- s. 831.29 Making or having instruments and material for counterfeiting driver licenses or identification cards
- s. 831.311 Unlawful sale, manufacture, alteration, delivery, uttering, or possession of counterfeit-resistant prescription blanks for controlled substances
- s. Section 836.05 relating to threats; Extortion
- s. 836.10 relating to written threats to kill or do bodily injury
- s. 838.015, relating to bribery
- s. 859.01, relating to poisoning food or water
- s. 873.01, Purchase or sale of human organs and tissue prohibited
- s. 876.32, relating to treason
- s. 951.22, relating to county detention facilities; contraband articles
- s. 973.01, relating to purchase or sale of human organs and tissue prohibited

The inclusion of these additional offenses would ensure that individuals charged with such crimes would not be permitted to work with Florida's vulnerable population as the law intended.

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

If yes, explain:	N/A
Is the change consistent with the agency's core mission?	Y ___ N ___
Rule(s) impacted (provide references to F.A.C., etc.):	N/A

4. WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?

Proponents and summary of position:	Unknown
Opponents and summary of position:	Unknown

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y ___ N _X__

If yes, provide a description:	N/A
Date Due:	N/A
Bill Section Number(s):	N/A

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

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

FISCAL ANALYSIS

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

Revenues:	N/A
Expenditures:	N/A
Does the legislation increase local taxes or fees? If yes, explain.	N/A

If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	N/A

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

Revenues:	N/A
Expenditures:	N/A
Does the legislation contain a State Government appropriation?	N/A
If yes, was this appropriated last year?	N/A

3. DOES THE BILL HAVE A THE FISCAL IMPACT TO THE PRIVATE SECTOR? Y ___ N _X__

Revenues:	N/A
Expenditures:	N/A
Other:	N/A

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

If yes, explain impact.	N/A
Bill Section Number:	N/A

TECHNOLOGY IMPACT

1. DOES THE BILL IMPACT THE AGENCY'S TECHNOLOGY SYSTEMS (I.E. IT SUPPORT, LICENSING SOFTWARE, DATA STORAGE, ETC.)? Y ___ N _X__

If yes, describe the anticipated impact to the agency including any fiscal impact.	N/A

FEDERAL IMPACT

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

If yes, describe the anticipated impact including any fiscal impact.	

ADDITIONAL COMMENTS

N/A

LEGAL – GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	N/A

The Florida Senate

Committee Agenda Request

To: Senator Colleen Burton, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: March 9, 2023

I respectfully request that **Senate Bill 1596**, relating to Provider Accountability, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Ileana Garcia
Florida Senate, District 36

File signed original with committee office

S-020 (03/2004)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3/27/23
Meeting Date

Health Policy
Committee

1596
Bill Number or Topic

584094
Amendment Barcode (if applicable)

Name Chris Nuland

Phone 904-233-3051

Address 4427 Herschel St
Street

Email nulandlaw@aol.com

Jacksonville, FL 32210
City State Zip

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3/27/2023
Meeting Date

Health Policy
Committee

SB1596
Bill Number or Topic

Amendment Barcode (if applicable)

Name Kim Smoak

Phone (904) 955-0331

Address 2727 Mahan Dr.
Street

Email ~~Kim.Smoak@AHCA.myflorida.com~~
Kimberly.Smoak

Tallahassee FL 32308
City State Zip

Speaking: ☐ For ☐ Against ☒ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☒ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

03/27/2003
Meeting Date

Health Policy
Committee

1596
Bill Number or Topic

Amendment Barcode (if applicable)

Name AARP - Ivonne Fernandez

Phone 954-850-7262

Address 215 S Monroe Street - 605
Street

Email ifernandez@aarp.org

Tallahassee FL
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:

AARP

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3/27/2023
Meeting Date

Health Policy
Committee

SB 596
Bill Number or Topic

Amendment Barcode (if applicable)

Name Patrick Steele

Phone (321) 305-9900

Address 2727 Mahan Dr.
Street

Email Patrick.Steele@AHCA.MyFlorida.com

Tallahassee FL 32308
City State Zip

Speaking: [X] For [ ] Against [ ] Information **OR** Waive Speaking: [X] In Support [ ] Against

PLEASE CHECK ONE OF THE FOLLOWING:

[ ] I am appearing without compensation or sponsorship.

[✓] I am a registered lobbyist, representing:
AHCA

[ ] I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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

S-001 (08/10/2021)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 454
INTRODUCER:	Health Policy Committee and Senator Avila
SUBJECT:	Physician Assistant Licensure
DATE:	March 29, 2023 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Vanwinkle	Brown	HP	**Fav/CS**
2.			HE	
3.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 454 revises the eligibility requirements for physician assistants (PAs) seeking licensure. The bill changes the requirement for graduation from an approved program to a requirement to have "completed" or "matriculated," as applicable. The bill authorizes the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) to grant a license to a PA applicant who does not meet the educational requirements for licensure but has passed the Physician Assistant National Certifying Examination (PANCE). These changes reinstate the licensure eligibility for PAs who graduated from accredited PA programs with a bachelor's degree who were negatively impacted by the Legislature's 2021 revisions to the PA licensure statutes.

The bill provides an effective date of July 1, 2023.

II. Present Situation:

Physician Assistants (PAs)

History of the Physician Assistant Profession

In 1965, physicians and educators recognized there was a shortage of primary care physicians, so Duke University Medical Center put together the first class of PAs. Duke selected four Navy

Vietnam-era hospital corpsmen who had received considerable medical training during their military service. The first PA class graduated from the Duke program in 1967.[1]

In Florida, physicians were first authorized to use PAs in their practice in 1979. The legislative intent for recognizing the PA profession was to allow physicians to delegate the performance of "medical services" to qualified PAs when such delegation was consistent with the patient's health and welfare, thereby freeing physicians to more effectively utilize their medical education, training, and experience. Physicians were required to apply to their board[2] to utilize and supervise a PA in their practice. PAs were required to be graduates of board-approved programs, or the equivalent, and to be approved by the Department of Health (DOH) to perform "medical services" under the supervision of a physician, who was certified by the board to supervise the PA. PAs were not required to be licensed by the DOH. Physicians utilizing PAs were liable for any act or omissions of the PAs while under the physician's supervision.[3]

Physician Assistant Education

Physician assistant programs must be recommended by the Council on Physician Assistants (Council) and approved by the BOM and the BOOM (collectively referenced in this analysis as the boards). The Council may only recommend PA programs that hold full accreditation or provisional accreditation from the Commission on Accreditation of Allied Health Programs or its successor organization. The boards are required to adopt program standards to ensure the health and welfare of patients that receive PA services, and review curricula, faculties, and facilities of PA programs to ensure they meet standards set forth by the boards.[4]

Currently there are 17 universities in Florida offering PA programs accredited by the Accreditation Review Commission on Education (ARC-PA).[5] Physician assistant programs are on average 24 to 27 months, or six or seven semesters, requiring 96 to 111 clinical and classroom credit hours to graduate. The programs are designed to prepare students to practice as part of a physician-PA team. Upon completion, graduates receive a Master of Science in PA Practice degree or a Master of PA Studies, or similar degree.

Following graduation, a PA candidate must take and pass the PANCE given by the National Commission on Certification of PAs (NCCPA) to become certified. It is a five-hour exam with 300 multiple-choice questions, with no didactic components.[6]

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[1] American Association of Physician Assistants, About, History, *History of the PA Profession*, available at: https://www.aapa.org/about/history/ (last visited Mar. 23, 2023).
[2] Section 456.001(1), F.S., defines "board" as any board, commission, or other statutorily created entity, to the extent such entity is authorized to exercise regulatory or rulemaking functions within the Department of Health or, in some cases, within the department's Division of Medical Quality Assurance.
[3] Chapter 79-230, s. 1., and ch. 79-320, s. 1., Laws of Fla. (Creating ss. 459.018 and 458.017, F.S., effective Jul. 1, 1979).
[4] Section 458.347(6) and 459.022(6), F.S.
[5] Florida Academy of PAs, *For Students - PA Programs in Florida*, available at: https://www.fapaonline.org/page/studentprograms (last visited Mar. 22, 2023).
[6] The National Commission on Certification of PA (NCCPA), *2021 Statistical Profile of Recently Certified PAs*. p. 5. (Nov. 15, 2022) available at: https://www.nccpa.net/wp-content/uploads/2022/12/2021-Statistical-Profile-of-Recently-Certified-PAs-11.15.22.pdf (last visited Mar. 22, 2023). The NCCPA is the only certifying organization for PAs in the United States. As of Nov. 15, 2021, there were more than 158,000 certified PAs in the United States.

Physician Assistant Scope of Practice

PAs may only practice under the direct or indirect supervision of a physician with whom they have a working relationship.[7] PA are licensed to perform only those medical services delegated to them by a supervising allopathic or osteopathic physician.[8]

A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice. A supervising physician decides whether to permit a PA to perform a task or procedure under direct or indirect supervision based on his or her reasonable medical judgment regarding the probability of morbidity and mortality to the patient, and the physician must be certain the PA has the knowledge and skills to perform the task or procedure assigned.[9]

Current law defines physician "supervision"[10] to mean responsible supervision and control. The boards have established by rule that "responsible supervision" of a PA means the ability of the supervising physician to exercise control and provide direction over the services or tasks performed by the PA. Whether the supervision of a PA is adequate is dependent upon the:

- Complexity of the task;
- Risk to the patient;
- Background, training, and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.[11]

Responsible supervision and control also require the supervising physician to periodically review the PA's performance[12] and to determine the level of supervision the PA requires for every task or procedure delegated to the PA as to whether it will be under:[13]

- Direct supervision: Requires the physical presence of the supervising physician on the premises so that the physician is immediately available to the PA when needed; or
- Indirect supervision: Requires the supervising physician to be within reasonable physical proximity, and easily availability, to the PA for communication with the PA, including via telecommunication.

A supervising physician may also delegate to a PA his or her authority to:[14]

- Prescribe or dispense any medicinal drug used in the supervising physician's practice unless such medication is listed in the negative formulary established by the Council, but only under the following circumstances:

[7] Sections 458.347(2)(f) and 459.022(2)(f), F.S.
[8] Sections 458.347(4) and 459.022(4), F.S.
[9] Fla. Admin. Code R. 64B8-30.012(3) and 64B15-6.010(3), (2022).
[10] Sections 458.247(2)(g) and 459.022(2)(g), F.S.
[11] Fla. Admin. Code R. 64B8-30.001 and 64B15-6.001, (2022).
[12] Fla. Admin. Code R. 64B8-30.001(3) and 64B15-6.001(3), (2022).
[13] Fla. Admin. Code R. 64B8-30.001(4) and (5) and 64B15-6.001(4) and (5), (2022).
[14] Sections 458.347(4) and 459.022(4), F.S.

  - The PA identifies himself or herself as a PA and advises the patient of his or her right to see a physician before the prescription is written or dispensed;
  - The supervising physician must be registered as a dispensing practitioner and have notified the DOH on an approved form of his or her intent to delegate prescriptive authority or to change prescriptive authority; and
  - The PA must have completed 10 hours of continuing medical education in the specialty practice in which the PA has prescriptive authority with each licensure renewal, and three of the 10 hours must be on the safe and effective prescribing of controlled substances.
- Order any medication for administration to the supervising physician's patient in a hospital or other facility licensed under ch. 395, F.S., or a nursing home licensed under Part II, ch. 400, F.S.; and
- Perform any other service that is not expressly prohibited in the PA practice acts, or the rules adopted thereunder.

Licensed PAs may prescribe and dispense any medicinal drug not listed in the negative formulary developed by the Council in consultation with a pharmacist licensed under ch. 465, F.S., but not licensed under chs. 458 or 459, F.S., including general anesthetics, radiographic contrast materials, and up to a 14-day supply of psychiatric mental health controlled substances to children under 18 years of age provided the PA is under the supervision of a pediatrician, a family practice physician, an internal medicine physician, or a psychiatrist; and the PA's prescribing authority of schedule II controlled substances is limited to a seven day supply.[15]

The supervising physician must notify the DOH of his or her intent to delegate prescriptive authority, on a DOH-approved form, before delegating the authority and must notify the DOH of any change in the PA's prescriptive privileges. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276, F.S.[16]

A primary supervising physician is responsible and legal liability for the services rendered by the a PA at all times the PA is not under the supervision and control of an alternate supervising physician[17] and may not supervise more than ten PAs at any time.[18]

Except for the physician certification required for the use of medical marijuana,[19] a PA may authenticate any document with his or her signature, certification, stamp, verification, affidavit, or endorsement if the document may be authenticated by a physician. Such documents include, but are not limited to, the following:[20]

- Initiation of an involuntary examination under the Baker Act;[21]
- Do-not-resuscitate orders or orders for the administration of life-sustaining treatment;
- Death certificates;
- School physical examinations;

[15] Sections 458.347(4)(i), and 459022(4)(h), F.S.
[16] *Id.*
[17] Fla. Admin. Code R. 64B8-30.001(1) and 64B15-6.001(1), (2022).
[18] Sections 458.347(3) and 459.022(3), F.S.
[19] *See* s. 381.986, F.S.
[20] Sections 458.347(4)(i), and 459.022(4)(i), F.S.
[21] *See* s. 394.463, F.S.

- Medical examinations for workers' compensation claims, except examinations required for the evaluation and assignment of the claimant's date of maximum medical improvement and impairment ratings;[22]; and
- Orders for physical therapy, occupational therapy, speech-language therapy, home health services, or durable medical equipment.

A physician assistant may supervise medical assistants.[23,24]

Third-party payers are also authorized to reimburse employers of PAs for covered services rendered by licensed PAs. Payment for services within the physician assistant's scope of practice must be made when ordered or performed by a PA if the same service would have been covered if ordered or performed by a physician. PAs are authorized to bill for and receive direct payment for the services they deliver.[25]

Physician Assistant Licensure

Any person desiring to be licensed as a PA must apply to the DOH. The DOH must issue a license to any person certified by the Council as having met all of the following requirements:

- Is at least 18 years of age;
- Has completed an application and remitted an application fee. The application must include:
  - A diploma from an approved program;
  - An acknowledgment of any prior felony convictions; and
  - An acknowledgment of any previous revocations or denials of licensure or certification in any state.
- Has graduated from an approved program;
  - For an applicant who graduated after December 31, 2020, has received a master's degree in accordance with the Accreditation Review Commission on Education for the Physician Assistant (ARCEPA)or, before 2001, its equivalent or predecessor organization; or
  - For an applicant who graduated on or before December 31, 2020, has received a bachelor's or master's degree from an approved program; or
  - For an applicant who graduated before July 1, 1994, has graduated from an approved program of instruction in primary health care or surgery; or
  - For an applicant who graduated before July 1, 1983, has received a certification as a PA from the boards; or
  - The board may also grant a license to an applicant who does not meet the specified educational requirement but has passed the PANCE administered by the National Commission on Certification of Physician Assistants (NCCPA) before 1986.
- Has obtained a passing score on the PANCE established by the NCCPA and has been nationally certified. If an applicant does not hold a current NCCPA certification and has not actively practiced as a PA within the preceding four years, the applicant must retake and successfully complete the entry-level examination of the NCCPA or its equivalent or successor, to be eligible for licensure.

[22]Section 440.02, F.S., defines the date of maximum medical improvement and s 440.15, F.S., defines impairment rating for the purposes of awarding permanent partial or total workers' compensation disability benefits.
[23] Sections 458.347(4)(j), and 459.022(4)(i), F.S.
[24] *See* s. 458.3485, F.S.
[25] Sections 458.347(4)(k), and 459.022(4)(j), F.S.

Physician assistants must renew their licenses biennially. During each biennial renewal cycle, a PA must complete 100 hours of continuing medical education or must demonstrate a current NCCPA certification.[26] To maintain certification, a PA must earn at least 100 hours of continuing medical education biennially, and must take and pass a re-certification examination every 10 years.[27]

The 2021 changes to the educational requirements for licensure as a PA created a situation where otherwise eligible PAs were rendered ineligible. Specifically, there are individuals who began their PA bachelor's degree program prior to the change in law who would have been eligible for licensure upon graduation, but because they graduated after December 31, 2020, they were rendered ineligible for licensure.

III. Effect of Proposed Changes:

CS/SB 454 amends ss. 458.347(6) and 459.022(6), F.S., for allopathic and osteopathic PAs licensure in an identical manner, so the effect of the changes are the same for both statute sections.

CS/SB 454 requires the DOH to issue a license to any person the PA council certifies has, among other things:

- "Completed," rather than "graduate from," an approved program; and
- Matriculated or graduated, as required:
  - After December 31, 2020, and received a master's degree;
  - On or before December 31, 2020, and received a bachelor's or master's degree;
  - Before July 1, 1994, from an approved program of instruction in primary health care or surgery; or
  - Before July 1, 1983, and received a certification as a PA from the boards.

CS/SB 454 eliminates the educational requirement that a PA's master's degree earned after December 31, 2020, be received in accordance with the Accreditation Review Commission on Education for the Physician Assistant or, before 2001, its equivalent or predecessor organization.

The bill expands the boards' authority to grant PA licenses on a case-by-case basis to any PA who did not meet the statutory educational requirements for licensure, but who has passed the PANCE, regardless of when, to not just those PAs who did not meet the licensure education requirements but passed the PANCE before 1986.

The bill provides an effective date of July 1, 2023.

[26] Sections 458.347(7)(c) and 459.022(7)(c), F.S.
[27] National Commission on Certification of Physician Assistants, *Maintain Certification*, available at: https://www.nccpa.net/maintain-certification/ (last visited Mar. 23, 2023).

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill could allow certain PAs to obtain licensure if they have passed the PANCE but not met the statutory education requirements.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 458.347 and 459.022.

IX. Additional Information:

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

CS by Health Policy on March 27, 2023:
The CS:

- Requires a PA licensure applicant to "complete" an approved program, rather than "graduate from" an approved program;
- Returns to ss. 458.347 and 459.022, F.S., the following educational licensure requirement options for PAs that are in current law:
  - Receiving a bachelor's or master's degree from an approved program before December 31, 2020;
  - Graduating from an approved program of instruction in primary health care or surgery before July 1, 1984; and
  - Graduating from an approved program and receiving a certification as a PA from the boards.
- Expands the boards' authority to grant PAs licenses on a case-by-case basis to any PA who does not meet the statutory educational requirements for licensure, but who has passed the PANCE, regardless of when.

B. Amendments:

None.

333290

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/28/2023	.	
	.	
	.	
	.	

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

Senate Amendment

Delete lines 24 - 81
and insert:
b. For an applicant who matriculated ~~graduated~~ on or before December 31, 2020, has received a bachelor's or master's degree from an approved program.
c. For an applicant who graduated before July 1, 1994, has graduated from an approved program of instruction in primary health care or surgery.

333290

d. For an applicant who graduated before July 1, 1983, has received a certification as a physician assistant from the boards.

e. The board may also grant a license to an applicant who does not meet the educational requirement specified in this subparagraph but who has passed the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants ~~before 1986~~.

3. Has obtained a passing score as established by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has been nationally certified. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants or its equivalent or successor organization to be eligible for licensure.

4. Has completed the application form and remitted an application fee not to exceed $300 as set by the boards. An application for licensure as a physician assistant must include:

a. A diploma from an approved program.

b. Acknowledgment of any prior felony convictions.

c. Acknowledgment of any previous revocation or denial of licensure or certification in any state.

Section 2. Paragraph (a) of subsection (6) of section 459.022, Florida Statutes, is amended to read:

333290

459.022 Physician assistants.—

(6) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met all of the following requirements:

1. Is at least 18 years of age.

2. Has completed ~~graduated from~~ an approved program.

a. For an applicant who matriculated ~~graduated~~ after December 31, 2020, has received a master's degree ~~in accordance with the Accreditation Review Commission on Education for the Physician Assistant or, before 2001, its equivalent or predecessor organization~~.

b. For an applicant who matriculated ~~graduated~~ on or before December 31, 2020, has received a bachelor's or master's degree from an approved program.

c. For an applicant who graduated before July 1, 1994, has graduated from an approved program of instruction in primary health care or surgery.

d. For an applicant who graduated before July 1, 1983, has received a certification as a physician assistant from the boards.

e. The board may also grant a license to an applicant who

By Senator Avila

39-00788A-23 2023454__

A bill to be entitled

An act relating to physician assistant licensure; amending ss. 458.347 and 459.022, F.S.; revising requirements for an applicant for licensure as a physician assistant; providing an effective date.

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

Section 1. Paragraph (a) of subsection (6) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.—

(6) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met all of the following requirements:

1. Is at least 18 years of age.

2. Has completed ~~graduated from~~ an approved program.

a. For an applicant who matriculated ~~graduated~~ after December 31, 2020, has received a master's degree ~~in accordance with the Accreditation Review Commission on Education for the Physician Assistant or, before 2001, its equivalent or predecessor organization~~.

b. ~~For an applicant who graduated on or before December 31, 2020, has received a bachelor's or master's degree from an approved program.~~

~~c. For an applicant who graduated before July 1, 1994, has graduated from an approved program of instruction in primary health care or surgery.~~

39-00788A-23 2023454__

~~d. For an applicant who graduated before July 1, 1983, has received a certification as a physician assistant from the boards.~~

~~c.~~ The board may also grant a license to an applicant who does not meet the educational requirement specified in this subparagraph but who has passed the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants ~~before 1986~~.

3. Has obtained a passing score as established by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has been nationally certified. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants or its equivalent or successor organization to be eligible for licensure.

4. Has completed the application form and remitted an application fee not to exceed $300 as set by the boards. An application for licensure as a physician assistant must include:

a. A diploma from an approved program.

b. Acknowledgment of any prior felony convictions.

c. Acknowledgment of any previous revocation or denial of licensure or certification in any state.

Section 2. Paragraph (a) of subsection (6) of section 459.022, Florida Statutes, is amended to read:

459.022 Physician assistants.—

(6) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met all of the following requirements:

1. Is at least 18 years of age.

2. Has completed ~~graduated from~~ an approved program.

a. For an applicant who matriculated ~~graduated~~ after December 31, 2020, has received a master's degree ~~in accordance with the Accreditation Review Commission on Education for the Physician Assistant or, before 2001, its equivalent or predecessor organization~~.

b. ~~For an applicant who graduated on or before December 31, 2020, has received a bachelor's or master's degree from an approved program.~~

~~c. For an applicant who graduated before July 1, 1994, has graduated from an approved program of instruction in primary health care or surgery.~~

~~d. For an applicant who graduated before July 1, 1983, has received a certification as a physician assistant from the boards.~~

~~c.~~ The board may also grant a license to an applicant who does not meet the educational requirement specified in this subparagraph but who has passed the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants ~~before 1986~~.

3. Has obtained a passing score as established by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has been nationally certified. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants or its equivalent or successor organization to be eligible for licensure.

4. Has completed the application form and remitted an application fee not to exceed $300 as set by the boards. An application for licensure as a physician assistant must include:

a. A diploma from an approved program.

b. Acknowledgment of any prior felony convictions.

c. Acknowledgment of any previous revocation or denial of licensure or certification in any state.

Section 3. This act shall take effect July 1, 2023.

SENATOR Bryan Avila
39th District

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Government Oversight and Accountability, Chair
Appropriations
Appropriations Committee on Education
Appropriations Committee of Health and Human Services
Education Pre-K 12
Ethics and Elections
Health Policy
Select Committee on Resiliency
Joint Select Committee on Collective Bargaining

February 20, 2023

Honorable Senator Colleen Burton
Chair
Committee on Health Policy

Honorable Chair Burton,

I respectfully request SB 454 Physician be placed on the next committee agenda.

The bill revises the requirements for an applicant for licensure as a physician assistant.

Sincerely,

Senator Bryan Avila
Florida Senate, District 39

CC: Allen Brown, Staff Director
Daniel Looke, Committee Administrative Assistant

REPLY TO:
❒ 10001 Northwest 87th Avenue, Hialeah Gardens, Florida 33016 (305) 364-3073
❒ 326 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5039

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

Kathleen Passidomo
President of the Senate

Dennis Baxley
President Pro Tempore

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3/27/23
Meeting Date

454
Bill Number or Topic

HP
Committee

Amendment Barcode (if applicable)

Name Corinne Mixon

Phone 766 5795

Address 511 N. Adams St
Street

Email corinne@rutledge-ecen.com

Tallahassee FL 32301
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☒ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☒ I am a registered lobbyist, representing:

Florida Academy of PA's

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

DUPLICATE

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3/27/2023
Meeting Date

Health Policy
Committee

SB454
Bill Number or Topic

Amendment Barcode (if applicable)

Name Monica Rodriguez

Phone 850-577-0441

Address 201 E. Park Avenue 5th floor
Street

Email monica@ballardpartners.com

Tallahassee, FL 32301
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing: Miami Dade College

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 1232
INTRODUCER:	Senator Brodeur
SUBJECT:	Telehealth Prescribing
DATE:	March 24, 2023
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Brown	HP	**Favorable**
2.			JU	
3.			RC	

I. Summary:

SB 1232 authorizes a controlled substance listed in Schedule II of s. 893.03, F.S., to be prescribed via telehealth by a telehealth provider for the treatment of a terminal condition or for the treatment of cancer.

The bill provides an effective date of July 1, 2023.

II. Present Situation:

Telehealth

Section 456.47, F.S., defines the term "telehealth" as the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide health care services, including, but not limited to, assessment, diagnosis, consultation, treatment, and monitoring of a patient; transfer of medical data; patient and professional health-related education; public health services; and health administration. The term does not include audio-only telephone calls, e-mail messages, or facsimile transmissions.[1]

In a general sense, "synchronous" telehealth happens in live, real-time settings where the patient interacts with a provider, usually via phone or video. Providers and patients communicate directly, often resulting in a diagnosis, treatment plan, or prescription. Synchronous telehealth can include additional at-home devices such as a blood pressure or heart rate monitors, thermometers, oximeters, cameras, or scales to help the provider more accurately assess the patient's health status.[2]

[1] Section 456.47(1)(a), F.S.

[2] TELEHEALTH.HHS.GOV, *Synchronous direct-to-consumer telehealth*, https://telehealth.hhs.gov/providers/direct-to-consumer/synchronous-direct-to-consumer-telehealth/ (last visited Mar. 2, 2023).

"Asynchronous" telehealth, also known as "store-and-forward," is often used for patient intake or follow-up care. For example, a patient sends a photo of a skin condition that is later reviewed by a dermatologist who recommends treatment.[3]

Section 456.47, F.S., also authorizes out-of-state health care providers to use telehealth to deliver health care services to Florida patients if they register with the applicable board,[4] or the Department of Health (DOH) if there is no board, and meet certain eligibility requirements.[5] A registered out-of-state telehealth provider may use telehealth, within the relevant scope of practice established by Florida law and rule, to provide health care services to Florida patients, but such providers are prohibited from opening an office in Florida, and from providing in-person health care services to patients located in Florida, without first becoming licensed by the state.[6]

A telehealth provider must document in the patient's medical record the health care services rendered using telehealth according to the same standard as used for in-person services. Medical records, including video, audio, electronic, or other records generated as a result of providing such services, are confidential.[7]

The website of an out-of-state telehealth provider registered under s. 456.47, F.S., must prominently display a hyperlink to the DOH website, and the DOH website must publish a list of all out-of-state registrants and include the following information for each:

- Name.
- Health care occupation.
- Health care training and education, including completion dates and any certificates or degrees obtained.
- Out-of-state health care licenses, including license numbers.
- Florida telehealth provider registration number.
- Specialty, if any.
- Board certification, if any.
- Five years of disciplinary history, including sanctions imposed and board actions.
- Medical malpractice insurance provider and policy limits, including whether the policy covers claims that arise in Florida.
- The name and address of the registered agent designated for service of process in Florida.[8]

A health care professional may not register under s. 456.47, F.S., if his or her license to provide health care services is subject to a pending disciplinary investigation or action, or has been revoked in any state or jurisdiction. A registered health care professional must notify the appropriate board, or the DOH if there is no board, of any restrictions placed on his or her license

[3] TELEHEALTH.HHS.GOV, *Asynchronous direct-to-consumer telehealth,* https://telehealth.hhs.gov/providers/direct-to-consumer/asynchronous-direct-to-consumer-telehealth/ (last visited Mar. 2, 2023).
[4] Under s. 456.001(1), F.S., the term "board" is defined as any board, commission, or other statutorily created entity, to the extent such entity is authorized to exercise regulatory or rulemaking functions within the DOH or, in some cases, within the DOH's Division of Medical Quality Assurance (MQA).
[5] *See generally* s. 456.47(4), F.S.
[6] *See* s. 456.47(4)(f), F.S.
[7] Section 456.47(3), F.S. (referencing ss. 395.3025(4) and 456.057, F.S., in connection with confidentiality).
[8] Section 456.47(4)(c) and (4)(h), F.S.

to practice, or any disciplinary action taken or pending against him or her, in any state or jurisdiction. This notification must be provided within five business days after the restriction is placed or the disciplinary action is initiated or taken.[9]

The board, or the DOH if there is no board, may take disciplinary action against an out-of-state telehealth provider registered under s. 456.47, F.S., if the registrant:

- Fails to notify the applicable board, or the DOH if there is no board, of any adverse action taken against his or her license;
- Has restrictions placed on, or disciplinary action taken against, his or her license in any state or jurisdiction;
- Violates any of the requirements of s. 456.47, F.S.; or
- Commits any act that constitutes grounds for disciplinary action for Florida-licensed providers.[10]

Disciplinary action taken by the applicable board, or the DOH if there is no board, may include suspension or revocation of the provider's registration, or the issuance of a reprimand or letter of concern. A suspension may be accompanied by a corrective action plan as determined by the board, or the DOH if there is no board, the completion of which may lead to the suspended registration being reinstated according to rules adopted by the board, or the DOH if there is no board.[11]

Venue for civil or administrative actions initiated by the DOH, the appropriate board, or a patient who receives telehealth services from an out-of-state telehealth provider may be located in the patient's county of residence or in Leon County.[12]

A health care professional who is not licensed to provide health care services in Florida, but who holds an active license to provide health care services in another state or jurisdiction, and who provides such services using telehealth to a patient located in Florida, is not subject to the registration requirement under s. 456.47, F.S., if the services are provided:

- In response to an emergency medical condition; or
- In consultation with a health care professional licensed in Florida who has ultimate authority over the diagnosis and care of the patient.[13]

Controlled Substances

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. This chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. The scheduling of substances in Florida law is generally consistent with the federal scheduling of substances under 21 U.S.C. s. 812:

[9] Section 456.47 (4)(d), F.S.
[10] Section 456.47(4)(i), F.S. (referencing s. 456.072(1), F.S, or the applicable practice act, as the grounds for disciplinary action).
[11] *Id.*
[12] Section 456.47(5), F.S.
[13] Section 456.47(6), F.S. (referencing s. 395.002, F.S., in connection with emergency medical conditions).

- A Schedule I substance has a high potential for abuse and no currently accepted medical use in treatment in the United States and its use under medical supervision does not meet accepted safety standards. Examples include heroin and lysergic acid diethylamide (LSD).
- A Schedule II substance has a high potential for abuse, a currently accepted but severely restricted medical use in treatment in the United States, and abuse may lead to severe psychological or physical dependence. Examples include cocaine and morphine.
- A Schedule III substance has a potential for abuse less than the substances contained in Schedules I and II, a currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. Examples include lysergic acid; ketamine; and some anabolic steroids.
- A Schedule IV substance has a low potential for abuse relative to the substances in Schedule III, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule III. Examples include alprazolam, diazepam, and phenobarbital.
- A Schedule V substance has a low potential for abuse relative to the substances in Schedule IV, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule IV. Examples include low dosage levels of codeine, certain stimulants, and certain narcotic compounds.

The prescribing of controlled substances in Florida is regulated under s. 456.44, F.S. and the various practice acts and board rules. Practitioners in Florida who are authorized to prescribe controlled substances within their scope of practice include allopathic physicians ch. 458, F.S., osteopathic physicians ch. 459, F.S., podiatrists ch. 461, F.S., dentists ch. 466, F.S., physician assistants licensed under ch. 458 or ch. 459, F.S., and advanced practice registered nurses licensed under part I, ch. 464, F.S.

Controlled substance prescribing is more tightly regulated under s. 456.44, F.S., for the treatment of acute pain and chronic nonmalignant pain, primarily due to the higher potential for substance abuse and addiction. Under this section:

- "Acute pain" is defined as the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness. The term does not include pain related to cancer, a terminal condition, palliative care to provide relief of symptoms related to an incurable, progressive illness or injury, or a traumatic injury with an Injury Severity Score of 9 or greater.
- "Chronic nonmalignant pain" is defined as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of pain or more than 90 days after surgery.

Evolution of Telehealth Prescribing of Controlled Substances

When the authorization for health care practitioners to practice through telehealth was initially enacted in 2019,[14] telehealth providers were prohibited from prescribing any controlled substance unless the controlled substance was prescribed for:

[14] Chapter 2019-137, Laws of Fla.

- The treatment of a psychiatric disorder;
- Inpatient treatment at a licensed hospital;
- The treatment of a patient receiving hospice services; or
- The treatment of a resident of a nursing home facility.

In 2022,[15] this prohibition against prescribing any controlled substance unless it was for one of the four exceptions was relaxed. Under current law, the restriction applies only to Schedule II[16] drugs, so that a telehealth provider may not use telehealth to prescribe a controlled substance listed in Schedule II of the state law establishing standards and schedules for controlled substances[17] unless the controlled substance is prescribed for the following:

- The treatment of a psychiatric disorder;
- Inpatient treatment at a licensed hospital;
- The treatment of a patient receiving hospice services;[18] or
- The treatment of a resident of a nursing home facility.[19, 20]

III. Effect of Proposed Changes:

SB 1232 expands the conditions under which a telehealth provider may use telehealth to prescribe a controlled substance listed in Schedule II to include the treatment of a terminal condition as defined in s. 456.44(1)(2)2, F.S., or the treatment of cancer.

A terminal condition is defined in s. 456.44(1)(2)2, F.S., as a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible without the administration of life-sustaining procedures, and will result in death within one year after diagnosis if the condition runs its normal course.

The bill provides an effective date of July 1, 2023.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

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[15] Chapter 2022-22, Laws of Fla.

[16] Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of Schedule II drugs are: combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin. U.S. Drug Enforcement Administration, *Drug Scheduling*, https://www.dea.gov/drug-information/drug-scheduling (last visited Mar. 2, 2023).

[17] Section 893.03, F.S.

[18] Section 400.601(14). F.S., defines "hospice services" as items and services furnished to a patient and family by a hospice, or by others under arrangements with such a program, in a place of temporary or permanent residence used as the patient's home for the purpose of maintaining the patient at home; or, if the patient needs short-term institutionalization, the services must be furnished in cooperation with those contracted institutions or in the hospice inpatient facility.

[19] Section 400.021(12), F.S, defines a "nursing home facility" as any facility which provides nursing services defined and licensed under ch. 464 part I, F.S..

[20] Section 456.47(2)(c), F.S.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 456.47 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

536114

LEGISLATIVE ACTION

Senate	.	House
Comm: UNFAV	.	
03/28/2023	.	
	.	
	.	
	.	

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

Senate Amendment (with directory and title amendments)

Between lines 27 and 28
insert:

(f) Notwithstanding s. 390.0111, a telehealth provider may use telehealth to prescribe medications that provide patients with access to all legal reproductive health care options available.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:

536114

Delete line 11

and insert:

456.47, Florida Statutes, is amended, and paragraph (f) is added to that subsection, to read:

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

And the title is amended as follows:

Delete line 5

and insert:

certain controlled substances; authorizing telehealth providers to use telehealth to prescribe certain medications, notwithstanding a specified provision; providing an effective

132784

LEGISLATIVE ACTION

Senate	.	House
Comm: UNFAV	.	
03/28/2023	.	
	.	
	.	
	.	

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

Senate Amendment (with directory and title amendments)

Between lines 27 and 28
insert:
(f) Notwithstanding s. 456.52, a telehealth provider may use telehealth to prescribe medications that provide treatment to address a diagnosis of gender dysphoria if the patient is 18 years of age or older.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:

132784

Delete line 11

and insert:

456.47, Florida Statutes, is amended, and paragraph (f) is added to that subsection, to read:

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

And the title is amended as follows:

Delete line 5

and insert:

certain controlled substances; authorizing telehealth providers to use telehealth to prescribe medications for treatment to address a diagnosis of gender dysphoria in adults; providing an effective

By Senator Brodeur

10-01096A-23 20231232__

A bill to be entitled

An act relating to telehealth prescribing; amending s. 456.47, F.S.; revising the circumstances under which a telehealth provider may use telehealth to prescribe certain controlled substances; providing an effective date.

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

Section 1. Paragraph (c) of subsection (2) of section 456.47, Florida Statutes, is amended to read:

456.47 Use of telehealth to provide services.—

(2) PRACTICE STANDARDS.—

(c) A telehealth provider may not use telehealth to prescribe a controlled substance listed in Schedule II of s. 893.03 unless the controlled substance is prescribed for the following:

1. The treatment of a psychiatric disorder;

2. Inpatient treatment at a hospital licensed under chapter 395;

3. The treatment of a patient receiving hospice services as defined in s. 400.601; ~~or~~

4. The treatment of a resident of a nursing home facility as defined in s. 400.021;

5. The treatment of a terminal condition as defined in s. 456.44(1)(a)2; or

6. The treatment of cancer.

Section 2. This act shall take effect July 1, 2023.

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

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Committee on Agriculture, Environment, and General Government, *Chair*
Health Policy, *Vice Chair*
Appropriations
Appropriations Committee on Health and Human Services
Children, Families, and Elder Affairs
Community Affairs
Regulated Industries
Rules

JOINT COMMITTEE:
Joint Legislative Auditing Committee

SENATOR JASON BRODEUR
10th District

March 14, 2023

The Honorable Colleen Burton
Chair, Health Policy
318 Senate Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Chair Burton,

I respectfully request that **Senate Bill 1232**, **Telehealth Prescribing**, be placed on the agenda of the Health Policy Committee meeting to be considered at your earliest convenience.

If you have any questions or concerns, please do not hesitate to reach out to me or my office.

Sincerely,

Jason Brodeur

Senator Jason Brodeur – District 10

CC: Allen Brown – Staff Director
Anhar Al-Asadi – Administrative Assistant
Daniel Looke – Deputy Staff Director

REPLY TO:
❒ 110 Timberlachen Circle, Suite 1012, Lake Mary, Florida 32746 (407) 333-1802
❒ 405 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5010

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

KATHLEEN PASSIDOMO
President of the Senate

DENNIS BAXLEY
President Pro Tempore

The Florida Senate

APPEARANCE RECORD

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3/27/2023
Meeting Date

HEALTH POLICY
Committee

SENATE BILL 1232
Bill Number or Topic

Amendment Barcode (if applicable)

Name ZACH HOOVER

Phone 321-842-0368

Address 1414 KUHL AVE
Street

Email zach.hoover@orlandohealth.com

ORLANDO FL 32806
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☒ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☒ I am a registered lobbyist, representing:

ORLANDO HEALTH

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

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3-27-23
Meeting Date

Health Policy
Committee

1232
Bill Number or Topic

Amendment Barcode (if applicable)

Name Jarrod Fowler

Phone 850-224-6496

Address 1430 Piedmont Dr. E
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Tallahassee FL 32308
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☒ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☒ I am a registered lobbyist, representing: Florida Medical Association

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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Meeting Date

Health Policy
Committee

1232
Bill Number or Topic

Amendment Barcode (if applicable)

Name Chris Nuland

Phone 904-233-3051

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Address 4427 Herschel St
Street

Jacksonville, FL 32210
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:

Florida Chapter, American College of Physicians

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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Health Policy
Committee

SB 1232
Bill Number or Topic

Amendment Barcode (if applicable)

Name Clay Meenan

Phone 682-276-5245

Email claym@fha.org

Address 306 E College Ave
Street

Tallahassee FL 32312
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
Florida Hospital Association

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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3-27-23
Meeting Date

Health Policy
Committee

1232
Bill Number or Topic

Amendment Barcode (if applicable)

Name Justin Senior

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Email justin@snhaf.net

Address 125 S. Gadsden St.
Street

Tallahassee FL 32301
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing: SNHAF Safety Net Hospital Alliance

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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03/27/2003	1232
Meeting Date	Bill Number or Topic
Health Policy	
Committee	Amendment Barcode (if applicable)

Name AARP - Ivonne Fernandez

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Address 215 S Monroe Street - 605
Street

Email ifernandez@aarp.org

Tallahassee FL
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:

AARP

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

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3/27/2023
Meeting Date

Health Policy
Committee

1232
Bill Number or Topic

Amendment Barcode (if applicable)

Name Ellen Navarro Anderson

Phone

Address
Street

Email ellen.anderson@moffitt.org

City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
Moffitt Cancer Center

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 344
INTRODUCER:	Health Policy Committee and Senator Brodeur
SUBJECT:	Physician Certifications for the Medical Use of Marijuana
DATE:	March 29, 2023 REVISED:

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 344 amends s. 381.986, F.S., to allow a qualified physician to conduct an examination for a renewal of a physician certification for medical marijuana by telehealth if he or she is the qualified physician who performed the initial in-person examination.

The bill also authorizes the Department of Health (DOH) to suspend a qualified physician's registration in the medical marijuana use registry for up to two years if he or she fails to comply with any of the statutory requirements for medical marijuana or provides, advertises, or markets telehealth services before July 1, 2023.

The bill provides an effective date of July 1, 2023.

II. Present Situation:

Medical Marijuana General Background

Amendment 2 and Implementing Statutes

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

- Qualifying patients who medically use marijuana in compliance with the amendment;

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

Subsequently, the Legislature passed SB 8-A in Special Session A of 2017.[1] The bill revised the Compassionate Medical Cannabis Act of 2014[2] in s. 381.986, F.S., to implement Article X, section 29 of the State Constitution.

Physician Certifications for Medical Marijuana

Subsection (4) of s. 381.986, F.S., establishes the requirements for a qualified physician[3] to issue a physician certification for medical marijuana. A qualified physician may only issue a physician certification if he or she:

- Conducted a physical examination while physically present in the same room as the patient and a full assessment of the medical history of the patient.
- Diagnosed the patient with at least one qualifying medical condition.
- Determined that the medical use of marijuana would likely outweigh the potential health risks for the patient, and such determination must be documented in the patient's medical record. If a patient is younger than 18 years of age, a second physician must concur with this determination, and such concurrence must be documented in the patient's medical record.
- Determined whether the patient is pregnant and documented such determination in the patient's medical record.
- Reviewed the patient's controlled substance prescription history in the prescription drug monitoring program database established pursuant to s. 893.055, F.S.
- Reviews the medical marijuana use registry and confirms that the patient does not have an active physician certification from another qualified physician.
- Registers as the issuer of the physician certification for the named qualified patient on the medical marijuana use registry in an electronic manner determined by the DOH and maintains such registration as required by the section.
- Obtains the voluntary and informed written consent, on a form prescribed by the DOH of the patient for medical use of marijuana each time the qualified physician issues a physician certification for the patient.

The subsection also requires the qualified physician to submit specified documentation to the Board of Medicine related to issuing certifications for medical conditions of the same kind or class as the listed conditions and issuing certifications for smoking medical marijuana. A physician may only issue a physician certification for smoking to a minor patient if that patient has a terminal condition and meets other specified criteria.

A physician may issue a physician certification for up to three 70-day supply limits of marijuana or six 35-day supply limits of marijuana in a form for smoking. The DOH is required to establish

[1] Chapter 2017-232, Laws of Fla.
[2] Chapter 2014-157, Laws of Fla.
[3] Defined as "a person who holds an active, unrestricted license as an allopathic physician under chapter 458 or as an osteopathic physician under chapter 459 and is in compliance with the physician education requirements" of the section.

daily dose limits by rule and a physician may request an exemption from the daily dose limits for a specified qualified patient by submitting a request form to the DOH.

A physician must evaluate an existing qualified patient at least once every 30 weeks before issuing a new physician certification. This evaluation must meet the criteria above for issuing a physician certification, including that the examination be conducted in person, and the physician must:

- Determine whether the patient still meets the criteria for a physician certification;
- Identify and document in the patient's medical record whether the patient has experienced adverse drug interactions with other medications or a reduction in the use of, or dependence on, other types of controlled substances; and
- Submit a report to the DOH with such findings.

As of March 17, 2023, there are 2,540 qualified physicians in Florida and 800,356 qualified patients.[4] The average cost for an examination to obtain a physician certification varies from physician to physician. One website indicated that the cost can range from $350-$600 per year[5] while another indicated that the costs average around $150 per visit.[6] Yet another site offered initial appointments at $199, renewal appointments at $169, and offered a membership plan for $29 per month plus a $50 application fee.[7] In addition to the cost of the physician's examination, a qualified patient is also required to pay a $75 application fee to the DOH to obtain his or her medical marijuana use identification card.

Telehealth

Telehealth is a mechanism for delivery of health care services. Health care professionals use telehealth as a platform to provide traditional health care services in a non-traditional manner. These services include, among others, preventative medicine and the treatment of chronic conditions.[8] Section 456.74, F.S., enacted in 2019, regulates the use of telehealth by Florida and out-of-state health care providers.

Current law broadly defines telehealth as the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide health care services, including, but not limited to:[9]

- Assessment, diagnosis, consultation, treatment, and monitoring of a patient;
- Transfer of medical data;
- Patient and professional health-related education;
- Public health services; and

[4] Office of Medical Marijuana Use Weekly Update, March 17, 2023, available at https://knowthefactsmmj.com/wp-content/uploads/ommu_updates/2023/031723-OMMU-Update.pdf, (last visited Mar. 23, 2023).
[5] See https://www.mmtcfl.com/florida-medical-marijuana-card-cost/, (last visited Mar. 23, 2023).
[6] See https://www.calmeffect.com/how-much-does-it-cost-to-get-a-medical-marijuana-card-in-florida/#:~:text=What%20Do%20Doctors%20in%20Florida,need%20to%20see%20the%20doctor., (last visited March 23, 2023)/
[7] See https://marijuanadoctor.com/pricing, (last visited March 23, 2023).
[8] U.S. Department of Health and Human Services, *Report to Congress: E-Health and Telemedicine* (August 12, 2016), available at https://aspe.hhs.gov/system/files/pdf/206751/TelemedicineE-HealthReport.pdf (last visited Mar. 23, 2023).
[9] S. 456.47(1)(a), F.S.

- Health administration.

A patient receiving telehealth services may be in any location at the time services are rendered and a telehealth provider may be in any location when providing telehealth services to a patient.

Health care services may be provided via telehealth by a Florida-licensed health care practitioner, a practitioner licensed under a multistate health care licensure compact of which Florida is a member,[10] or an out-of-state-health care provider who registers with the DOH.[11]

Current law requires telehealth providers to meet the same standard of care required for in-person health care services to patients in this state. This ensures that a patient receives the same standard of care irrespective of the modality used by the health care professional to deliver the services.[12]

III. Effect of Proposed Changes:

CS/SB 344 amends s. 381.986, F.S., to specify that an initial examination for a physician certification for medical marijuana must be conducted in-person with the patient but that for a certification renewal, the examination may be conducted through telehealth as defined in s. 456.47, F.S., provided it is with the same qualified physician who performed the initial exam.

The bill also authorizes the DOH to suspend a qualified physician's registration in the medical marijuana use registry for up to two years if he or she fails to comply with any of the statutory requirements for medical marijuana or provides, advertises, or markets telehealth services before July 1, 2023.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

[10] Florida is a member of the Nurse Licensure Compact. *See* s. 464.0095, F.S.
[11] S. 456.47(4), F.S.
[12] S. 456.47(2), F.S.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 344 may have an indeterminate positive fiscal impact on qualified patients who are able to have their physician certification renewal examinations conducted via telehealth and on the qualified physicians who are authorized to conduct such examinations via telehealth.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 381.986 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy March 27, 2023:
The CS specifies that a renewal exam for medical marijuana conducted by telehealth must be conducted by the same qualified physician who conducted the initial exam. The CS also adds a provision allowing the DOH to suspend a qualified physician's registration with the medical marijuana use registry for up to two years if he or she violates the provisions of s. 381.986, F.S.; or provides, advertises, or markets telehealth services before July 1, 2023.

B. Amendments:

None.

889518

LEGISLATIVE ACTION

Senate	.	House
Comm: RS	.	
03/28/2023	.	
	.	
	.	
	.	

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

Senate Amendment (with directory and title amendments)

Delete lines 23 - 104
and insert:
defined in s. 456.47, provided it is with the qualified physician or practice group that performed the initial in-person examination.

2. Diagnosed the patient with at least one qualifying medical condition.

3. Determined that the medical use of marijuana would

889518

likely outweigh the potential health risks for the patient, and such determination must be documented in the patient's medical record. If a patient is younger than 18 years of age, a second physician must concur with this determination, and such concurrence must be documented in the patient's medical record.

4. Determined whether the patient is pregnant and documented such determination in the patient's medical record. A physician may not issue a physician certification, except for low-THC cannabis, to a patient who is pregnant.

5. Reviewed the patient's controlled drug prescription history in the prescription drug monitoring program database established pursuant to s. 893.055.

6. Reviews the medical marijuana use registry and confirmed that the patient does not have an active physician certification from another qualified physician.

7. Registers as the issuer of the physician certification for the named qualified patient on the medical marijuana use registry in an electronic manner determined by the department, and:

a. Enters into the registry the contents of the physician certification, including the patient's qualifying condition and the dosage not to exceed the daily dose amount determined by the department, the amount and forms of marijuana authorized for the patient, and any types of marijuana delivery devices needed by the patient for the medical use of marijuana.

b. Updates the registry within 7 days after any change is made to the original physician certification to reflect such change.

c. Deactivates the registration of the qualified patient

and the patient's caregiver when the physician no longer recommends the medical use of marijuana for the patient.

8. Obtains the voluntary and informed written consent of the patient for medical use of marijuana each time the qualified physician issues a physician certification for the patient, which shall be maintained in the patient's medical record. The patient, or the patient's parent or legal guardian if the patient is a minor, must sign the informed consent acknowledging that the qualified physician has sufficiently explained its content. The qualified physician must use a standardized informed consent form adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine, which must include, at a minimum, information related to:

a. The Federal Government's classification of marijuana as a Schedule I controlled substance.

b. The approval and oversight status of marijuana by the Food and Drug Administration.

c. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

d. The potential for addiction.

e. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

f. The potential side effects of marijuana use, including the negative health risks associated with smoking marijuana.

g. The risks, benefits, and drug interactions of marijuana.

889518

h. That the patient's deidentified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

(g) A qualified physician must evaluate an existing qualified patient at least once every 52 ~~30~~ weeks before issuing a new physician certification. The evaluation may be conducted through telehealth as defined in s. 456.47, provided it is with the qualified physician or practice group that performed the initial in-person examination of the qualified patient. A physician must:

1. Determine if the patient still meets the requirements to be issued a physician certification under paragraph (a).

2. Identify and document in the qualified patient's medical records whether the qualified patient experienced either of the following related to the medical use of marijuana:

a. An adverse drug interaction with any prescription or nonprescription medication; or

b. A reduction in the use of, or dependence on, other types of controlled substances as defined in s. 893.02.

3. Submit a report with the findings required pursuant to subparagraph 2. to the department. The department shall submit such reports to the Consortium for Medical Marijuana Clinical Outcomes Research established pursuant to s. 1004.4351.

(i) The department shall monitor physician registration in the medical marijuana use registry and the issuance of physician certifications for practices that could facilitate unlawful diversion or misuse of marijuana or a marijuana delivery device and shall take disciplinary action as appropriate. The department may suspend the registration of a qualified physician

889518

in the medical marijuana use registry for a period of up to 2 years if the qualified physician:

1. Fails to comply with this section; or

2. Provides, advertises, or markets telehealth services before July 1, 2023.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======

And the directory clause is amended as follows:

Delete line 11

and insert:

Section 1. Paragraphs (a), (g), and (i) of subsection (4) of

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

And the title is amended as follows:

Delete line 7

and insert:

use of marijuana under certain circumstances; revising the frequency with which qualified physicians must reevaluate qualified patients for purposes of issuing new certifications; authorizing the Department of Health to suspend the registration of a qualified physician in the medical marijuana use registry for a specified timeframe under certain circumstances; providing an effective date.

958848

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/28/2023	.	
	.	
	.	
	.	

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

Senate Substitute for Amendment (889518) (with directory and title amendments)

Delete lines 23 - 104
and insert:
defined in s. 456.47, provided it is with the qualified physician who performed the initial in-person examination.

2. Diagnosed the patient with at least one qualifying medical condition.

3. Determined that the medical use of marijuana would

likely outweigh the potential health risks for the patient, and such determination must be documented in the patient's medical record. If a patient is younger than 18 years of age, a second physician must concur with this determination, and such concurrence must be documented in the patient's medical record.

4. Determined whether the patient is pregnant and documented such determination in the patient's medical record. A physician may not issue a physician certification, except for low-THC cannabis, to a patient who is pregnant.

5. Reviewed the patient's controlled drug prescription history in the prescription drug monitoring program database established pursuant to s. 893.055.

6. Reviews the medical marijuana use registry and confirmed that the patient does not have an active physician certification from another qualified physician.

7. Registers as the issuer of the physician certification for the named qualified patient on the medical marijuana use registry in an electronic manner determined by the department, and:

a. Enters into the registry the contents of the physician certification, including the patient's qualifying condition and the dosage not to exceed the daily dose amount determined by the department, the amount and forms of marijuana authorized for the patient, and any types of marijuana delivery devices needed by the patient for the medical use of marijuana.

b. Updates the registry within 7 days after any change is made to the original physician certification to reflect such change.

c. Deactivates the registration of the qualified patient

and the patient's caregiver when the physician no longer recommends the medical use of marijuana for the patient.

8. Obtains the voluntary and informed written consent of the patient for medical use of marijuana each time the qualified physician issues a physician certification for the patient, which shall be maintained in the patient's medical record. The patient, or the patient's parent or legal guardian if the patient is a minor, must sign the informed consent acknowledging that the qualified physician has sufficiently explained its content. The qualified physician must use a standardized informed consent form adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine, which must include, at a minimum, information related to:

a. The Federal Government's classification of marijuana as a Schedule I controlled substance.

b. The approval and oversight status of marijuana by the Food and Drug Administration.

c. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

d. The potential for addiction.

e. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

f. The potential side effects of marijuana use, including the negative health risks associated with smoking marijuana.

g. The risks, benefits, and drug interactions of marijuana.

h. That the patient's deidentified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

(g) A qualified physician must evaluate an existing qualified patient at least once every 30 weeks before issuing a new physician certification. The evaluation may be conducted through telehealth as defined in s. 456.47, provided it is with the qualified physician who performed the initial in-person examination of the qualified patient. A physician must:

1. Determine if the patient still meets the requirements to be issued a physician certification under paragraph (a).

2. Identify and document in the qualified patient's medical records whether the qualified patient experienced either of the following related to the medical use of marijuana:

a. An adverse drug interaction with any prescription or nonprescription medication; or

b. A reduction in the use of, or dependence on, other types of controlled substances as defined in s. 893.02.

3. Submit a report with the findings required pursuant to subparagraph 2. to the department. The department shall submit such reports to the Consortium for Medical Marijuana Clinical Outcomes Research established pursuant to s. 1004.4351.

(i) The department shall monitor physician registration in the medical marijuana use registry and the issuance of physician certifications for practices that could facilitate unlawful diversion or misuse of marijuana or a marijuana delivery device and shall take disciplinary action as appropriate. The department may suspend the registration of a qualified physician in the medical marijuana use registry for a period of up to 2

958848

years if the qualified physician:

1. Fails to comply with this section; or

2. Provides, advertises, or markets telehealth services before July 1, 2023.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======

And the directory clause is amended as follows:

Delete line 11

and insert:

Section 1. Paragraphs (a), (g), and (i) of subsection (4) of

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

And the title is amended as follows:

Delete line 7

and insert:

use of marijuana, subject to certain conditions; authorizing the Department of Health to suspend the registration of a qualified physician in the medical marijuana use registry for a specified timeframe for noncompliance with the act; providing an effective date.

By Senator Brodeur

10-00320-23 2023344__

A bill to be entitled

An act relating to physician certifications for the medical use of marijuana; amending s. 381.986, F.S.; authorizing qualified physicians to perform patient examinations and evaluations through telehealth for renewals of physician certifications for the medical use of marijuana; providing an effective date.

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

Section 1. Paragraphs (a) and (g) of subsection (4) of section 381.986, Florida Statutes, are amended to read:

381.986 Medical use of marijuana.—

(4) PHYSICIAN CERTIFICATION.—

(a) A qualified physician may issue a physician certification only if the qualified physician:

1. Conducted an ~~a physical~~ examination of ~~while physically present in the same room as~~ the patient and a full assessment of the medical history of the patient. For an initial certification, the examination must be a physical examination conducted in person with the patient. For a certification renewal, the examination may be conducted through telehealth as defined in s. 456.47.

2. Diagnosed the patient with at least one qualifying medical condition.

3. Determined that the medical use of marijuana would likely outweigh the potential health risks for the patient, and such determination must be documented in the patient's medical record. If a patient is younger than 18 years of age, a second

10-00320-23 2023344__

physician must concur with this determination, and such concurrence must be documented in the patient's medical record.

4. Determined whether the patient is pregnant and documented such determination in the patient's medical record. A physician may not issue a physician certification, except for low-THC cannabis, to a patient who is pregnant.

5. Reviewed the patient's controlled drug prescription history in the prescription drug monitoring program database established pursuant to s. 893.055.

6. Reviews the medical marijuana use registry and confirmed that the patient does not have an active physician certification from another qualified physician.

7. Registers as the issuer of the physician certification for the named qualified patient on the medical marijuana use registry in an electronic manner determined by the department, and:

a. Enters into the registry the contents of the physician certification, including the patient's qualifying condition and the dosage not to exceed the daily dose amount determined by the department, the amount and forms of marijuana authorized for the patient, and any types of marijuana delivery devices needed by the patient for the medical use of marijuana.

b. Updates the registry within 7 days after any change is made to the original physician certification to reflect such change.

c. Deactivates the registration of the qualified patient and the patient's caregiver when the physician no longer recommends the medical use of marijuana for the patient.

8. Obtains the voluntary and informed written consent of

the patient for medical use of marijuana each time the qualified physician issues a physician certification for the patient, which shall be maintained in the patient's medical record. The patient, or the patient's parent or legal guardian if the patient is a minor, must sign the informed consent acknowledging that the qualified physician has sufficiently explained its content. The qualified physician must use a standardized informed consent form adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine, which must include, at a minimum, information related to:

a. The Federal Government's classification of marijuana as a Schedule I controlled substance.

b. The approval and oversight status of marijuana by the Food and Drug Administration.

c. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

d. The potential for addiction.

e. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

f. The potential side effects of marijuana use, including the negative health risks associated with smoking marijuana.

g. The risks, benefits, and drug interactions of marijuana.

h. That the patient's deidentified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

(g) A qualified physician must evaluate an existing qualified patient at least once every 30 weeks before issuing a new physician certification. The evaluation may be conducted through telehealth as defined in s. 456.47. A physician must:

1. Determine if the patient still meets the requirements to be issued a physician certification under paragraph (a).

2. Identify and document in the qualified patient's medical records whether the qualified patient experienced either of the following related to the medical use of marijuana:

a. An adverse drug interaction with any prescription or nonprescription medication; or

b. A reduction in the use of, or dependence on, other types of controlled substances as defined in s. 893.02.

3. Submit a report with the findings required pursuant to subparagraph 2. to the department. The department shall submit such reports to the Consortium for Medical Marijuana Clinical Outcomes Research established pursuant to s. 1004.4351.

Section 2. This act shall take effect July 1, 2023.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Committee on Agriculture, Environment, and General Government, *Chair*
Health Policy, *Vice Chair*
Appropriations
Appropriations Committee on Health and Human Services
Children, Families, and Elder Affairs
Community Affairs
Regulated Industries
Rules

JOINT COMMITTEE:
Joint Legislative Auditing Committee

SENATOR JASON BRODEUR
10th District

February 10, 2023

The Honorable Colleen Burton
Chair, Committee on Health Policy
318 Senate Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Chair Burton,

I respectfully request that **Senate Bill 344**, **Physician Certifications for the Medical Use of Marijuana**, be placed on the agenda of the Health Policy Committee meeting to be considered at your earliest convenience.

If you have any questions or concerns, please do not hesitate to reach out to me or my office.

Sincerely,

Senator Jason Brodeur – District 10

CC: Allen Brown – Staff Director
Anhar Al-Asadi – Administrative Assistant
Daniel Looke – Deputy Staff Director

REPLY TO:
❒ 110 Timberlachen Circle, Suite 1012, Lake Mary, Florida 32746 (407) 333-1802
❒ 405 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5010

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

KATHLEEN PASSIDOMO
President of the Senate

DENNIS BAXLEY
President Pro Tempore

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

March 27, 2023
Meeting Date

Health Policy
Committee

344
Bill Number or Topic

958848
Amendment Barcode (if applicable)

Name Dr. Ajay Desai

Phone 863-816-3449

Address 1046 South Florida Avenue
Street

Email addes05@gmail.com

Lakeland FL 33803
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3/27/23
Meeting Date

Health Policy
Committee

SB 344
Bill Number or Topic

Amendment Barcode (if applicable)

Name Ron Watson

Phone 850 567-1202

Address 9114 Feather Lane
Street

Email Watson.strategies@comcast.net

Tallahassee FL 32317
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☒ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☒ I am a registered lobbyist, representing:

MÜV (move)

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

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MARCH 27, 2023
Meeting Date

HEALTH POLICY
Committee

344
Bill Number or Topic

Amendment Barcode (if applicable)

Name DR. AJAY DESAI

Phone (863) 816-3449

Address 1046 Florida Avenue South
Street

Email ajdes05@gmail.com1046 Florida

LAKELAND FL 33803
City *State* *Zip*

Speaking: ☐ For ☐ Against ☑ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3/27/23
Meeting Date

Health Policy
Committee

344
Bill Number or Topic

Amendment Barcode (if applicable)

Name Bob Lotane

Phone 850-544-9444

Address
Street

Email Robertl[illegible]

Tallahassee, FL
City State Zip

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3/27/23
Meeting Date

Health Policy
Committee

344
Bill Number or Topic

Amendment Barcode (if applicable)

Name Jodi James

Phone 321 890 7302

Address 1375 Cypress
Street

Email jodi@FLCANN.org

Melbourne FL 32935
City State Zip

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☒ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:
FL CANNABIS Action Network

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3/27/23
Meeting Date

Health Policy
Committee

344
Bill Number or Topic

889518
Amendment Barcode (if applicable)

Name Jodi James

Phone 321 890 7302

Address 1375 Cypress Ave
Street

Email jodi@flcan.org

Melbourne 32935
City *State* *Zip*

Speaking: ☒ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☒ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:
FL Cannabis Action Network

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 1550
INTRODUCER:	Health Policy Committee and Senator Brodeur, and others.
SUBJECT:	Prescription Drugs
DATE:	March 29, 2023 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Brown	HP	**Fav/CS**
2.			FP	
3.				

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1550 addresses the transparency of a manufacturer's prescription drug price increases above certain thresholds and the relationships between pharmacy benefit managers, pharmacy benefits plans and programs, and pharmacy providers for delivering pharmacy services to covered persons.

The bill requires prescription drug manufacturers and nonresident prescription drug manufacturers to disclose reportable prescription drug price increases. This information will be published on the Florida Health Finder website. A reportable prescription drug price increase refers to a prescription drug with a wholesale acquisition cost of at least $100 for a course of therapy before the effective date of the increase, and the bill requires the following to be reported:

- Any increase of 15 percent or more of the wholesale acquisition cost during the preceding 12-month period; or
- Any increase of 40 percent or more of the wholesale acquisition cost during the preceding three calendar years.

The bill requires pharmacy benefit managers (PBMs) to obtain a certificate of authority for an administrator under the Florida Insurance Code (FIC) and makes them subject to existing and enhanced requirements as set forth in the bill under the FIC. The bill proscribes and prescribes certain disclosures and actions governing contractual relationships between PBMs and pharmacy benefits plans and programs and also between PBMs and pharmacy providers.

The bill provides a $1 million appropriation to the Office of Insurance Regulation.

The bill provides an effective date of July 1, 2023.

II. Present Situation:

Prescription drugs can dramatically improve a person's quality of life, with some therapies being the only thing separating a person from death – but the price can be steep.[1] In 2021, the U.S. health care system spent $421 billion on retail prescription drugs. As reflected in the chart below, spending growth on drugs was largely due to growth in spending per prescription, and to a lesser extent by increased utilization (i.e., more prescriptions). The following chart depicts prescription drug expenditures (in inflation-adjusted dollars) and the number of retail prescriptions from 2016-2021.[2]

	Retail Expenditures, Billions ($)	Retail Prescriptions, Millions (#)
2016	374	4,816
2017	369	4,923
2018	377	5,118
2019	389	5,243
2020	406	4,970
2021	421	5,089
% Change, 2016-2021	12.5%	5.7%

Source: ASPE analysis of IQVIA National Sales Perspective (NSP) Data

Four locations of sale for retail drug expenditures are reported in the chart above – chain store pharmacy, mail-order pharmacy, independent pharmacy, and food store pharmacy. Three of the four locations experienced an increase in sales between 2016 and 2021. Expenditures increased by 4 percent in chain store pharmacies, 35 percent for mail order pharmacies, and 1 percent for food store pharmacies, but decreased 5 percent for independent pharmacies.[3]

Pharmacy Benefit Managers

PBMs are companies that manage prescription drug benefits on behalf of pharmacy benefit plans or programs (health insurers, Medicare Part D drug plans, large employers, state health plans, and other payers).[4] Key PBM functions may include administration and management of prescription drug benefits; developing and maintaining formularies; negotiating discounts and

[1] *See* NCSL State Policy Options and Pharmacy Benefit Managers (PBMs) updated March 23, 2022, available at: https://www.ncsl.org/health/state-policy-options-and-pharmacy-benefit-managers (last visited Mar. 23, 2023).
[2] Parasrampuria, S. and Murphy, S. Trends in Prescription Drug Spending, 2016-202. Washing, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. September 2022, available at: https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf (last visited Mar. 23, 2023).
[3] *Id.*
[4] The Commonwealth Fund, Pharmacy Benefit Managers and Their Role in Drug Spending, (April 22, 2019) available at: https://www.commonwealthfund.org/sites/default/files/2019-04/Explainer_PBMs_1.pdf (last visited Mar. 23, 2023).

rebates between payers and pharmaceutical manufacturers; providing access to a contracted pharmacy network; real-time pharmacy claims processing; and performing utilization management, retroactive claims review, prior authorization, and other medication management programs.[5]

The three largest PBMs control about 80 percent of the total PBM market. In 2021, CVS Caremark led the industry, controlling 34 percent of total adjusted claims, followed by Express Scripts (25%) and Optum Rx (21%). The next group includes Humana's in-house PBM (8%), Prime Therapeutics LLC (6%) and MedImpact (4%). Approximately 60 smaller PBMs also participate in the marketplace.[6]

The FTC announced on June 7, 2022, that it would launch an investigation into contracting and other business practices in the PBM industry, requiring CVS Caremark, Express Scripts, Inc., OptumRx, Inc., Humana Inc., Prime Therapeutics LLC, and MedImpact Healthcare Systems, Inc., to provide information and records regarding their business practices.[7] The announcement frames the inquiry as follows:

> The Commission's inquiry will examine PBMs' role at the center of the U.S. pharmaceutical system. PBMs are the middlemen who are hired to negotiate rebates and fees with drug manufacturers, create drug formularies and surrounding policies, and reimburse pharmacies for patients' prescriptions. The largest PBMs are now vertically integrated with the largest health insurance companies and wholly owned mail order and specialty pharmacies.
>
> In these roles, pharmacy benefits managers often have enormous influence on which drugs are prescribed to patients, which pharmacies patients can use, and how much patients ultimately pay at the pharmacy counter. Many of these functions depend on highly complicated, opaque contractual relationships that are difficult or impossible to understand for patients and independent businesses across the prescription drug system.
>
> The inquiry is aimed at shedding light on several practices that have drawn scrutiny in recent years including:
> - Fees and clawbacks charged to unaffiliated pharmacies;
> - Methods to steer patients towards PBM-owned pharmacies;
> - Potentially unfair audits of independent pharmacies;
> - Complicated and opaque methods to determine pharmacy reimbursement;

[5] U.S. Pharmacist, State PBM Regulations Protecting Community Pharmacies, (August 16, 2022) *US Pharm. 2022;47(8):21-25* available at: https://www.uspharmacist.com/article/state-pbm-regulations-protecting-community-pharmacies (last visited Mar. 23, 2023).
[6] Managed Healthcare Executive: Beyond the Big Three PBMs, (December 14, 2022), *MHE December 2022, Vol 32, Issue 12*, available at: https://www.managedhealthcareexecutive.com/view/beyond-the-big-three-pbms (last visited Mar. 23, 2023).
[7] Federal Trade Commission: FTC Launches Inquiry Into Prescription Drug Middlemen Industry, Agency to Scrutinize the Impact of Vertically Integrated Pharmacy Benefit Managers on the Access and Affordability of Medicine (June 7, 2022) available at: https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry (last visited Mar. 23, 2023).

- The prevalence of prior authorizations and other administrative restrictions;
- The use of specialty drug lists and surrounding specialty drug policies; and
- The impact of rebates and fees from drug manufacturers on formulary design and costs of prescription drugs to payers and patients.

Minnesota Attorney General Keith Ellison is participating in a bipartisan coalition of at least 35 attorneys general[8] from across the country in an amicus brief to the Tenth Circuit Court of Appeals supporting Oklahoma's laws that regulate abusive behavior of PBMs. In his press release announcing his participation in the coalition, he states: [9]

> … PBMs profit from fees charged to market participants and by reimbursing pharmacies less than the PBM is paid by plans for dispensing medications. PBMs have imposed self-serving protections that reduce competition, limit prescription medication access, and impose various confidentiality requirements. For example, PBMs have tried to force consumers to use PBM-affiliated pharmacies at the expense of independent, often more convenient, pharmacies, by giving consumers preferential rates if they use a PBM-affiliated pharmacy, or by denying coverage at non-affiliated pharmacies altogether.

Regulation and Registration of PBMs in Florida

PBMs that contract to administer prescription drug benefits on behalf of a health insurer or health maintenance organization to residents of Florida have been required to register with the Office of Insurance Regulation (OIR) pursuant to s. 624.490, F.S., since 2019. To initially register, a PBM must submit incorporation of similar documents, identifying information pertaining to officers and directors, and non-refundable fee of $5.00.[10] The statute authorizes a fee not to exceed $500, but it restricts fees from exceeding the cost of administering the registration process.

The registration certificate is valid for two years after its date of issue. Renewal requires submission of organizational documents if any changes have occurred, a completed registration application form, and a renewal fee of $5.00. Similarly, the statute authorizes a renewal fee not to exceed $500, but the same restriction applies to the amount of the renewal fee as it does to the initial fee.

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[8] The jurisdictions participating include: Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Texas, Utah, Virginia, Washington, and the District of Columbia. *See* Pharmaceutical Care Management Association vs. Glen Mulready et. al., Brief of Amici Curiae; in the US Court of Appeals for the Tenth Circuit (No. 22-6074) available at: https://www.ag.state.mn.us/Office/Communications/2022/docs/PCMA_AmicusBrief.pdf (last visited Mar 22, 2023).

[9] *See* The Office of Minnesota Attorney General Keith Ellison, Attorney General Ellison leads bipartisan coalition to regulate abusive practices of pharmacy benefit manager (October 18, 2022); available at: https://www.ag.state.mn.us/Office/Communications/2022/10/18_PCMA.asp (last visited Mar 22, 2023).

[10] See Florida Office of Insurance Regulation Pharmacy Benefit Managers Registration and Renewal, https://www.floir.com/Sections/AppCoord/is_ac_PBM.aspx (last visited Mar 22, 2023).

A person who fails to register with the office while operating as a PBM is subject to a fine of $10,000 for each violation. The OIR does not have explicit authority to conduct examinations of a PBM, suspend or revoke a PBM's registration, or impose a fine or civil penalty if a registered PBM violates Florida Statutes.[11]

Currently, there are 71 PBMs registered in Florida.[12]

Other States' PBM Laws

All 50 states have enacted some form of licensure, registration, and regulation pertaining to PBMs.[13] Common themes, some or all of which may be in included in a state's law are:

- Prohibiting spread pricing. Spread pricing is typically demonstrated by a PBM reimbursing a pharmacy a lower amount than the amount the pharmacy benefits plan or program (plan or program) paid the PBM, with the PBM retaining the difference.
- Ensuring adequate pharmacy networks that are based on reasonably available retail pharmacies for patients without basing adequacy on mail-order pharmacies.
- Prohibiting PBMs from implementing arbitrary or excessive accreditation or credentialing requirements.
- Prohibiting patient steering. Patient steering can include, but is not limited to, requiring or incentivizing a patient to use a pharmacy, specialty pharmacy, or mail-order pharmacy that is affiliated (through some form of ownership interest) with the PBM or by using certain advertising practices.
- Requiring PBMs that negotiate rebates from manufacturers on behalf of the plan or program to pass all or most of the rebate amount to the plan or program to reduce premiums or to be used to reduce the cost-sharing amount the patient pays for the drug at the pharmacy.
- Banning gag clauses that restrict or penalize pharmacists for disclosing certain information to patients such as lower cost options or other alternatives, or for disclosing information to regulatory authorities.
- Prohibiting retroactive claim adjustments, such as certain clawbacks or other recoupments that reduce the amount paid by the PBM to the pharmacy but are not based on error or similar conditions.
- Requiring fair auditing procedures and appeal opportunities.
- Requiring reasonable reimbursement rates and appeal opportunities to reimbursements.
- Limiting the fees a PBM charges to a pharmacy for such things as network participation or claim adjudication.
- Providing regulatory enforcement authority for state agencies.

[11] The Office of Insurance Regulation 2023 Agency Legislative Bill Analysis for SB 1550, dated March 23, 2023.
[12] *See* The Senate Health Policy Committee recording for February 6, 2023, presentation by Kevin Jacobs from OIR at or about the 3:38 minute mark, recording available at: https://flsenate.gov/media/videoplayer?EventID=1_ky7xx6qg-202302061530&Redirect=true.
[13] *See:* National Conference of State Legislatures: State Policy Options and Pharmacy Benefit Managers, (updated March 23, 2022) available at: State Policy Options and Pharmacy Benefit Managers (ncsl.org) (last visited Mar 22, 2023) and National Community Pharmacists Association's Excel spreadsheet entitled PBM laws by state with cites available at: https://ncpa.org/how-states-protect-pharmacy-and-patients-pbm-abuses (last visited Mar 22, 2023).

Several states have enacted comprehensive laws regulating pharmacy benefit plans or programs and PBMs. Two such states are Arkansas and Oklahoma. A summary of their laws are presented below.

Arkansas

Arkansas' law[14] became effective September 1, 2018. It requires PBMs to be licensed by the Insurance Commissioner (commissioner) who has enforcement authority for a PBM's compliance with the law. Among other provisions, it addresses:

- Network adequacy. PBMs must provide a reasonably adequate and accessible network and a mail-order pharmacy may not be included in the calculations for determining network adequacy.
- Prohibits a PBM from conducting spread pricing.
- Requires PBMs to report quarterly to the commissioner for each health care payer [plan or program]:
  - The individual and aggregate amount paid by the healthcare payer to the PBM for pharmacist services and the individual and aggregate amount the PBM paid for pharmacist services, both itemized by pharmacy, by product, and by goods and services. The commissioner may review and approve the compensation program of a PBM with a health benefit plan to ensure that the reimbursement for pharmacist services paid to a pharmacist or pharmacy is fair and reasonable to provide an adequate network for a health benefit plan.
  - The aggregate amount of rebates received and distributed to the healthcare payer.
  - The aggregate amount of rebates passed on to the enrollees of the healthcare payer at the point of sale that reduced the enrollees' applicable cost-sharing amount.
  - The information in these quarterly reports, the information in the compensation program review, and the data acquired in an examination are not subject to the Freedom of Information Act under Arkansas law.
- Prohibiting a PBM from:
  - Using any advertisements, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading;
  - Charging a pharmacist or pharmacy a fee related to adjudication of a claim or participation in a network, unless reviewed and approved by the commissioner;
  - Requiring pharmacy accreditation standards or certification requirements inconsistent with, more stringent than, or in addition to requirements of the State Board of Pharmacy (board), unless approved by the commission and board;
  - Reimbursing a pharmacy or pharmacist less than the amount reimbursed to an affiliate of the PBM for the same pharmacist services;
  - Reimbursing for the ingredient drug product component of pharmacist services less than the national average drug acquisition cost, or if that information is unavailable, the wholesale acquisition cost, with certain exceptions;
  - Reducing the payment for pharmacist services under a reconciliation process to an effective rate of reimbursement, including generic effective rates, brand effective rates, direct and indirect remuneration fees, or any other reduction or aggregate reduction of payment; retroactively denying or reducing after adjudication of a claim or aggregate of

[14] Arkansas Pharmacy Benefits Manager Licensure Act, A.C.A. Title 23, Subtitle 3, Chapter 92.

claims unless the claim was submitted fraudulently, the claim was a duplicate claim already reimbursed, or the pharmacist services were not properly rendered; and
- Failing to pay a pharmacy or pharmacist that is terminated from the network any payment due for pharmacist services properly rendered.
- Imposing gag clauses such as: (1) prohibiting, restricting, or penalizing a pharmacy or pharmacist from disclosing to any covered person any healthcare information that the participating provider deems appropriate regarding the nature of treatment, risks, or alternatives thereto; the availability of alternate therapies, consultations, or tests; the decision of utilization reviewers or similar persons to authorize or deny services; the process that is used to authorize or deny healthcare services or benefits, or information on financial incentives and structures used by the insurer; (2) restricting a pharmacy or pharmacist from providing to an insured information regarding the insured's total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the insured if one is available; and (3) prohibiting, restricting, or limiting disclosure of information to the commissioner, law enforcement, or state and federal governmental officials investigating or examining a complaint or conducting a review of a PBM's compliance with the law.

Oklahoma

Oklahoma's Patient's Right to Pharmacy Choice Act, (Act) was enacted and effective in 2019.[15] The stated purpose of the Act is to establish minimum and uniform access to a provider and standards and prohibitions on restrictions of a patient's right to choose a pharmacy provider.[16] Under the Act, a PBM may not, among other things:
- Use mail-order pharmacies to meet access standards for retail pharmacy networks.
- Require patients to use affiliated pharmacies.
- Include the name of any pharmacy unless it specifically lists all pharmacies participating in the network, in advertising or other materials, or provide information that is untrue, deceptive, or misleading.
- Charge a pharmacy or pharmacist a fee for claim submission, adjudications, or for participation in a network.
- Reimburse a pharmacy or pharmacist less than the amount the PBM reimburses to an affiliated pharmacy.
- Deny a pharmacy the opportunity to participate in a network at preferred participation status if the pharmacy is willing to accept the terms and conditions for such providers.
- Retroactively deny or reduce reimbursement for a covered service claim previously paid, with certain exceptions.
- Fail to make a payment due for a properly rendered covered service upon termination of the pharmacy from the network.
- Use spread pricing.
- Restrict a pharmacy from informing a person about lower cost alternatives, such as paying a cash price without using the plan or program's coverage.

[15] *See* H.B. 2632, Enrolled; Laws 2019, c. 426, effective November 1, 2019, available at: http://www.oklegislature.gov/BillInfo.aspx?Bill=hb2632&Session=1900 (last visited Mar. 22, 2023).
[16] Codified at s. 36-6959

- Restrict a pharmacy from informing governmental officials or law enforcement about the PBM's compliance with the Act.
- Fail to maintain an electronic claim inquiry processing system in accordance with national standards.

Additional provisions relate to imposing responsibility on the health insurer for ensuring that requirements of the Act are met, including but not limited to ensuring an individual may choose any in-network provider which may include a retail pharmacy or a mail-order pharmacy without incentivizing through discounts that choice.

The Oklahoma Insurance Commissioner is responsible for enforcing the Act and as a part of that function must establish an Advisory Committee to assist with this responsibility. The Commissioner must provide for the receiving and processing of individual complaints alleging violations of the Act. The Advisory Committee is responsible for reviewing the individual complaints, holding hearings and taking disciplinary action for any violations, as appropriate. If the Commissioner determines, based on an investigation of complaints, that a PBM has engaged in violations of the Act with such frequency that it indicates a general business practice that warrants closer supervision, the Commissioner may impose more stringent oversight of the PBM.

Legal Discussion

Over the past ten years, states have been more active in regulating PBMs. Several challenges to certain provisions in these laws have been brought by the Pharmaceutical Care Management Association (PCMA). PCMA is the national association representing America's PBMs.[17] Typically two theories support the challenges: the provisions are preempted by one or both federal laws relating to ERISA and Medicare Part D.

ERISA Preemption

The Employee Retirement Income Security Act of 1974 (ERISA) is a federal law designed to govern how employers provide benefit plans to employees. It regulates all employer-sponsored benefit plans, including group health plans. In enacting ERISA in 1974, Congress sought to provide national standards for employee benefit plans, including reporting, disclosures, fiduciary responsibilities, claims/appeals and remedies for noncompliance with the goal of making the benefits promised by an employer more secure.

To minimize the administrative and financial burden of complying with the potential patchwork effect of each state enacting their own laws regulating employee benefits, Congress included a preemption of state laws that would interfere with the uniform administration of ERISA plans. That preemption states, ERISA "supersede[s] any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" covered by ERISA.[18] Determining whether ERISA preempts a particular state law has not always been straightforward and until recently federal

[17] PCMA, About PCMA available at: https://www.pcmanet.org/about/ (last visited Mar. 23, 2023).
[18] 29 U.S.C. s. 1144(a).

court decisions considering whether state laws regulating pharmacy benefits were preempted by ERISA were inconsistent.[19]

In 2020, the U.S. Supreme Court took up a challenge by the Pharmaceutical Care Management Association (PCMA) to the Arkansas statute regulating PBMs' reimbursement to pharmacies on grounds that the statute was preempted by ERISA. The court in *Rutledge v. Pharmaceutical Care Management Association*,[20] opined that the statute in dispute was not preempted by ERISA and provided a roadmap for determining whether a state law would be preempted by ERISA.

In *Rutledge*, the court considered whether the state law had an "impermissible connection" with an ERISA plan by requiring providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status.[21] The court ruled that the statute at issue did not "relate to" an ERISA plan because the requirement that PBMs reimburse pharmacies at a rate equal to or higher than the pharmacy's acquisition cost was merely a form of cost regulation which did not dictate plan choices or design. The court stated that ERISA preempts laws that require providers to structure benefit plans in particular ways, such as requiring the payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status. The court further opined that the statute did not "refer to" ERISA, as the state did not act immediately and exclusively upon ERISA plans and the existence of such plans was not essential to the law's operation, since it regulated PBMs whether or not the plans they service fell within ERISA's coverage.[22] The Arkansas law defined a plan or program as "any plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services to individuals who reside in or are employed in [Arkansas]."

Medicare Part D Preemption

Medicare Part D is an optional coverage for prescription drugs under the federal Medicare program. The preemption under Medicare Part D incorporates the express preemption provision contained in Medicare Part C.[23] Applying the Medicare Part C exemption to Medicare Part D, the preemption provides: "The standards established under this part shall supersede any State law or regulation (other than state licensing laws or state laws relating to plan solvency) with respect to prescription drug plans.[24] The Supreme Court has not ruled on this preemption as it relates to state regulation of PBMs and similar to the ERISA preemption challenges, lower courts have approached the analysis differently with differing outcomes.

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[19] *See* for example, *Pharmaceutical Care Management Association v. Gerhart*, 852 F 3d 722 (8th Cir. 2017), concluding the Iowa statute was pre-empted due to an "implicit reference" to ERISA and it was impermissibly connected with an ERISA plan because the law limited a plan administrator's ability to control the calculation of drug benefits; *Pharmaceutical Care Management Association v. Rowe*, 429 F.3d 294 (1st Cir. 2005), concluding Maine's Unfair Prescription Drug Practices Act was not pre-empted by ERISA; and *Pharmaceutical Care Management Association v. District of Columbia*, 613 F.3d 179 (D.C. Cir. 2010), holding the Access Rx Act, referred to at 186 as a substantially identical law to Maine's provisions addressed in *Rowe*, was pre-empted by ERISA.

[20] *Rutledge v. Pharmaceutical Care Management Association* 141 S. Ct. 474 (2020).

[21] *Rutledge*, at 480, citing *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85 (1983) and *Engelhoff v. Engelhoff*, 532 U.S. 141 (2001).

[22] *Rutledge*, at 481.

[23] Medicare Part C is Medicare Advantage.

[24] *See* 42 U.S.C. c. 1395w-26(b)(3), which contains Medicare Part C's preemption and 42 U.S.C. s. 1395w-112(g) (Medicare Part D's adoption of Medicare Part C's preemption.

Currently a case challenging Oklahoma's Act is in the United States Court of Appeals for the Tenth Circuit, *Pharmaceutical Care Management Association v. Mulready*.[25] As discussed previously in this analysis, at least 35 attorneys general[26] from across the country have joined in an amicus brief to the Tenth Circuit Court supporting Oklahoma's laws that regulate PBMs. Other stakeholders have also submitted briefs as amici curiae to the court. Both ERISA and Medicare Part D preemption are part of this challenge. Oral arguments before the Court are scheduled for mid-May of 2023.[27]

Insurance Administrators in Florida

An insurance administrator is any person who directly or indirectly solicits or effects coverage of, collects charges or premiums from, or adjusts or settles claims on residents of this state in connection with an insurance policy… or provides billing and collection services to health insurers and health maintenance organizations on behalf of health care providers.[28]

A person must obtain a certificate of authority to act as an administrator from the Office of Insurance Regulation (OIR).[29] The certificate of authority remains valid, unless suspended or revoked by the OIR, so long as the certificate holder continues in business in the state.[30] The failure to hold this certificate while acting as an administrator subjects the person to a fine ranging from $5,000 to $10,000 for each violation.[31]

An application for a certificate of authority for an insurance administrator requires submitting:[32]

- Basic organizational documents;
- By-laws;
- The names, addresses, official positions, and professional qualifications of the individuals employed by or retained by the administrator who are responsible for the conduct of the affairs of the administrator, including all members of the board of directors, board of trustees, executive committee or other governing bodies, and the principal officers or partners;
- A complete list of officers, directors, and shareholders (holding 10% or more of voting shares) having direct or indirect control of the organization, along with a biographical affidavit, background investigative report, and fingerprint card for each person listed;
- Audited annual financial statements for the two most recent fiscal years or other specified documents if the applicant has been in existence for less than two years;

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[25] The appeal is to *Pharmaceutical Care Management Association v. Mulready*, 598 F. Supp. 3d 1200(2022), the United States District Court, W.D. Oklahoma.

[26] The jurisdictions participating include: Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Texas, Utah, Virginia, Washington, and the District of Columbia. *See* Pharmaceutical Care Management Association vs. Glen Mulready et. al., Brief of Amici Curiae; in the US Court of Appeals for the Tenth Circuit (No. 22-6074) available at: https://www.ag.state.mn.us/Office/Communications/2022/docs/PCMA_AmicusBrief.pdf (last visited Mar. 23, 2023).

[27] *Pharmaceutical Care v. Mulready* et. al., Court Docket updated 3/17/2023.

[28] *See* s. 626.88, F.S. Numerous exceptions of are provided in the Statute.

[29] *See* s. 626.8805, F.S.

[30] *See* s. 626.8805(5), F.S.

[31] *See* s. 626.8805(1), F.S.

[32] *See* ss. 626.8805(2), 624.34, and 624.501, F.S., and the Application for Certificate of Authority Insurance administrator available at https://www.floir.com/siteDocuments/Applications/TPA.pdf (last visited Mar. 23, 2023).

- A statement describing the business plan;
- Evidence of the sources of funds to demonstrate financial viability if the applicant is not currently acting as an administrator; and
- A $100 filing fee.

On an ongoing basis, an administrator must:
- Maintain a fidelity bond.[33]
- Have a written agreement between itself and each insurer for which it performs administrative functions that addresses the services to be provided and maintain books and records related thereto. These documents must be made available to the OIR for inspection and retained for 5 years after the contract ends.[34]
- Disclose any ownership interest or affiliation of any kind with any insurance company responsible for providing benefits directly or through reinsurance to any plan for which the administrator provides administrative services.[35]
- Immediately notify the OIR of any material change in its ownership.
- File an annual financial statement with the OIR containing the administrator's financial condition, transactions, and affairs as well as submit an audited financial statement and a filing fee.[36]

With respect to insurance administrators, the term "affiliate" or "affiliated" means an entity or person who directly or indirectly through one or more intermediaries controls, is controlled by, or is under common control with a specified entity or person.[37] The term "control," including the terms "controlling," "controlled by," and "under common control with," means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership or voting securities, by contract other than a commercial contract for goods or non-management services, or otherwise, unless the power is the result of an official position with or corporate office held by the person. Control shall be presumed to exist if any person directly or indirectly owns, controls, holds with the power to vote, or holds proxies representing 10 percent or more of the voting securities of any other person.[38]

An insurer who uses an insurance administrator that administers more than 100 certificate-holders of that insurer must conduct, at least semiannually, a review of the administrator's operations[39]

The OIR may suspend or revoke the certificate of administration for an administrator. Conditions are set forth in statute for mandatory and discretionary revocation or suspension, as well as discretionary suspension, without notice.[40] In lieu of discretionary suspension or revocation, the OIR may impose administrative fines on administrators. Non-willful violations arising from the

[33] See s. 626.8809, F.S.
[34] See ss. 626.8805(3), 626.882, and 626.884, F.S.
[35] See s. 626.8814, F.S.
[36] See s. 626.89, F.S.
[37] Section 626.88(2), F.S.
[38] Section 626.88(3), F.S.
[39] See s. 626.8817, F.S.
[40] *See generally* ss. 626.891 – 626.893, F.S.

same action are subject to: up to $1,000 fine per violation, but not to exceed an aggregate fine of $5,000. Willful violations arising from the same action are subject to: up to $5,000 per violation but not to exceed an aggregate fine of $25,000.[41]

The OIR has authority under s. 624.307, F.S., to conduct investigations of insurance matters that it deems necessary to determine whether a person has violated the insurance code. With regard to administrators specifically, the OIR, under s. 624.317, F.S., has authority to investigate accounts, records, documents, and transactions pertaining to the insurance affairs of any administrator. The decision whether to investigate an administrator is at the discretion of the OIR. The OIR may examine, audit, and inspect the books and records of an administrator, which must be maintained for at least five years after the duration of its written agreement with an insurer.[42] Insurers are subject to heavier examination oversight than administrators.[43]

Pharmacies and Pharmacy Audits

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (act) in ch. 465, F.S. The Board of Pharmacy (board), created under the Department of Health (DOH), adopts rules to implement provisions of the act and takes other actions according to duties conferred on it by the act.[44] Each pharmacy is subject to inspection by the DOH and disciplined for violations of applicable laws relating to a pharmacy.[45]

Section 624.491, F.S., establishes procedures that must be followed when a pharmacy licensed in Florida is audited by a managed care plan, insurer, third-party payer, PBM, or an entity that represents companies or groups that provides pharmacy benefits. The person or entity conducting the audit must:

- Provide at least seven days prior notice of each initial on-site audit, except for a pharmacy located within a designated Health Care Fraud Prevention and Enforcement Act Team (HEAT) Task Force area that has been a member of a credentialed provider network for less than 12 months;
- Schedule the on-site audit after the first three days of the month, unless the pharmacist consents otherwise;
- Limit the audit period to 24 months after the date a claim is submitted to or adjudicated by the entity;
- Have a pharmacist conduct the audit or conduct it in consultation with a pharmacist if the audit requires clinical or professional judgment;
- Allow the pharmacy to use the written and verifiable records of a hospital, physician, or other authorized practitioner to validate the pharmacy records in accordance with state and federal law;
- Reimbursed the pharmacy for a claim that was retroactively denied for a clerical, typographical, scrivener's, or computer error, if the prescription was properly dispensed,

[41] *See* s. 626.894, F.S.
[42] *See generally* ss. 624.307(3), 624.317, and 626.884, F.S.
[43] *See* s. 624.316 and 624.3161, F.S.
[44] Sections 465.005 and 465.022, F.S.
[45] Sections 465.015 and 465.016, F.S.

unless the pharmacy has a pattern of such errors, fraudulent billing is alleged, or the error results in actual financial loss to the entity;
- Provide the pharmacy with the preliminary audit report within 120 days after the audit is concluded and the final audit report within 6 months after receiving the preliminary report;
- Allow the pharmacy 10 business days after the preliminary audit report is delivered to produce documentation to address a discrepancy or audit finding; and
- Calculate any recoupment or penalties based on actual overpayments, not extrapolation.

These required procedures do not apply to audits that are based on a suspected fraud or other willful misrepresentation evidenced by reviews or other investigative methods; audits of claims paid for by federally-funded programs; or concurrent reviews or desk audits that occur within three business days after transmission where no chargeback or recoupment is demanded.

A pharmacy may appeal the findings of the final audit report as to whether a claim payment is due and the amount of a claim payment in accordance with s. 408.7057, F.S. This law establishes a claim dispute resolution program using an independent resolution organization under contract with the Agency for Health Care Administration (AHCA). A health insurer or health maintenance organization that uses a PBM for paying pharmacies for pharmacy benefit claims for covered persons remain responsible for compliance with the pharmacy audit procedures set forth above.

Prescription Drug Manufacturers

The Department of Business and Professional Regulation (DBPR) is responsible for licensing and regulating prescription drug manufacturers under the Florida Drug and Cosmetic Act, Chapter 499, F.S. (FDCA).

A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufacturers or distributes those prescription drugs in this state.[46] A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs located outside of this state or outside the United States and that engages in the distribution in this state of such prescription drugs.[47] Prescription drug manufacturers and nonresident prescription drug manufacturers are required to comply with all provisions required of such permit holder under part I of the FDCA.

The failure to comply with requirements under part I of the FDCA include the imposition of an administrative fine of up to $5,000 per violation per day and each day a violation continues constitutes a separate violation. Additional enforcement authority exists under the FDCA, including but not limited to denial, suspension, or revocation of a permit.

[46] Section 499.01(2)(a), F.S.
[47] Section 499.01(2)(c), F.S. An exemption exists from holding a permit as a nonresident prescription drug manufacturer for a person that is permitted as a third party logistics provider under s. 499.01(2)(q), F.S. A third party logistics provider does not take title to prescription drugs or have responsibility to direct the sale or distribution of the prescription drug, but merely warehouses and distributes a manufacturer's prescription drug into the state.

III. Effect of Proposed Changes:

This part of the document is presented by topic and may not follow the section order of the bill.

Section 1. Titles the act the "Prescription Drug Reform Act."

Drug Price Increase Transparency

The bill requires manufacturers of prescription drugs to report to the state certain drug price increases as defined in the bill. This information will be made publicly available on the Florida Health Finder website.[48]

Section 2. Amends s. 499.005, F.S., to create a new prohibited act for a Florida permitted prescription drug manufacturer or nonresident prescription drug manufacturer to fail to submit required drug price increase forms and reports as required under Section 4 of the bill.

Section 3. Amends s. 499.012, F.S., which requires, among other things, a permit for a prescription drug manufacturer located in Florida and a nonresident prescription drug manufacturer permit for a drug manufacturer that is not located in Florida but distributes its prescription drugs into the state. The bill establishes requirements for a prescription drug manufacturer or a nonresident prescription drug manufacturer permitted in Florida to notify the DBPR of reportable drug price increases as required in s. 499.026, F.S.

Section 4. Creates s. 499.026, F.S., to establish transparency parameters for Florida permitted manufacturers of prescription drugs intended for human use to submit information to the state regarding certain prescription drug price increases that will be publicly disclosed on a website maintained by the AHCA.

The bill defines:

- "Course of therapy" to mean the recommended daily dose units of a prescription drug pursuant to its prescribing label for 30 days or the recommended daily dose units pursuant to its prescribing label for a normal course of treatment that is less than 30 days.
- "Manufacturer" to mean a person holding a prescription drug manufacturer permit or a nonresident prescription drug manufacturer permit under s. 499.01, F.S.
- "Prescription drug" to have the same meaning as in s. 499.003, F.S.,[49] and includes biological products but is limited to those prescription drugs and biological products intended for human use.
- "Reportable drug price increase" to mean, for a prescription drug with a wholesale acquisition cost of at least $100 for a course of therapy before the effective date of an increase:

[48] Available at: https://ahca.myflorida.com/medicaid/quality_mc/health_finder.shtml.

[49] Section 499.003, F.S., defines a prescription drug to mean a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal act or s. 465.003, s. 499.007(13), subsection (31), or subsection (47), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

  - Any increase of 15 percent or more of the wholesale acquisition cost during the preceding 12-month period; or
  - Any increase of 40 percent or more of the wholesale acquisition cost during the preceding three calendar years.
- "Wholesale acquisition cost" to mean, with respect to a prescription drug or biological, the manufacturer's list price for the prescription drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reduction in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

Under the bill, Florida-licensed manufacturers of prescription drugs must submit two sets of information to the DBPR, portions of which may be claimed as trade secret under s. 119.0715, F.S., and therefore exempt from the public records provisions of ch. 119, F.S. The bill protects DBPR employees from release of the information in the forms and reports. The submissions are as follows:

- On the effective date of a reportable drug price increase, the manufacturer must submit on a form adopted by the DBPR all of the following information for each reportable drug price increase:[50]
  - The proprietary and nonproprietary names of the prescription drug, as applicable.
  - The wholesale acquisition cost before the reportable drug price increase.
  - The dollar amount of the reportable drug price increase.
  - The percentage amount of the reportable drug increase from the wholesale acquisition cost before the reportable drug price increase.
  - A statement regarding whether a change or improvement in the prescription drug necessitates the reportable drug price increase and a description of the change or improvements if it does. The manufacturer may designate this information as trade secret, if applicable.
  - The intended uses of the prescription drug.
- By April 1 of each year, the manufacturer must submit a report to the DBPR. The report is not deemed submitted until it is approved by the department. The report must include all of the following:
  - A list of all prescription drugs identified by proprietary and nonproprietary names, as applicable, affected by a reportable drug price increase during the previous calendar year, along with the dollar amount and the percentage increase of each reportable drug price increase relative to the previous wholesale acquisition cost.
  - If more than one form was filed for reportable drug price increases for a prescription drug, the percentage increase of the prescription drug from the earliest form filed to the most recent form filed.
  - The intended uses of each prescription drug listed and whether the manufacturer benefits from market exclusivity for the prescription drug.
  - The length of time the prescription drug has been available for purchase.
  - A complete description of the factors contributing to each reportable drug price increase, provided with such specificity as to explain the need or justification for each reportable drug price increase. The DBPR may request additional information from a manufacturer

[50] The bill provides that this disclosure requirement to the DBPR does not prohibit a manufacturer from notifying other parties before the effective date of the increase.

relating to the need or justification for any reportable drug price increase before it accepts and approves the manufacturer's report. The manufacturer may designate this information as trade secret, if applicable.
- Any action that the manufacturer has filed to extend a patent report after the first extension has been granted. The manufacturer may designate this information as trade secret, if applicable.

The DBPR is responsible for submitting all forms and reports to the AHCA for posting on the MyFloridaRX website maintained pursuant to s. 408.062, F.S. The AHCA must compile all information on the forms and reports submitted by manufacturers and make it available upon request to the Governor, The President of the Senate, and the Speaker of the House of Representatives.

The DBPR, in consultation with the AHCA, must adopt rules to implement these provisions. The DBPR is tasked with adopting an emergency rule initially. The bill provides a statutory process to follow if the initial emergency rule is held to be unconstitutional or an invalid exercise of delegated legislative authority and becomes void. In that case, the DBPR may adopt another emergency rule to replace the first one that became void. If the second emergency rule is also held to be unconstitutional or an invalid exercise of delegated legislative authority and becomes void, the DBPR must then proceed with nonemergency rulemaking under the Administrative Procedure Act (APA). If an emergency rule is challenged, within seven days after the Division of Administrative Hearings receives a sufficient petition challenging the validity of the emergency rule, an administrative law judge must be assigned who shall conduct a hearing within 14 days, unless the petition is withdrawn.

The bill exempts the emergency rulemaking from finding that an immediate danger to the public health, safety, or welfare requires emergency rulemaking under s. 120.54(4)(a), F.S., and preparing a statement of estimated regulatory costs under s. 120.54(3)(b), and s. 120.541, F.S. The bill also exempts the emergency rule from the 90-day timeframes that an emergency rule may the effective in s. 120.54(4)(c), F.S., and allows a valid emergency rule to remain in effect until replaced by rules adopted under the nonemergency rulemaking procedures of the APA.

PBMs as Administrators

Section 6. Amends s. 624.490, F.S., retaining the registration requirement for PBMs and conforming the definition of a PBM to the new definition in s. 626.88, F.S.

Section 8. Amends s. 626.88, F.S., to include PBMs in the definition of an administrator under the Florida Insurance Code and to define a PBM. Under the bill, a "PBM" means a person or entity doing business in this state which contracts to administer prescription drug benefits on behalf of a plan or program, as defined in s. 626.8825, F.S. The term includes, but is not limited to, a person or entity that performs one or more of the following services:
- Pharmacy claims processing.
- Administration or management of pharmacy discount card programs.
- Managing pharmacy networks or pharmacy reimbursement.
- Paying or managing claims for pharmacist services provided to covered persons.

- Developing or managing a clinical formulary, including utilization management or quality assurance programs.
- Pharmacy rebate administration.
- Managing patient compliance, therapeutic intervention, or generic substitution programs.
- Administration or management of a mail-order pharmacy program.

Section 9. Amends s. 626.8805, F.S., to establish the process for PBMs to obtain a certificate of authority to act as an administrator.

In order to allow time for PBMs that are currently operating in Florida to obtain a certificate of authority to act as an administrator, the bill authorizes a PBM that is registered under s. 624.490, F.S., as of June 30, 2023, to continue to operate as a PBM under that authority until January 1, 2024. By that date, a PBM must have obtained a certificate of authority to act as an administrator. A person who, on or after January 1, 2024, does not hold a certificate of authority to act as an administrator while operating as a PBM, is subject to a fine of $10,000 per violation, per day.

The bill requires a PBM applying for a certificate of authority to act as an administrator to submit an application that includes:

- Basic organizational documents;
- By-laws;
- The names, addresses, official positions, and professional qualifications of the individuals employed by or retained by the administrator who are responsible for the conduct of the affairs of the administrator, including all members of the board of directors, board of trustees, executive committee or other governing bodies, and the principal officers or partners;
- A complete list of officers, directors, and shareholders (holding 10% or more of voting shares) having direct or indirect control of the organization, along with a biographical affidavit, background investigative report, and fingerprint card for each person listed;
- Audited annual financial statements for the two most recent fiscal years or other specified documents if the applicant has been in existence for less than two years;
- A statement describing the business plan;
- Evidence of the sources of funds to demonstrate financial viability if the applicant is not currently acting as an administrator; and
- A self-disclosure of any administrative, civil, or criminal complaints, settlements or discipline of the applicant or any of the applicant's affiliates, which relate to a violation of the insurance laws, including PBM laws, in any state.
- A statement attesting to compliance with the network requirements in s. 626.8825, F.S., beginning January 1, 2024.

A PBM applicant is required by the bill to make available for inspection by the OIR copies of all contract templates with any pharmacy and copies of all subcontracts to support its operations.

A PBM is exempt under the bill from fees associated with the initial application and the annual filing fees.

Section 14. Amends s. 626.89, F.S., to require PBMs annually to submit:
- A statement of financial condition.
- Audited financial statement prepared by an independent certified public accountant.
- A statement attesting to its compliance with the network requirements of s. 626.8825, F.S.

PBMs must also notify the OIR immediately of any material change in its ownership and within 30 days after any administrative, civil, or criminal complaints, settlements, or discipline of the PBM or any of its affiliates which relate to a violation of the insurance laws, including pharmacy benefit laws in any state.

Section 10. Amends s. 626.8814, F.S., to require PBMs to disclose to the OIR:
- Any ownership interest or affiliation with any insurance company responsible for providing benefits for which the PBM acts as an administrator, and
- Any ownership affiliation of any kind with any pharmacy that:
  - Has an investment or ownership interest in a PBM in Florida;
  - Shares common ownership with a PBM in Florida; or
  - Has an investor or a holder of an ownership interest which is a PBM in Florida.

Any change in this information must be reported in writing to the OIR within 60 days after the change occurs.

PBM Transparency and Accountability

Section 11. Creates s. 626.8825, F.S., to provide definitions, and regulate contractual agreements between PBMs and pharmacy benefits plans and programs and between PBMs and pharmacies.

Definitions

The follow definitions apply to s. 626.8825, F.S.:
- "Adjudication transaction fee" means a fee charged by the PBM to the pharmacy for electronic claim submissions.
- "Affiliated pharmacy" means a pharmacy that, either directly or indirectly through one or more intermediaries:
  - Has an investment or ownership interest in a PBM holding a certificate of authority issued under this part;
  - Shares common ownership with a PBM holding a certificate of authority issued under this part; or
  - Has an investor or a holder of an ownership interest which is a PBM holding a certificate of authority issued under this part.
- "Brand name or generic effective rate" means the contractual rate set forth by a PBM for the reimbursement of covered brand name or generic drugs, calculated using the total payments in the aggregate, by drug type, during the performance period. The effective rates are typically calculated as a discount from industry benchmarks, such as average wholesale price or wholesale acquisition cost.
- "Covered person" means a person covered by, participating in, or receiving the benefit of a plan or program.

- "Direct and indirect remuneration fees" means price concessions that are paid to the PBM by the pharmacy retrospectively and that cannot be calculated at the point of sale. The term may also include discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, upfront payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies, or similar entities.
- "Dispensing fee" means a fee intended to cover reasonable costs associated with providing the drug to a covered person. This cost includes the pharmacist's services and the overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.
- "Effective rate guarantee" means the minimum ingredient cost reimbursement a PBM guarantees it will pay for pharmacist services during the applicable measurement period.
- "Erroneous claims" means pharmacy claims submitted in error, including, but not limited to, unintended, incorrect, fraudulent, or test claims.
- "Incentive payment" means a retrospective monetary payment made as a reward or recognition by the plan or program or PBM to a pharmacy for meeting or exceeding predefined pharmacy performance metrics as related to quality measure, such as Healthcare Effectiveness Data and Information Set measures.
- "Maximum allowable cost appeal pricing adjustment" means a retrospective positive payment adjustment made to a pharmacy by the plan or program or by the PBM pursuant to an approved maximum allowable cost appeal request submitted by the same pharmacy to dispute the amount reimbursed for a drug based on the PBM's listed maximum allowable cost price.
- "Monetary recoupments" means rescinded or recouped payments from a pharmacy or provider by the plan or program or by the PBM.
- "Network" means a group of pharmacies that agree to provide pharmacist services to covered persons on behalf of a plan or program or a group of pharmacy benefits plans or programs in exchange for payment for such services. The term includes a pharmacy that generally dispenses outpatient prescription drugs to covered persons.
- "Network reconciliation offsets" means a process during annual payment reconciliation between a PBM and a pharmacy which allows the PBM to offset an amount for over-performance or under-performance of contractual guarantees across guaranteed line items, channels, networks, or payers, as applicable.
- "Participation contract" means any agreement between a PBM and pharmacy for the provision and reimbursement of pharmacist services and any exhibits, attachments, amendments, or addendums to such agreement.
- "Pass-through pricing model" means a payment model used by a PBM in which the payments made by the plan or program to the PBM for the covered outpatient drugs are:
    - Equivalent to the payments the PBM makes to a dispensing pharmacy or provider for such drugs, including any contracted professional dispensing fee between the PBM and its network of pharmacies. Such dispensing fee would be paid if the plan or program was making the payments directly.
    - Passed through in their entirety by the plan or program or by the PBM to the pharmacy or provider that dispenses the drugs, and the payments are made in a manner that is not offset by any reconciliation.
- "Pharmacist" means a pharmacist as defined in s. 465.003, F.S.

- "Pharmacist services" means products, goods, and services or any combination of products, goods, and services provided as part of the practice of the profession of pharmacy as defined in s. 465.003, F.S., or otherwise covered by a plan or program.
- "Pharmacy benefit manager" has the same meaning as in s. 626.88, F.S.
- "Pharmacy benefits plan or program" means a plan or program that pays for, reimburses, covers the cost of, or provides access to discounts on pharmacist services provided by one or more pharmacies to covered persons who reside in, are employed by, or receive pharmacist services from this state. The term includes, but is not limited to, health maintenance organizations, health insurers, self-insured employer health plans, discount card programs, and government-funded health plans, including the Statewide Medicaid Managed Care program established pursuant to part IV, ch. 409, F.S., and the state group insurance program pursuant to part I, ch. 110, F.S.
- "Rebate" means all payments that accrue to a PBM or its plan or program client, directly or indirectly, from a pharmaceutical manufacturer, including, but not limited to, discounts, administration fees, credits, incentives, or penalties associated directly or indirectly in any way with claims administered on behalf of a plan or program client.
- "Spread pricing" is the practice in which a PBM charges a plan or program a different amount for pharmacist services than the amount the PBM reimburses a pharmacy for such pharmacist services.
- "Usual and customary price" means the amount charged to cash customers for a pharmacist service exclusive of sales tax or other amounts claimed.

Contracts between a PBM and pharmacy benefits plan or program – Subsection (2)

The following provisions apply to all contractual arrangements executed, amended, adjusted, or renewed on or after July 1, 2023, which are applicable to pharmacy benefits covered on or after January 1, 2024, between a PBM and a plan or program. These requirements are in addition to any other requirements in the FIC. The contract must:

- Use a pass-through pricing model, consistent with the next requirement.
- Excludes terms that allow for the direct or indirect practice of spread pricing unless the PBM passes along the entire amount of any difference to the plan or program.
- Ensure that funds received in relation to providing services for a plan or program or a pharmacy are received by the PBM in trust for the plan or program or pharmacy, as applicable and are used or distributed only in accordance with the PBM's contract with the plan or program or pharmacy or as otherwise required by law.
- Require the PBM to pass 100 percent of all manufacturer rebates received to the plan or program, if the contractual arrangement delegates the negotiation of rebates to the PBM, for the sole purpose of offsetting defined cost sharing and reducing premiums of covered persons. If any excess rebate revenue remains, it must be used for the sole purpose of offsetting copayments and deductibles of covered persons. Medicaid managed care plans are excluded from this rebate provision.
- Include network adequacy requirements that meet or exceed the Medicare Part D program standards for convenient access to network pharmacies and that:
    - Do not limit a network to solely include affiliated pharmacies.
    - Require the PBM to offer a provider network contract to a pharmacy physically located onsite with essential providers as determined by the AHCA that are located within the plan's geographic service area solely for the administration or dispensing of covered

prescription drugs, including biologics, that are administered through infusions, intravenously injected, inhaled during a surgical procedures, or a covered parenteral drug, as part of onsite outpatient care.

- Require the PBM to offer a provider network contract to a pharmacy physically located onsite with Designated Cancer Centers of Excellence, organ transplant hospitals, specialty children's hospitals, or regional perinatal intensive care centers, regardless of the plan's geographic service area solely for the administration or dispensing of covered prescription drugs, including biologics, that are administered through infusions, intravenously injected, inhaled during a surgical procedures, or a covered parenteral drug, as part of onsite outpatient care.
- Do not require a covered person to receive a prescription drug by mail, or some type of delivery service. However, this provision does not prohibit a PBM from operating mail-order or delivery programs on an opt-in basis at the sole discretion of a covered person.
- Do not require a covered person, through network development; incentives, which does not include a reduced copay or premium of a covered drug; marketing; or otherwise, to receive pharmacist services from an affiliated pharmacy or affiliated health care provider for the inpatient administration of covered prescription drugs. Subject to the preceding sentence, a PBM may include an affiliated pharmacy in communications to covered persons regarding network pharmacies and prices, provided that information, such as links to all nonaffiliated network pharmacies, is included in the communications. The information for all network pharmacies must be accurate and of equal prominence. This provision does not prohibit a PBM from entering into an agreement with an affiliated pharmacy to provide pharmacist services to covered persons.
- Prohibit the ability of a PBM to condition participation in one pharmacy network on participation in any other pharmacy network or penalize a pharmacy for exercising its prerogative not to participate in a specific pharmacy network.
- Prohibit a PBM from instituting a network that requires a pharmacy to meet accreditation standards that are inconsistent with or exceed state pharmacy licensure requirements.

Contracts between a PBM and a participating pharmacy – Subsection (3)

In addition to any other requirements in the FIC, all participation contracts between a PBM and one or more pharmacies or pharmacists that are executed, amended, adjusted, or renewed on or after July 1, 2023, and which are applicable to pharmacist services on or after January 1, 2024, must include, in substantial form, terms that ensure compliance with all the following requirements and which, except to the extent not allowed by law, shall superseded any contractual terms in the participation contract to the contrary:

- At the time of adjudication or reimbursement of claims, the PBM must provide the pharmacy with detailed information in accordance with national standards that is sufficient for the pharmacy to identify and validate the payment. The OIR is required to adopt rules to implement this requirement.
- The PBM must ensure that reimbursement information relating to reconciliation transactions are accurate and reliable and are communicated to the pharmacy in accordance with national standards.
- A prohibition of financial clawbacks, reconciliation offsets, or retroactive recoupments, with limited exceptions related to performance measures; erroneous claims, fraud, waste, or abuse;

claims adjudicated in error, adjustments made as part of a pharmacy audit, or recoupments returned to the state for certain programs.

- A PBM may not unilaterally change the terms of a participation contract.
- A PBM may not prevent a pharmacy or pharmacist from offering and providing mail or delivery services on an opt-in basis at the sole discretion of the covered person or charging a shipping or handling fee to the covered person if the pharmacy or pharmacist disclosed before the service the amount of the fee that will be charged and that the fee may not be reimbursable by the covered person's plan or program.
- If a pharmacy requests, a PBM must provide a list of plans or programs in which that pharmacy is a part of the network, with applicable updates. The pharmacy may disclose this information to the public.
- A PBM must ensure that the electronic remittance advice contains claim level payment adjustments in accordance with national standards with the appropriate level of detail to reconcile debits and credits.
- A PBM must provide a reasonable administrative appeal procedure for a pharmacy to challenge the maxim allowable cost (MAC) reimbursement or price update. Timeframes of 30 business days are provided for the pharmacy to appeal the MAC rate and for the PBM to respond after receipt of the appeal. If the appeal is upheld, the PBM must update the MAC information, allow the pharmacy to rebill the claim, provide the pharmacy with information on which the increase or change is based, and make the change effective for each similarly situated pharmacy that is subject to the applicable MAC pricing information. If the appeal is denied, the PBM must provide the pharmacy with the national drug code (NDC) and the name of a national or regional wholesaler operating in Florida with that drug in stock at a price below the MAC pricing information. PBMs are required to report to the OIR every 90 days the total number of appeals received and denied in the preceding 90-day period for each specific drug for which an appeal was submitted.

Section 12. Creates s. 626.8827, F.S., to specify prohibited practices of PBMs. In addition to other prohibitions related to practices of administrators, a PBM may not:

- Prohibit, restrict, or penalize a pharmacy or pharmacist from:
  - Disclosing to any person information that the pharmacy or pharmacist deems appropriate, including, but not limited to:
    - The nature of treatment, risks, or alternatives thereto.
    - The availability of alternate treatment, consultations, or tests.
    - The decision of utilization reviewers to authorize or deny pharmacist services.
    - The process used to authorize or deny pharmacist services or benefits.
    - Information on financial incentives and structures used by the plan or program.
    - Information that may reduce the costs of pharmacist services.
    - Whether the cost-sharing obligation exceeds the retail price for a covered prescription drug and the availability of a more affordable alternative drug.
  - Disclosing information to the OIR, the AHCA, the Department of Management Services, law enforcement, or state and federal government officials provided the recipient represents it has the authority to maintain proprietary information as confidential and the pharmacy or pharmacist marks documents with such proprietary information as confidential or requests confidential treatment for any oral communication of the information.

- Communicate at the point-of-sale, or otherwise require, a cost-sharing obligation for a covered person in an amount that exceeds the lesser of the cost-sharing amount under the applicable plan or program or the usual and customary price of the pharmacist services.
- Transfer or share patient-identifiable or prescriber-identifiable prescription data to an affiliated pharmacy for any commercial purpose other than the limited purposes of the PBM's responsibilities of the applicable plan or program.
- Fail to pay a pharmacy for an adjudicated claim with a date of service before any termination of the pharmacy in the network, unless payment is withheld due to actual fraud on the pharmacy's part or as otherwise required by law.
- Terminate the contract of, penalize, or disadvantage a pharmacist or pharmacy that:
  - Discloses information about the PBM's practices in accordance with the act.
  - Exercises any of its prerogatives under the sections of law relating to administrators.
  - Shares any portion of the PBM contract with the OIR pursuant to a complaint or query regarding whether the contract is in compliance with the act.
- Fail to comply with the requirements in s. 626.8825, F.S., which contains the contracting provisions created in this bill or s. 624.491, F.S., relating to pharmacy audit requirements.

Investigations and Examinations of PBMs

Section 5. Amends s. 624.307, F.S., to require the Division of Consumer Services (Division) within the Department of Financial Services to designate an employee as the primary contact for consumers and pharmacies on issues relating to PBMs. All complaints that allege conduct that may constitute a violation of part VII, ch. 626. F.S., relating to Insurance administrators, or if a PBM does not respond to a written requires for documents and information pertaining to a consumer complaint, must be referred to the Office of Insurance Regulation for further action.

Section 13. Creates s. 626.8828, F.S., to provide specific parameters for conducting investigations and examinations of PBMs, paying the expenses associated with these investigations and examinations, and assessing penalties, as appropriate.

The bill confers upon the OIR the authority to investigate administrators who are PBMs and an applicant for authorization to act as an administrator who is a PBM. The OIR is required to:
- Review referrals from the Division relating to PBMs and investigate any referral that the Commissioner of Insurance Regulation, or designee, has determined reasonably indicates a possible violation of the statutes regulating administrators.
- Examine the business and affairs of each PBM at least every two years, beginning July 1, 2023. This biennial examination must be a systematic review to determine the PBM's compliance with the laws and rules applicable to PBMs, and include a detailed review of the PBM's compliance with ss. 626.8825 and 626.8827, F.S.
- Deliver a report by January 1 of the year following a 2-year cycle, to the Governor, President of the Senate, and Speaker of the House of Representatives summarizing the results of the biennial examination, including a detailed description of any violations committed by each PBM and detailed actions taken by the OIR related to the violations.
- Begin an examination of a PBM or include findings within an ongoing examination if a referral is made from the Division pursuant to s. 624.307, F.S., which reasonably indicates a pattern or practice of violations by a PBM.

Based on the findings of an examination that a PBM or applicant for authorization has exhibited a pattern or practice of knowing and willful violations of s. 626.8825, F.S., or s. 626.8827, F.S., the office may, pursuant to ch. 120, F.S., order a PBM to file all contracts between the PBM and pharmacies or the PBM and plans or programs to which s. 626.8825, F.S., applies, and any policies, guidelines, rules, protocols, standard operating procedures, instructions, or directives that govern or guide the manner in which the PBM or applicant conducts business related to such knowing and willful violations for review and inspection for the following 36-month period. These documents are public records and are not trade secrets or otherwise exempt from s. 119.07(1), F.S. "Knowing and willful" means any act or commission or omission which is committed intentionally, as opposed to accidentally, and which is committed with knowledge of the act's unlawfulness or with reckless disregard as to the unlawfulness of the act.

The OIR also may conduct additional examinations of PBMs and applicants for authorization as often as it deems advisable or necessary to ascertain compliance with the laws and rules applicable to PBMs.

The bill cross-references other sections of the FIC that are also applicable to the investigations and examinations of PBMs relating to: the conduct of examinations; examination and investigation report; witnesses and evidence; compelled testimony; hearings; fingerprinting; and any other provision of ch. 624, F.S., applicable to the investigation or examination of an administrator.

The bill requires PBMs to maintain an accurate record of all contracts and records with all pharmacies and plans or programs for five years after the contract ends. These contracts must be made available and kept in a form accessible to the OIR. In addition, the PBM must produce any records, book, files, contracts, advertising and solicitation materials, or other information to the OIR. The OIR may take statements under oath to determine whether the PBM or applicant is in violation of the law or is acting contrary to the public interest.

Examinations may be conducted by an independent professional examiner under contract with the OIR. In this case, the PBM must pay the contracted examiner directly in accordance with the rates and terms agreed to by the OIR and the examiner. Otherwise, the PBM or applicant for authorization must pay to the OIR the expenses of the examination or investigation in accordance with the detailed statement submitted by the examiner. The bill provides that all moneys collected from the PBMs relating to the expenses of examinations or investigations must be deposited into the Insurance Regulatory Trust Fund. The bill requires the Commission to adopt rules for the qualifications of the examiners, that rates charged to the PBM are consistent and comparable with rates charged by other firms in a similar profession for comparable examinations, and that a firm selected to perform the examination must have no conflicts of interest that might affect its ability to independently perform its responsibilities for the examination.

The bill requires the OIR to impose an administrative fine of $5,000 for each violation of s. 626.8825, F.S., or s. 626.8827, F.S. Each instance of a PBM's violation of these sections against each individual pharmacy or plan or program is a separate violation and there is no limitation on aggregate fines assessed under this statute. These fines are in addition to any other enforcement

authority available to the OIR. A PBM that fails to pay expenses incurred for investigations and examinations or imposed administrative fines may have its certificate of authority denied, suspended, or revoked.

Other Provisions

Section 7. Amends s. 624.491, F.S., to extend the pharmacy audit requirements in this section to pharmacy benefits plans or programs. The exemptions pertaining to claims paid for by federally funded programs currently in that section remains unchanged.

Section 15 and Section 18. Amend ss. 627.42393, F.S., and s. 641.31, F.S., respectively, relating to step-therapy protocols to extend the application of these provisions to PBMs acting on behalf of a health insurer or health maintenance organization (HMO). These sections currently forbid an insurer or HMO from requiring an insured to complete a step therapy protocol for a covered prescription drug if the insured recently completed a step therapy protocol under a previous health coverage plan and otherwise meets the criteria set forth in the statute. These statutes also set forth a process for requesting a protocol exception and appealing a denial of the protocol exception.

Section 16, Section 17, and Section 19. Amend ss. 627.64741**,** 627.6572, and 641.314, F.S., relating to PBM contracts with individual health plans, group health plans, and HMOs, respectively, to specify these plans must also comply with the contractual requirements between PBMs and plans and programs in Part VII, ch. 626, F.S. Additional provisions that are in these statutory sections have been moved into s. 626.8825, F.S., created in this bill.

Section 19. Conforms the cross-reference for the definition of a PBM in s. 624.491, F.S., relating to pharmacy audits to the definition of a PBM as an administrator.

Section 20. Creates a non-statutory section of the Laws of Florida addressing three subjects:

- Expresses Legislative intent that the act establishes requirements for PBMs acting for or otherwise on behalf of a plan or program, as defined in s. 626.8825, Florida Statutes, which includes providing coverage for, including but not limited to, governmental programs. The specific governmental programs enumerated include Titles XVIII, XIX, or XXI of the Social Security Act, 42 U.S.C. ss. 1395 et. seq., 1396 et seq., and 1397aa et seq., known as Medicare, Medicaid, or any other similar coverage under a state or Federal government funded health plan, including the Statewide Medicaid Managed Care program established pursuant to part IV, ch. 409, F.S., and the state group insurance program pursuant to part I, ch. 110, F.S. This provision is not intended to be a limiting statement of applicability.
- The act is not intended, nor may it be construed, to conflict with existing, relevant federal law.
- A severability clause: If any provision of this act or its application to any person or circumstances is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 21. Creates a non-statutory section of the Laws of Florida providing a $1,127,525-appropriation ($980,705 recurring and $146,820 nonrecurring) from the Insurance Regulatory Trust Fund to the Office of Insurance Regulation, along with salary rate for 10 full-time equivalent positions to implement the bill.

The bill provides an effective date of July 1, 2023.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

A separate bill, CS/SB 1552, addresses extending the current exemptions from s. 119.07(1), F.S., the public record law and s. 24(a), Art. I of the State Constitution that are applicable to Administrators under the FIC to PBMs, which are a new class of Administrator. Section 119.0715, F.S., provides that a trade secret held by an agency is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

Similar legislation in other states has been challenged on the grounds that certain provisions are preempted by ERISA or Medicare Part D.

In 2020, the U.S. Supreme Court took up a challenge by the Pharmaceutical Care Management Association (PCMA) to an Arkansas statute regulating PBMs' reimbursement to pharmacies on grounds that the statute was preempted by ERISA. The court in *Rutledge v. Pharmaceutical Care Management Association*,[51] opined that the statute in dispute was not preempted by ERISA and provided a roadmap for determining whether a state law would be preempted by ERISA.

In *Rutledge*, the court considered whether the state law had an "impermissible connection" with an ERISA plan by requiring providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status.[52] The court ruled that the statute at issue did not "relate to" an ERISA plan because the requirement that PBMs

[51] *Supra 20. Rutledge*.
[52] *Supra 21.*

reimburse pharmacies at a rate equal to or higher than the pharmacy's acquisition cost was merely a form of cost regulation which did not dictate plan choices or design. The court stated that ERISA preempts laws that require providers to structure benefit plans in particular ways, such as requiring the payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status. The court further opined that the statute did not "refer to" ERISA, as the state did not act immediately and exclusively upon ERISA plans and the existence of such plans was not essential to the law's operation, since it regulated PBMs whether or not the plans they service fell within ERISA's coverage.[53]

The preemption under Medicare Part D incorporates the express preemption provision contained in Medicare Part C. Applying the Medicare Part C exemption to Medicare Part D, the preemption provides: "The standards established under this part shall supersede any State law or regulation (other than state licensing laws or state laws relating to plan solvency) with respect to prescription drug plans.[54] The Supreme Court has not ruled on this preemption as it relates to state regulation of PBMs and lowers courts have approached the analysis differently. Currently a case challenging Oklahoma's Act is in the United States Court of Appeals for the Tenth Circuit, *Pharmaceutical Care Management Association v. Mulready*.[55] Although this decision would not be dispositive of the provisions in CS/SB 1550, or similar legislation, if enacted, it is of interest to the majority of states that have taken an active role in enacting laws to regulate PBMs.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Violation of the provisions in the bill might result in significant fines and penalties to PBMs. The actual fiscal impact is indeterminate.

Some of the bill's provisions may prohibit PBMs from employing mechanisms designed to reduce costs of prescription drugs for insurers, HMOs, and other pharmacy benefits plans and programs, which could have the effect of increasing premiums and/or other costs for such payers or for persons with individual coverage. The extent of such effect is indeterminate.

Retail pharmacies may be able to negotiate with PBMs on a more even status under the bill; however, the fiscal impact is indeterminate.

[53] *Supra 22.*
[54] *Supra 24*.
[55] *Supra 25.*

C. Government Sector Impact:

The Department of Financial Services Division of Consumer Services will need to designate an employee as the primary contact to receive complaints on issues relating to PBMs and to process preliminary reviews of the complaints.

The State Group Health Insurance program utilizes a PBM to manage its pharmacy benefit. The Department of Management Services, which operates state group health insurance, has submitted an analysis estimating a recurring cost to general revenue of approximately $2.2 million, attributed to the bill's requirement that state group health insurance must discontinue its use of an exclusive specialty pharmacy arrangement with its PBM and the inability to utilize a cost accumulator program under the bill.

The OIR will require additional staff to regulate PBMs as administrators. The OIR indicates additional staff in the Life and Health Market Regulation Unit and the Life and Health Financial Oversight Unit will be needed to process applications, respond to and investigate complaints, and conduct examinations and investigations. In addition, legal resources to pursue enforcement or administrative discipline as applicable will be needed. The OIR estimates salary and benefits at $1,127,525.

The DBPR indicates a position and information technology resources will be needed to process manufacturer reportable drug price increase submissions but indicates this may be accomplished within existing resources.

The AHCA will incur costs to receive and publish on its website manufacturer reportable drug price increase information.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 499.005, 499.012, 624.307, 624.490, 624.491, 626.88, 626.8805, 626.8814, 626.89, 627.42393, 627.64741, 627.6572, 641.31, and 641.314.

This bill creates the following sections of the Florida Statutes: 499.026, 626.8825, 626.8827, and 626.8828.

This bill creates two non-statutory sections of the Laws of Florida.

IX. Additional Information:

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

CS by Health Policy on March 27, 2023:
The substantive changes in the CS compared to the underlying bill include:

- Allowing manufacturers to claim certain information as trade secret in the submissions of reportable drug price increases.
- Providing a designated point of contact for pharmacies to complain about PBM practices.
- Extending the pharmacy audit requirements in s. 624.491 to pharmacy benefits plans or programs, while retaining the exemptions pertaining to claims paid for by federally funded programs currently in that section and including the failure to comply with these requirements as a prohibited act in s. 626.6627.
- Revising definitions of PBM and network.
- Requiring PBMs to pass 100 percent of all rebates received to the plan or program, if the contractual arrangement delegates the negotiation of rebates to the PBM, for the sole purpose of offsetting defined cost sharing and reducing premiums of covered persons. If any excess remains, the rebate revenue must be used for the sole purpose of offsetting copayments and deductibles of covered persons. The Medicaid managed care plans are exempted from this requirement.
- Expanding the pharmacies to which a PBM must offer a network contract to those co-located in designated Cancer Centers of Excellence, organ transplant hospitals, specialty children's hospitals, and Regional Perinatal Intensive Care Centers.
- Clarifying that a reduced copay or premium of a covered drug is not a prohibited promotional item or an incentive.
- Prohibiting PBMs from preventing pharmacies from providing mail-order or delivery services.
- Streamlining the MAC appeal process when an appeal has been denied to providing a pharmacy with an NDC (national drug code) and identification of wholesalers that have the drug in stock at a price below the MAC pricing information, and authorizing appeals to be submitted by a pharmacy's agent.
- Authorizing the Commission to adopt rules for the qualifications of professional examiners and the requirement for comparable rates and independence with no conflicts of interest.
- Extending a 15-day reporting timeframe to 30 days for notifying OIR of administrative, civil, or criminal events.
- Providing a more detailed appropriation.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/28/2023	.	
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The Committee on Health Policy (Brodeur) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. This act may be cited as the "Prescription Drug Reform Act."

Section 2. Subsection (29) is added to section 499.005, Florida Statutes, to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in

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this state:

(29) Failure to accurately complete and timely submit reportable drug price increase forms and reports as required under this part and rules adopted thereunder.

Section 3. Subsection (16) is added to section 499.012, Florida Statutes, to read:

499.012 Permit application requirements.—

(16) A permit for a prescription drug manufacturer or a nonresident prescription drug manufacturer is subject to the requirements of s. 499.026.

Section 4. Section 499.026, Florida Statutes, is created to read:

499.026 Notification of manufacturer prescription drug price increases.—

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

(a) "Course of therapy" means the recommended daily dose units of a prescription drug pursuant to its prescribing label for 30 days or the recommended daily dose units of a prescription drug pursuant to its prescribing label for a normal course of treatment which is less than 30 days.

(b) "Manufacturer" means a person holding a prescription drug manufacturer permit or a nonresident prescription drug manufacturer permit under s. 499.01.

(c) "Prescription drug" has the same meaning as in s. 499.003 and includes biological products but is limited to those prescription drugs and biological products intended for human use.

(d) "Reportable drug price increase" means, for a prescription drug with a wholesale acquisition cost of at least

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$100 for a course of therapy before the effective date of an increase:

1. Any increase of 15 percent or more of the wholesale acquisition cost during the preceding 12-month period; or

2. Any increase of 40 percent or more of the wholesale acquisition cost during the preceding 3 calendar years.

(e) "Wholesale acquisition cost" means, with respect to a prescription drug or biological product, the manufacturer's list price for the prescription drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data.

(2) On the effective date of a manufacturer's reportable drug price increase, the manufacturer must provide notification of each reportable drug price increase to the department on a form prescribed by the department. The form must require the manufacturer to specify all of the following:

(a) The proprietary and nonproprietary names of the prescription drug, as applicable.

(b) The wholesale acquisition cost before the reportable drug price increase.

(c) The dollar amount of the reportable drug price increase.

(d) The percentage amount of the reportable drug price increase from the wholesale acquisition cost before the reportable drug price increase.

(e) A statement regarding whether a change or improvement

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in the prescription drug necessitates the reportable drug price increase. If so, the manufacturer must describe the change or improvement.

(f) The intended uses of the prescription drug.

This subsection does not prohibit a manufacturer from notifying other parties, such as pharmacy benefit managers, of a drug price increase before the effective date of the drug price increase.

(3) By April 1 of each year, each manufacturer shall submit a report to the department on a form prescribed by the department. A report is not deemed to be submitted until approved by the department. The report must include all of the following:

(a) A list of all prescription drugs affected by a reportable drug price increase during the previous calendar year and both the dollar amount of each reportable drug price increase and the percentage increase of each reportable drug price increase relative to the previous wholesale acquisition cost of the prescription drug. The prescription drugs must be identified using their proprietary names and nonproprietary names, as applicable.

(b) If more than one form has been filed under this section for previous reportable drug price increases, the percentage increase of the prescription drug from the earliest form filed to the most recent form filed.

(c) The intended uses of each prescription drug listed in the report and whether the prescription drug manufacturer benefits from market exclusivity for such drug.

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(d) The length of time the prescription drug has been available for purchase.

(e) A complete description of the factors contributing to each reportable drug price increase. The factors must be provided with such specificity as to explain the need or justification for each reportable drug price increase. The department may request additional information from a manufacturer relating to the need or justification of any reportable drug price increase before approving the manufacturer's report.

(f) Any action that the manufacturer has filed to extend a patent report after the first extension has been granted.

(4)(a) The department shall submit all forms and reports submitted by manufacturers to the Agency for Health Care Administration, to be posted on the agency's website pursuant to s. 408.062. The agency may not post on its website any of the information provided pursuant to paragraph (2)(e), paragraph (3)(e), or paragraph (3)(f) which is marked as a trade secret. The agency shall compile all information on the forms and reports submitted by manufacturers and make it available upon request to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

(b) Except for information provided pursuant to paragraph (2)(e), paragraph (3)(e), or paragraph (3)(f), a manufacturer may not claim a public records exemption for a trade secret under s. 119.0715 for any information required by the department under this section. Department employees remain protected from liability for release of forms and reports pursuant to s. 119.0715(4).

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(5) The department, in consultation with the Agency for Health Care Administration, shall adopt rules to implement this section.

(a) The department shall adopt necessary emergency rules pursuant to s. 120.54(4) to implement this section. If an emergency rule adopted under this section is held to be unconstitutional or an invalid exercise of delegated legislative authority and becomes void, the department may adopt an emergency rule pursuant to this section to replace the rule that has become void. If the emergency rule adopted to replace the void emergency rule is also held to be unconstitutional or an invalid exercise of delegated legislative authority and becomes void, the department must follow the nonemergency rulemaking procedures of the Administrative Procedure Act to replace the rule that has become void.

(b) For emergency rules adopted under this section, the department need not make the findings required under s. 120.54(4)(a). Emergency rules adopted under this section are also exempt from:

1. Sections 120.54(3)(b) and 120.541. Challenges to emergency rules adopted under this section are subject to the time schedules provided in s. 120.56(5).

2. Section 120.54(4)(c) and remain in effect until replaced by rules adopted under the nonemergency rulemaking procedures of the Administrative Procedure Act.

Section 5. Paragraph (a) of subsection (10) of section 624.307, Florida Statutes, is amended, and paragraph (b) of that subsection is republished, to read:

624.307 General powers; duties.—

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(10)(a) The Division of Consumer Services shall perform the following functions concerning products or services regulated by the department or office:

1. Receive inquiries and complaints from consumers.

2. Prepare and disseminate information that the department deems appropriate to inform or assist consumers.

3. Provide direct assistance to and advocacy for consumers who request such assistance or advocacy.

4. With respect to apparent or potential violations of law or applicable rules committed by a person or entity licensed by the department or office, report apparent or potential violations to the office or to the appropriate division of the department, which may take any additional action it deems appropriate.

5. Designate an employee of the division as the primary contact for consumers on issues relating to sinkholes.

6. Designate an employee of the division as the primary contact for consumers and pharmacies on issues relating to pharmacy benefit managers. The division must refer to the office any consumer complaint that alleges conduct that may constitute a violation of part VII of chapter 626 or for which a pharmacy benefit manager does not respond in accordance with paragraph (b).

(b) Any person licensed or issued a certificate of authority by the department or the office shall respond, in writing, to the division within 20 days after receipt of a written request for documents and information from the division concerning a consumer complaint. The response must address the issues and allegations raised in the complaint and include any

requested documents concerning the consumer complaint not subject to attorney-client or work-product privilege. The division may impose an administrative penalty for failure to comply with this paragraph of up to $2,500 per violation upon any entity licensed by the department or the office and $250 for the first violation, $500 for the second violation, and up to $1,000 for the third or subsequent violation upon any individual licensed by the department or the office.

Section 6. Subsection (1) of section 624.490, Florida Statutes, is amended to read:

624.490 Registration of pharmacy benefit managers.—

(1) As used in this section, the term "pharmacy benefit manager" has the same meaning as in s. 626.88 ~~means a person or entity doing business in this state which contracts to administer prescription drug benefits on behalf of a health insurer or a health maintenance organization to residents of this state~~.

Section 7. Subsections (1) and (5) of section 624.491, Florida Statutes, are amended to read:

624.491 Pharmacy audits.—

(1) A pharmacy benefits plan or program as defined in s. 626.8825 ~~health insurer or health maintenance organization~~ providing pharmacy benefits ~~through a major medical individual or group health insurance policy or a health maintenance contract, respectively,~~ must comply with the requirements of this section when the pharmacy benefits plan or program ~~health insurer or health maintenance organization~~ or any person or entity acting on behalf of the pharmacy benefits plan or program ~~health insurer or health maintenance organization~~, including,

but not limited to, a pharmacy benefit manager as defined in s. 626.88 ~~s. 624.490(1)~~, audits the records of a pharmacy licensed under chapter 465. The person or entity conducting such audit must:

(a) Except as provided in subsection (3), notify the pharmacy at least 7 calendar days before the initial onsite audit for each audit cycle.

(b) Not schedule an onsite audit during the first 3 calendar days of a month unless the pharmacist consents otherwise.

(c) Limit the duration of the audit period to 24 months after the date a claim is submitted to or adjudicated by the entity.

(d) In the case of an audit that requires clinical or professional judgment, conduct the audit in consultation with, or allow the audit to be conducted by, a pharmacist.

(e) Allow the pharmacy to use the written and verifiable records of a hospital, physician, or other authorized practitioner, which are transmitted by any means of communication, to validate the pharmacy records in accordance with state and federal law.

(f) Reimburse the pharmacy for a claim that was retroactively denied for a clerical error, typographical error, scrivener’s error, or computer error if the prescription was properly and correctly dispensed, unless a pattern of such errors exists, fraudulent billing is alleged, or the error results in actual financial loss to the entity.

(g) Provide the pharmacy with a copy of the preliminary audit report within 120 days after the conclusion of the audit.

(h) Allow the pharmacy to produce documentation to address a discrepancy or audit finding within 10 business days after the preliminary audit report is delivered to the pharmacy.

(i) Provide the pharmacy with a copy of the final audit report within 6 months after the pharmacy's receipt of the preliminary audit report.

(j) Calculate any recoupment or penalties based on actual overpayments and not according to the accounting practice of extrapolation.

(5) A pharmacy benefits plan or program ~~health insurer or health maintenance organization~~ that, under terms of a contract, transfers to a pharmacy benefit manager the obligation to pay a pharmacy licensed under chapter 465 for any pharmacy benefit claims arising from services provided to or for the benefit of an insured or subscriber remains responsible for a violation of this section.

Section 8. Subsection (1) of section 626.88, Florida Statutes, is amended, and subsection (6) is added to that section, to read:

626.88 Definitions.—For the purposes of this part, the term:

(1) "Administrator" means ~~is~~ any person who directly or indirectly solicits or effects coverage of, collects charges or premiums from, or adjusts or settles claims on residents of this state in connection with authorized commercial self-insurance funds or with insured or self-insured programs which provide life or health insurance coverage or coverage of any other expenses described in s. 624.33(1); ~~or~~ any person who, through a health care risk contract as defined in s. 641.234 with an

insurer or health maintenance organization, provides billing and collection services to health insurers and health maintenance organizations on behalf of health care providers; or a pharmacy benefit manager. The term does not include~~, other than~~ any of the following ~~persons~~:

(a) An employer or wholly owned direct or indirect subsidiary of an employer, on behalf of such employer's employees or the employees of one or more subsidiary or affiliated corporations of such employer.

(b) A union on behalf of its members.

(c) An insurance company which is either authorized to transact insurance in this state or is acting as an insurer with respect to a policy lawfully issued and delivered by such company in and pursuant to the laws of a state in which the insurer was authorized to transact an insurance business.

(d) A health care services plan, health maintenance organization, professional service plan corporation, or person in the business of providing continuing care, possessing a valid certificate of authority issued by the office, and the sales representatives thereof, if the activities of such entity are limited to the activities permitted under the certificate of authority.

(e) An entity that is affiliated with an insurer and that only performs the contractual duties, between the administrator and the insurer, of an administrator for the direct and assumed insurance business of the affiliated insurer. The insurer is responsible for the acts of the administrator and is responsible for providing all of the administrator's books and records to the insurance commissioner, upon a request from the insurance

commissioner. For purposes of this paragraph, the term "insurer" means a licensed insurance company, health maintenance organization, prepaid limited health service organization, or prepaid health clinic.

(f) A nonresident entity licensed in its state of domicile as an administrator if its duties in this state are limited to the administration of a group policy or plan of insurance and no more than a total of 100 lives for all plans reside in this state.

(g) An insurance agent licensed in this state whose activities are limited exclusively to the sale of insurance.

(h) A person appointed as a managing general agent in this state, whose activities are limited exclusively to the scope of activities conveyed under such appointment.

(i) An adjuster licensed in this state whose activities are limited to the adjustment of claims.

(j) A creditor on behalf of such creditor's debtors with respect to insurance covering a debt between the creditor and its debtors.

(k) A trust and its trustees, agents, and employees acting pursuant to such trust established in conformity with 29 U.S.C. s. 186.

(l) A trust exempt from taxation under s. 501(a) of the Internal Revenue Code, a trust satisfying the requirements of ss. 624.438 and 624.439, or any governmental trust as defined in s. 624.33(3), and the trustees and employees acting pursuant to such trust, or a custodian and its agents and employees, including individuals representing the trustees in overseeing the activities of a service company or administrator, acting

pursuant to a custodial account which meets the requirements of s. 401(f) of the Internal Revenue Code.

(m) A financial institution which is subject to supervision or examination by federal or state authorities or a mortgage lender licensed under chapter 494 who collects and remits premiums to licensed insurance agents or authorized insurers concurrently or in connection with mortgage loan payments.

(n) A credit card issuing company which advances for and collects premiums or charges from its credit card holders who have authorized such collection if such company does not adjust or settle claims.

(o) A person who adjusts or settles claims in the normal course of such person’s practice or employment as an attorney at law and who does not collect charges or premiums in connection with life or health insurance coverage.

(p) A person approved by the department who administers only self-insured workers’ compensation plans.

(q) A service company or service agent and its employees, authorized in accordance with ss. 626.895-626.899, serving only a single employer plan, multiple-employer welfare arrangements, or a combination thereof.

(r) Any provider or group practice, as defined in s. 456.053, providing services under the scope of the license of the provider or the member of the group practice.

(s) Any hospital providing billing, claims, and collection services solely on its own and its physicians’ behalf and providing services under the scope of its license.

(t) A corporation not for profit whose membership consists entirely of local governmental units authorized to enter into

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risk management consortiums under s. 112.08.

A person who provides billing and collection services to health insurers and health maintenance organizations on behalf of health care providers shall comply with the provisions of ss. 627.6131, 641.3155, and 641.51(4).

(6) "Pharmacy benefit manager" means a person or an entity doing business in this state which contracts to administer prescription drug benefits on behalf of a pharmacy benefits plan or program as defined in s. 626.8825. The term includes, but is not limited to, a person or an entity that performs one or more of the following services:

(a) Pharmacy claims processing.

(b) Administration or management of pharmacy discount card programs.

(c) Managing pharmacy networks or pharmacy reimbursement.

(d) Paying or managing claims for pharmacist services provided to covered persons.

(e) Developing or managing a clinical formulary, including utilization management or quality assurance programs.

(f) Pharmacy rebate administration.

(g) Managing patient compliance, therapeutic intervention, or generic substitution programs.

(h) Administration or management of a mail-order pharmacy program.

Section 9. Present subsections (3) through (6) of section 626.8805, Florida Statutes, are redesignated as subsections (4) through (7), respectively, a new subsection (3) and subsection (8) are added to that section, and subsection (1) and present

subsection (3) of that section are amended, to read:

626.8805 Certificate of authority to act as administrator.—

(1) It is unlawful for any person to act as or hold himself or herself out to be an administrator in this state without a valid certificate of authority issued by the office pursuant to ss. 626.88-626.894. A pharmacy benefit manager that is registered with the office under s. 624.490 as of June 30, 2023, may continue to operate until January 1, 2024, as an administrator without a certificate of authority and is not in violation of the requirement to possess a valid certificate of authority as an administrator during that timeframe. To qualify for and hold authority to act as an administrator in this state, an administrator must otherwise be in compliance with this code and with its organizational agreement. The failure of any person, excluding a pharmacy benefit manager, to hold such a certificate while acting as an administrator shall subject such person to a fine of not less than $5,000 or more than $10,000 for each violation. A person who, on or after January 1, 2024, does not hold a certificate of authority to act as an administrator while operating as a pharmacy benefit manager is subject to a fine of $10,000 per violation per day.

(3) An applicant that is a pharmacy benefit manager must also submit all of the following:

(a) A complete biographical statement on forms prescribed by the commission, an independent investigation report, and fingerprints obtained pursuant to chapter 624 of all of the individuals referred to in paragraph (2)(c).

(b) A self-disclosure of any administrative, civil, or criminal complaints, settlements, or discipline of the

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applicant, or any of the applicant's affiliates, which relate to a violation of the insurance laws, including pharmacy benefit manager laws, in any state.

(c) A statement attesting to compliance with the network requirements in s. 626.8825 beginning January 1, 2024.

(4)(a) ~~(3)~~ The applicant shall make available for inspection by the office copies of all contracts relating to services provided by the administrator to insurers or other persons using the services of the administrator.

(b) An applicant that is a pharmacy benefit manager shall also make available for inspection by the office:

1. Copies of all contract templates with any pharmacy as defined in s. 465.003; and

2. Copies of all subcontracts to support its operations.

(8) A pharmacy benefit manager is exempt from fees associated with the initial application and the annual filing fees in s. 626.89.

Section 10. Section 626.8814, Florida Statutes, is amended to read:

626.8814 Disclosure of ownership or affiliation.—

(1) Each administrator shall identify to the office any ownership interest or affiliation of any kind with any insurance company responsible for providing benefits directly or through reinsurance to any plan for which the administrator provides administrative services.

(2) Pharmacy benefit managers shall also identify to the office any ownership affiliation of any kind with any pharmacy which, either directly or indirectly, through one or more intermediaries:

(a) Has an investment or ownership interest in a pharmacy benefit manager holding a certificate of authority issued under this part;

(b) Shares common ownership with a pharmacy benefit manager holding a certificate of authority issued under this part; or

(c) Has an investor or a holder of an ownership interest which is a pharmacy benefit manager holding a certificate of authority issued under this part.

(3) A pharmacy benefit manager shall report any change in information required by subsection (2) to the office in writing within 60 days after the change occurs.

Section 11. Section 626.8825, Florida Statutes, is created to read:

626.8825 Pharmacy benefit manager transparency and accountability.—

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

(a) "Adjudication transaction fee" means a fee charged by the pharmacy benefit manager to the pharmacy for electronic claim submissions.

(b) "Affiliated pharmacy" means a pharmacy that, either directly or indirectly through one or more intermediaries:

1. Has an investment or ownership interest in a pharmacy benefit manager holding a certificate of authority issued under this part;

2. Shares common ownership with a pharmacy benefit manager holding a certificate of authority issued under this part; or

3. Has an investor or a holder of an ownership interest which is a pharmacy benefit manager holding a certificate of authority issued under this part.

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(c) "Brand name or generic effective rate" means the contractual rate set forth by a pharmacy benefit manager for the reimbursement of covered brand name or generic drugs, calculated using the total payments in the aggregate, by drug type, during the performance period. The effective rates are typically calculated as a discount from industry benchmarks, such as average wholesale price or wholesale acquisition cost.

(d) "Covered person" means a person covered by, participating in, or receiving the benefit of a pharmacy benefits plan or program.

(e) "Direct and indirect remuneration fees" means price concessions that are paid to the pharmacy benefit manager by the pharmacy retrospectively and that cannot be calculated at the point of sale. The term may also include discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, upfront payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies, or similar entities.

(f) "Dispensing fee" means a fee intended to cover reasonable costs associated with providing the drug to a covered person. This cost includes the pharmacist's services and the overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.

(g) "Effective rate guarantee" means the minimum ingredient cost reimbursement a pharmacy benefit manager guarantees it will pay for pharmacist services during the applicable measurement period.

(h) "Erroneous claims" means pharmacy claims submitted in

error, including, but not limited to, unintended, incorrect, fraudulent, or test claims.

(i) "Incentive payment" means a retrospective monetary payment made as a reward or recognition by the pharmacy benefits plan or program or pharmacy benefit manager to a pharmacy for meeting or exceeding predefined pharmacy performance metrics as related to quality measures, such as Healthcare Effectiveness Data and Information Set measures.

(j) "Maximum allowable cost appeal pricing adjustment" means a retrospective positive payment adjustment made to a pharmacy by the pharmacy benefits plan or program or by the pharmacy benefit manager pursuant to an approved maximum allowable cost appeal request submitted by the same pharmacy to dispute the amount reimbursed for a drug based on the pharmacy benefit manager's listed maximum allowable cost price.

(k) "Monetary recoupments" means rescinded or recouped payments from a pharmacy or provider by the pharmacy benefits plan or program or by the pharmacy benefit manager.

(l) "Network" means a group of pharmacies that agree to provide pharmacist services to covered persons on behalf of a pharmacy benefits plan or program or a group of pharmacy benefits plans or programs in exchange for payment for such services. The term includes a pharmacy that generally dispenses outpatient prescription drugs to covered persons.

(m) "Network reconciliation offsets" means a process during annual payment reconciliation between a pharmacy benefit manager and a pharmacy which allows the pharmacy benefit manager to offset an amount for overperformance or underperformance of contractual guarantees across guaranteed line items, channels,

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networks, or payors, as applicable.

(n) "Participation contract" means any agreement between a pharmacy benefit manager and pharmacy for the provision and reimbursement of pharmacist services and any exhibits, attachments, amendments, or addendums to such agreement.

(o) "Pass-through pricing model" means a payment model used by a pharmacy benefit manager in which the payments made by the pharmacy benefits plan or program to the pharmacy benefit manager for the covered outpatient drugs are:

1. Equivalent to the payments the pharmacy benefit manager makes to a dispensing pharmacy or provider for such drugs, including any contracted professional dispensing fee between the pharmacy benefit manager and its network of pharmacies. Such dispensing fee would be paid if the pharmacy benefits plan or program was making the payments directly.

2. Passed through in their entirety by the pharmacy benefits plan or program or by the pharmacy benefit manager to the pharmacy or provider that dispenses the drugs, and the payments are made in a manner that is not offset by any reconciliation.

(p) "Pharmacist" has the same meaning as in s. 465.003.

(q) "Pharmacist services" means products, goods, and services or any combination of products, goods, and services provided as part of the practice of the profession of pharmacy as defined in s. 465.003 or otherwise covered by a pharmacy benefits plan or program.

(r) "Pharmacy" has the same meaning as in s. 465.003.

(s) "Pharmacy benefit manager" has the same meaning as in s. 626.88.

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(t) "Pharmacy benefits plan or program" means a plan or program that pays for, reimburses, covers the cost of, or provides access to discounts on pharmacist services provided by one or more pharmacies to covered persons who reside in, are employed by, or receive pharmacist services from this state. The term includes, but is not limited to, health maintenance organizations, health insurers, self-insured employer health plans, discount card programs, and government-funded health plans, including the Statewide Medicaid Managed Care program established pursuant to part IV of chapter 409 and the state group insurance program pursuant to part I of chapter 110.

(u) "Rebate" means all payments that accrue to a pharmacy benefit manager or its pharmacy benefits plan or program client, directly or indirectly, from a pharmaceutical manufacturer, including, but not limited to, discounts, administration fees, credits, incentives, or penalties associated directly or indirectly in any way with claims administered on behalf of a pharmacy benefits plan or program client.

(v) "Spread pricing" is the practice in which a pharmacy benefit manager charges a pharmacy benefits plan or program a different amount for pharmacist services than the amount the pharmacy benefit manager reimburses a pharmacy for such pharmacist services.

(w) "Usual and customary price" means the amount charged to cash customers for a pharmacist service exclusive of sales tax or other amounts claimed.

(2) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A PHARMACY BENEFITS PLAN OR PROGRAM.—In addition to any other requirements in the Florida Insurance Code, all contractual

arrangements executed, amended, adjusted, or renewed on or after July 1, 2023, which are applicable to pharmacy benefits covered on or after January 1, 2024, between a pharmacy benefit manager and a pharmacy benefits plan or program must:

(a) Use a pass-through pricing model, remaining consistent with the prohibition in paragraph (3)(c).

(b) Exclude terms that allow for the direct or indirect engagement in the practice of spread pricing unless the pharmacy benefit manager passes along the entire amount of such difference to the pharmacy benefits plan or program as allowable under paragraph (a).

(c) Ensure that funds received in relation to providing services for a pharmacy benefits plan or program or a pharmacy are received by the pharmacy benefit manager in trust for the pharmacy benefits plan or program or pharmacy, as applicable, and are used or distributed only pursuant to the pharmacy benefit manager's contract with the pharmacy benefits plan or program or with the pharmacy or as otherwise required by applicable law.

(d) Require the pharmacy benefit manager to calculate a covered person's defined cost-sharing obligation at the point of sale based on a price that is reduced by an amount equal to at least 100 percent of all rebates received, or to be received, in connection with the dispensing or administration of the covered prescription drug, if the contractual arrangement delegates the negotiation of rebates to the pharmacy benefit manager. All rebates above the defined cost-sharing obligation must be passed to the pharmacy benefits plan or program for the purpose of reducing premiums. This paragraph does not preclude a pharmacy

benefits plan or program from decreasing a covered person's defined cost-sharing obligation by an amount greater than that provided for under this paragraph. The commission shall adopt rules to implement this paragraph.

(e) Include network adequacy requirements that meet or exceed the Medicare Part D program standards for convenient access to network pharmacies set forth in 42 C.F.R. s. 423.120, and that:

1. Do not limit a network to solely include affiliated pharmacies;

2. Require a pharmacy benefit manager to offer a provider contract to licensed pharmacies physically located on the physical site of providers that are:

a. Within the pharmacy benefits plan's or program's geographic service area and that have been specifically designated as essential providers by the Agency for Health Care Administration pursuant to s. 409.975(1)(a);

b. Designated as a Cancer Center of Excellence under s. 381.925, regardless of the pharmacy benefits plan's or program's geographic service area;

c. Organ transplant hospitals, regardless of the pharmacy benefits plan's or program's geographic service area;

d. Hospitals licensed as specialty children's hospitals as defined in s. 395.002; or

e. Regional perinatal intensive care centers as defined in s. 383.16(2), regardless of the pharmacy benefits plan's or program's geographic service area.

Such provider contracts must be solely for the administration or

649 dispensing of covered prescription drugs, including biological
650 products, that are administered through infusions, intravenously
651 injected, inhaled during a surgical procedure, or a covered
652 parenteral drug, as part of onsite outpatient care;
653 3. Do not require a covered person to receive a
654 prescription drug by United States mail, common carrier, local
655 courier, third-party company or delivery service, or pharmacy
656 direct delivery. This subparagraph does not prohibit a pharmacy
657 benefit manager from operating mail order or delivery programs
658 on an opt-in basis at the sole discretion of a covered person;
659 4. Prohibit a requirement for a covered person to receive
660 pharmacist services from an affiliated pharmacy or an affiliated
661 health care provider for the in-person administration of covered
662 prescription drugs; offering or implementing pharmacy networks
663 that require or provide a promotional item or an incentive,
664 defined as anything other than a reduced copay or premium of a
665 covered drug, to a covered person to use an affiliated pharmacy
666 or an affiliated health care provider for the in-person
667 administration of covered prescription drugs; or advertising,
668 marketing, or promoting an affiliated pharmacy to covered
669 persons. Subject to the foregoing, a pharmacy benefit manager
670 may include an affiliated pharmacy in communications to covered
671 persons regarding network pharmacies and prices, provided that
672 the pharmacy benefit manager includes information, such as links
673 to all nonaffiliated network pharmacies, in such communications
674 and that the information provided is accurate and of equal
675 prominence. This paragraph may not be construed to prohibit a
676 pharmacy benefit manager from entering into an agreement with an
677 affiliated pharmacy to provide pharmacist services to covered

persons.

(f) Prohibit the ability of a pharmacy benefit manager to condition participation in one pharmacy network on participation in any other pharmacy network or penalize a pharmacy for exercising its prerogative not to participate in a specific pharmacy network.

(g) Prohibit a pharmacy benefit manager from instituting a network that requires a pharmacy to meet accreditation standards inconsistent with or more stringent than applicable federal and state requirements for licensure and operation as a pharmacy in this state.

(3) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A PARTICIPATING PHARMACY.—In addition to other requirements in the Florida Insurance Code, a participation contract executed, amended, adjusted, or renewed on or after July 1, 2023, that applies to pharmacist services on or after January 1, 2024, between a pharmacy benefit manager and one or more pharmacies or pharmacists, must include, in substantial form, terms that ensure compliance with all of the following requirements, and that, except to the extent not allowed by law, shall supersede any contractual terms in the participation contract to the contrary:

(a) At the time of adjudication for electronic claims or the time of reimbursement for nonelectronic claims, the pharmacy benefit manager shall provide the pharmacy with a remittance, including such detailed information as is necessary for the pharmacy or pharmacist to identify the reimbursement schedule for the specific network applicable to the claim and which is the basis used by the pharmacy benefit manager to calculate the

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amount of reimbursement paid. This information must include, but is not limited to, the applicable network reimbursement ID or plan ID as defined in the most current version of the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, or its nationally recognized successor industry guide. The commission shall adopt rules to implement this paragraph.

(b) The pharmacy benefit manager must ensure that any basis of reimbursement information is communicated to a pharmacy in accordance with the NCPDP Telecommunication Standard Implementation Guide, or its nationally recognized successor industry guide, when performing reconciliation for any effective rate guarantee, and that such basis of reimbursement information communicated is accurate, corresponds with the applicable network rate, and may be relied upon by the pharmacy.

(c) A prohibition of financial clawbacks or reconciliation offsets. A pharmacy benefit manager may not recoup direct or indirect remuneration fees, dispensing fees, brand name or generic effective rate adjustments through reconciliation, or any other monetary recoupments as related to discounts, multiple network reconciliation offsets, adjudication transaction fees, and any other instance when a fee may be recouped from a pharmacy. For purposes of this section, the terms "financial clawbacks" or "reconciliation offsets" do not include:

1. Any incentive payments provided by the pharmacy benefit manager to a network pharmacy for meeting or exceeding predefined quality measures, such as Healthcare Effectiveness Data and Information Set measures; recoupment due to an erroneous claim, fraud, waste, or abuse; a claim adjudicated in

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error; a maximum allowable cost appeal pricing adjustment; or an adjustment made as part of a pharmacy audit pursuant to s. 624.491.

2. Any recoupment that is returned to the state for programs in chapter 409 or the state group insurance program in s. 110.123.

(d) A pharmacy benefit manager may not unilaterally change the terms of any participation contract.

(e) Unless otherwise prohibited by law, a pharmacy benefit manager may not prohibit a pharmacy or pharmacist from:

1. Offering mail or delivery services on an opt-in basis at the sole discretion of the covered person.

2. Mailing or delivering a prescription drug to a covered person upon his or her request.

3. Charging a shipping or handling fee to a covered person requesting a prescription drug be mailed or delivered if the pharmacy or pharmacist discloses to the covered person before the mailing or delivery the amount of the fee that will be charged and that the fee may not be reimbursable by the covered person’s pharmacy benefits plan or program.

(f) The pharmacy benefit manager must provide a pharmacy, upon its request, a list of pharmacy benefits plans or programs in which the pharmacy is a part of the network. Updates to the list must be communicated to the pharmacy within 7 days. The pharmacy benefit manager may not restrict the pharmacy or pharmacist from disclosing this information to the public.

(g) The pharmacy benefit manager must ensure that the Electronic Remittance Advice contains claim level payment adjustments in accordance with the American National Standards

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Institute Accredited Standards Committee, X12 format, and includes or is accompanied by the appropriate level of detail for the pharmacy to reconcile any debits or credits, including, but not limited to, pharmacy NCPDP or NPI identifier, date of service, prescription number, refill number, adjustment code, if applicable, and transaction amount.

(h) The pharmacy benefit manager shall provide a reasonable administrative appeal procedure to allow a pharmacy or pharmacist to challenge the maximum allowable cost pricing information and the reimbursement made under the maximum allowable cost as defined in s. 627.64741 for a specific drug as being below the acquisition cost available to the challenging pharmacy or pharmacist.

1. The administrative appeal procedure must include a telephone number and e-mail address, or a website, for the purpose of submitting the administrative appeal. The appeal may be submitted by the pharmacy or an agent of the pharmacy directly to the pharmacy benefit manager or through a pharmacy service administration organization. The pharmacy or pharmacist must be given at least 30 business days after a maximum allowable cost update or after an adjudication for an electronic claim or reimbursement for a nonelectronic claim to file the administrative appeal.

2. The pharmacy benefit manager must respond to the administrative appeal within 30 business days after receipt of the appeal.

3. If the appeal is upheld, the pharmacy benefit manager must:

a. Update the maximum allowable cost pricing information to

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at least the acquisition cost available to the pharmacy;

b. Permit the pharmacy or pharmacist to reverse and rebill the claim in question;

c. Provide to the pharmacy or pharmacist the national drug code on which the increase or change is based; and

d. Make the increase or change effective for each similarly situated pharmacy or pharmacist who is subject to the applicable maximum allowable cost pricing information.

4. If the appeal is denied, the pharmacy benefit manager must provide to the pharmacy or pharmacist the national drug code and the name of the national or regional pharmaceutical wholesalers operating in this state which have the drug currently in stock at a price below the maximum allowable cost pricing information.

5. Every 90 days, a pharmacy benefit manager shall report to the office the total number of appeals received and denied in the preceding 90-day period for each specific drug for which an appeal was submitted pursuant to this paragraph.

Section 12. Section 626.8827, Florida Statutes, is created to read:

626.8827 Pharmacy benefit manager prohibited practices.—In addition to other prohibitions in this part, a pharmacy benefit manager may not do any of the following:

(1) Prohibit, restrict, or penalize in any way a pharmacy or pharmacist from disclosing to any person any information that the pharmacy or pharmacist deems appropriate, including, but not limited to, information regarding any of the following:

(a) The nature of treatment, risks, or alternatives thereto.

(b) The availability of alternate treatment, consultations, or tests.

(c) The decision of utilization reviewers or similar persons to authorize or deny pharmacist services.

(d) The process used to authorize or deny pharmacist services or benefits.

(e) Information on financial incentives and structures used by the pharmacy benefits plan or program.

(f) Information that may reduce the costs of pharmacist services.

(g) Whether the cost-sharing obligation exceeds the retail price for a covered prescription drug and the availability of a more affordable alternative drug, pursuant to s. 465.0244.

(2) Prohibit, restrict, or penalize in any way a pharmacy or pharmacist from disclosing information to the office, the Agency for Health Care Administration, Department of Management Services, law enforcement, or state and federal governmental officials, provided that the recipient of the information represents it has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential; and before disclosure of information designated as confidential, the pharmacist or pharmacy marks as confidential any document in which the information appears or requests confidential treatment for any oral communication of the information.

(3) Communicate at the point-of-sale, or otherwise require, a cost-sharing obligation for the covered person in an amount that exceeds the lesser of:

(a) The applicable cost-sharing amount under the applicable

pharmacy benefits plan or program; or

(b) The usual and customary price, as defined in s. 626.8825, of the pharmacist services.

(4) Transfer or share records relative to prescription information containing patient-identifiable or prescriber-identifiable data to an affiliated pharmacy for any commercial purpose other than the limited purposes of facilitating pharmacy reimbursement, formulary compliance, or utilization review on behalf of the applicable pharmacy benefits plan or program.

(5) Fail to make any payment due to a pharmacy for an adjudicated claim with a date of service before the effective date of a pharmacy's termination from a pharmacy benefit network unless payments are withheld because of actual fraud on the part of the pharmacy or except as otherwise required by law.

(6) Terminate the contract of, penalize, or disadvantage a pharmacist or pharmacy due to a pharmacist or pharmacy:

(a) Disclosing information about pharmacy benefit manager practices in accordance with this act;

(b) Exercising any of its prerogatives under this part; or

(c) Sharing any portion, or all, of the pharmacy benefit manager contract with the office pursuant to a complaint or a query regarding whether the contract is in compliance with this act.

(7) Fail to comply with the requirements in s. 626.8825 or s. 624.491.

Section 13. Section 626.8828, Florida Statutes, is created to read:

626.8828 Investigations and examinations of pharmacy benefit managers; expenses; penalties.—

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(1) The office may investigate administrators who are pharmacy benefit managers and applicants for authorization as provided in ss. 624.307 and 624.317. The office shall review any referral made pursuant to s. 624.307(10) and shall investigate any referral that, as determined by the Commissioner of Insurance Regulation or his or her designee, reasonably indicates a possible violation of this part.

(2)(a) The office shall examine the business and affairs of each pharmacy benefit manager at least biennially. The biennial examination of each pharmacy benefit manager must be a systematic review for the purpose of determining the pharmacy benefit manager's compliance with all provisions of this part and all other laws or rules applicable to pharmacy benefit managers and must include a detailed review of the pharmacy benefit manager's compliance with ss. 626.8825 and 626.8827. The first 2-year cycle for conducting biennial reviews begins July 1, 2023. By January 1 of the year following a 2-year cycle, the office must deliver to the Governor, the President of the Senate, and the Speaker of the House of Representatives a report summarizing the results of the biennial examinations during the most recent 2-year cycle which includes detailed descriptions of any violations committed by each pharmacy benefit manager and detailed reporting of actions taken by the office against each pharmacy benefit manager for such violations.

(b) The office also may conduct additional examinations as often as it deems advisable or necessary for the purpose of ascertaining compliance with this part and any other laws or rules applicable to pharmacy benefit managers or applicants for authorization.

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(c) If a referral made pursuant to s. 624.307(10) reasonably indicates a pattern or practice of violations of this part by a pharmacy benefit manager, the office must begin an examination of the pharmacy benefit manager or include findings related to such referral within an ongoing examination.

(d) Based on the findings of an examination that a pharmacy benefit manager or an applicant for authorization has exhibited a pattern or practice of knowing and willful violations of s. 626.8825 or s. 626.8827, the office may, pursuant to chapter 120, order a pharmacy benefit manager to file all contracts between the pharmacy benefit manager and pharmacies or pharmacy benefits plans or programs and any policies, guidelines, rules, protocols, standard operating procedures, instructions, or directives that govern or guide the manner in which the pharmacy benefit manager or applicant conducts business related to such knowing and willful violations for review and inspection for the following 36-month period. Such documents are public records and are not trade secrets or otherwise exempt from s. 119.07(1). As used in this section, the term:

1. "Contracts" means any contract to which s. 626.8825 is applicable.

2. "Knowing and willful" means any act of commission or omission which is committed intentionally, as opposed to accidentally, and which is committed with knowledge of the act's unlawfulness or with reckless disregard as to the unlawfulness of the act.

(e) Examinations may be conducted by an independent professional examiner under contract to the office, in which case payment must be made directly to the contracted examiner by

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the pharmacy benefit manager examined in accordance with the rates and terms agreed to by the office and the examiner. The commission shall adopt rules providing for the types of independent professional examiners who may conduct examinations under this section, which types must include, but need not be limited to, independent certified public accountants, actuaries, investment specialists, information technology specialists, or others meeting criteria specified by commission rule. The rules must also require that:

1. The rates charged to the pharmacy benefit manager being examined are consistent with rates charged by other firms in a similar profession and are comparable with the rates charged for comparable examinations.

2. The firm selected by the office to perform the examination has no conflicts of interest which might affect its ability to independently perform its responsibilities for the examination.

(3) In making investigations and examinations of pharmacy benefit managers and applicants for authorization, the office and such pharmacy benefit manager are subject to all of the following provisions:

(a) Section 624.318, as to the conduct of examinations.

(b) Section 624.319, as to examination and investigation reports.

(c) Section 624.321, as to witnesses and evidence.

(d) Section 624.322, as to compelled testimony.

(e) Section 624.324, as to hearings.

(f) Section 624.34, as to fingerprinting.

(g) Any other provision of chapter 624 applicable to the

investigation or examination of a licensee under this part.

(4)(a) A pharmacy benefit manager must maintain an accurate record of all contracts and records with all pharmacies and pharmacy benefits plans or programs for the duration of the contract, and for 5 years thereafter. Such contracts must be made available to the office and kept in a form accessible to the office.

(b) The office may order any pharmacy benefit manager or applicant to produce any records, books, files, contracts, advertising and solicitation materials, or other information and may take statements under oath to determine whether the pharmacy benefit manager or applicant is in violation of the law or is acting contrary to the public interest.

(5)(a) Notwithstanding s. 624.307(3), each pharmacy benefit manager and applicant for authorization must pay to the office the expenses of the examination or investigation. Such expenses include actual travel expenses, a reasonable living expense allowance, compensation of the examiner, investigator, or other person making the examination or investigation, and necessary costs of the office directly related to the examination or investigation. Such travel expenses and living expense allowances are limited to those expenses necessarily incurred on account of the examination or investigation and shall be paid by the examined pharmacy benefit manager or applicant together with compensation upon presentation by the office to such pharmacy benefit manager or applicant of such charges and expenses after a detailed statement has been filed by the examiner and approved by the office.

(b) All moneys collected from pharmacy benefit managers and

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applicants for authorization pursuant to this subsection shall be deposited into the Insurance Regulatory Trust Fund, and the office may make deposits from time to time into such fund from moneys appropriated for the operation of the office.

(c) Notwithstanding s. 112.061, the office may pay to the examiner, investigator, or person making such examination or investigation out of such trust fund the actual travel expenses, reasonable living expense allowance, and compensation in accordance with the statement filed with the office by the examiner, investigator, or other person, as provided in paragraph (a).

(6) In addition to any other enforcement authority available to the office, the office shall impose an administrative fine of $5,000 for each violation of s. 626.8825 or s. 626.8827. Each instance of a violation of such sections by a pharmacy benefit manager against each individual pharmacy or prescription benefits plan or program constitutes a separate violation. Notwithstanding any other provision of law, there is no limitation on aggregate fines issued pursuant to this section. The proceeds from any administrative fine shall be deposited into the General Revenue Fund.

(7) Failure by a pharmacy benefit manager to pay expenses incurred or administrative fines imposed under this section is grounds for the denial, suspension, or revocation of its certificate of authority.

Section 14. Section 626.89, Florida Statutes, is amended to read:

626.89 Annual financial statement and filing fee; notice of change of ownership; pharmacy benefit manager filings.—

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(1) Each authorized administrator shall annually file with the office a full and true statement of its financial condition, transactions, and affairs within 3 months after the end of the administrator's fiscal year or within such extension of time as the office for good cause may have granted. The statement must be for the preceding fiscal year and must be in such form and contain such matters as the commission prescribes and must be verified by at least two officers of the administrator.

(2) Each authorized administrator shall also file an audited financial statement performed by an independent certified public accountant. The audited financial statement must ~~shall~~ be filed with the office within 5 months after the end of the administrator's fiscal year and be for the preceding fiscal year. An audited financial statement prepared on a consolidated basis must include a columnar consolidating or combining worksheet that must be filed with the statement and must comply with the following:

(a) Amounts shown on the consolidated audited financial statement must be shown on the worksheet;

(b) Amounts for each entity must be stated separately; and

(c) Explanations of consolidating and eliminating entries must be included.

(3) At the time of filing its annual statement, the administrator shall pay a filing fee in the amount specified in s. 624.501 for the filing of an annual statement by an insurer.

(4) In addition, the administrator shall immediately notify the office of any material change in its ownership.

(5) A pharmacy benefit manager shall also notify the office within 30 days after any administrative, civil, or criminal

complaints, settlements, or discipline of the pharmacy benefit manager or any of its affiliates which relate to a violation of the insurance laws, including pharmacy benefit laws in any state.

(6) A pharmacy benefit manager shall also annually submit to the office a statement attesting to its compliance with the network requirements of s. 626.8825.

(7) The commission may by rule require all or part of the statements or filings required under this section to be submitted by electronic means in a computer-readable form compatible with the electronic data format specified by the commission.

Section 15. Subsection (5) is added to section 627.42393, Florida Statutes, to read:

627.42393 Step-therapy protocol.—

(5) This section applies to a pharmacy benefit manager acting on behalf of a health insurer.

Section 16. Subsections (2), (3), and (4) of section 627.64741, Florida Statutes, are amended to read:

627.64741 Pharmacy benefit manager contracts.—

(2) In addition to the requirements of part VII of chapter 626, a contract between a health insurer and a pharmacy benefit manager must require that the pharmacy benefit manager:

(a) Update maximum allowable cost pricing information at least every 7 calendar days.

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product

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availability.

~~(3) A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from limiting a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.~~

~~(4) A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from requiring an insured to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:~~

~~(a) The applicable cost-sharing amount; or~~

~~(b) The retail price of the drug in the absence of prescription drug coverage.~~

Section 17. Subsections (2), (3), and (4) of section 627.6572, Florida Statutes, are amended to read:

627.6572 Pharmacy benefit manager contracts.—

(2) In addition to the requirements of part VII of chapter 626, a contract between a health insurer and a pharmacy benefit manager must require that the pharmacy benefit manager:

(a) Update maximum allowable cost pricing information at least every 7 calendar days.

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

~~(3) A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from~~

~~limiting a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.~~

~~(4) A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from requiring an insured to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:~~

~~(a) The applicable cost-sharing amount; or~~

~~(b) The retail price of the drug in the absence of prescription drug coverage.~~

Section 18. Paragraph (e) is added to subsection (46) of section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(46)

(e) This subsection applies to a pharmacy benefit manager acting on behalf of a health maintenance organization.

Section 19. Subsections (2), (3), and (4) of section 641.314, Florida Statutes, are amended to read:

641.314 Pharmacy benefit manager contracts.—

(2) In addition to the requirements of part VII of chapter 626, a contract between a health maintenance organization and a pharmacy benefit manager must require that the pharmacy benefit manager:

(a) Update maximum allowable cost pricing information at least every 7 calendar days.

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in

formulating maximum allowable cost prices and product availability.

~~(3) A contract between a health maintenance organization and a pharmacy benefit manager must prohibit the pharmacy benefit manager from limiting a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.~~

~~(4) A contract between a health maintenance organization and a pharmacy benefit manager must prohibit the pharmacy benefit manager from requiring a subscriber to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:~~

~~(a) The applicable cost-sharing amount; or~~

~~(b) The retail price of the drug in the absence of prescription drug coverage.~~

Section 20. (1) This act establishes requirements for pharmacy benefit managers as defined in s. 626.88, Florida Statutes, including, without limitation, pharmacy benefit managers in their performance of services for or otherwise on behalf of a pharmacy benefits plan or program as defined in s. 626.8825, Florida Statutes, which includes coverage pursuant to Titles XVIII, XIX, or XXI of the Social Security Act, 42 U.S.C. ss. 1395 et seq., 1396 et seq., and 1397aa et seq., known as Medicare, Medicaid, or any other similar coverage under a state or Federal Government funded health plan, including the Statewide Medicaid Managed Care program established pursuant to part IV of chapter 409, Florida Statutes, and the state group insurance program pursuant to part I of chapter 110, Florida

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Statutes.

(2) This act is not intended, nor may it be construed, to conflict with existing, relevant federal law.

(3) If any provision of this act or its application to any person or circumstances is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 21. The sum of $1.5 million is hereby appropriated to the Office of Insurance Regulation to implement this act.

Section 22. This act shall take effect July 1, 2023.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to prescription drugs; providing a short title; amending s. 499.005, F.S.; specifying additional prohibited acts related to the Florida Drug and Cosmetic Act; amending s. 499.012, F.S.; providing that prescription drug manufacturer and nonresident prescription drug manufacturer permitholders are subject to specified requirements; creating s. 499.026, F.S.; defining terms; requiring certain drug manufacturers to notify the Department of Business and Professional Regulation of reportable drug price increases on a specified form on the effective date of such increase; providing requirements for the form;

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providing construction; requiring such manufacturers to submit certain reports to the department by a specified date each year; providing requirements for the reports; authorizing the department to request certain additional information from the manufacturer before approving the report; requiring the department to submit the forms and reports to the Agency for Health Care Administration to be posted on the agency's website; prohibiting the agency from posting on its website certain submitted information that is marked as a trade secret; requiring the agency to compile all information from the submitted forms and reports and make it available to the Governor and the Legislature upon request; prohibiting manufacturers from claiming a public records exemption for trade secrets for certain information provided in such forms or reports; providing that department employees remain protected from liability for releasing the forms and reports as public records; authorizing the department, in consultation with the agency, to adopt rules; providing for emergency rulemaking; amending s. 624.307, F.S.; requiring the Division of Consumer Services of the Department of Financial Services to designate an employee as the primary contact for consumer complaints involving pharmacy benefit managers; requiring the division to refer certain complaints to the Office of Insurance Regulation; amending s. 624.490, F.S.; revising the definition of the term "pharmacy benefit manager"; amending s.


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624.491, F.S.; revising provisions related to pharmacy audits; amending s. 626.88, F.S.; revising the definition of the term "administrator"; defining the term "pharmacy benefit manager"; amending s. 626.8805, F.S.; providing a grandfathering provision for certain pharmacy benefit managers operating as administrators; providing a penalty for certain persons who do not hold a certificate of authority to act as an administrator on or after a specified date; providing additional requirements for pharmacy benefit managers applying for a certificate of authority to act as an administrator; exempting pharmacy benefit managers from certain fees; amending s. 626.8814, F.S.; requiring pharmacy benefit managers to identify certain ownership affiliations to the office; requiring pharmacy benefit managers to report any change in such information to the office within a specified timeframe; creating s. 626.8825, F.S.; defining terms; providing requirements for certain contracts between a pharmacy benefit manager and a pharmacy benefits plan or program or a participating pharmacy; requiring the Financial Services Commission to adopt rules; specifying requirements for certain administrative appeal procedures that such contracts with participating pharmacies must include; requiring pharmacy benefit managers to submit reports on submitted appeals to the office every 90 days; creating s. 626.8827, F.S.; specifying prohibited practices for pharmacy benefit managers; creating s.

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626.8828, F.S.; authorizing the office to investigate administrators that are pharmacy benefit managers and certain applicants; requiring the office to review certain referrals and investigate them under certain circumstances; providing for biennial reviews of pharmacy benefit managers; authorizing the office to conduct additional examinations; requiring the office to conduct an examination under certain circumstances; providing procedures and requirements for such examinations; defining the terms "contracts" and "knowing and willful"; providing that independent professional examiners under contract with the office may conduct examinations of pharmacy benefit managers; requiring the commission to adopt specified rules; specifying provisions that apply to such investigations and examinations; providing recordkeeping requirements for pharmacy benefit managers; authorizing the office to order the production of such records and other specified information; authorizing the office to take statements under oath; requiring pharmacy benefit managers and applicants subjected to an investigation or examination to pay the associated expenses; specifying covered expenses; providing for collection of such expenses; providing for the deposit of certain moneys into the Insurance Regulatory Trust Fund; authorizing the office to pay examiners, investigators, and other persons from such fund; providing administrative penalties; providing grounds for administrative action

against a certificate of authority; amending s. 626.89, F.S.; requiring pharmacy benefit managers to notify the office of specified complaints, settlements, or discipline within a specified timeframe; requiring pharmacy benefit managers to annually submit a certain attestation statement to the office; amending s. 627.42393, F.S.; providing that certain step-therapy protocol requirements apply to a pharmacy benefit manager acting on behalf of a health insurer; amending ss. 627.64741 and 627.6572, F.S.; conforming provisions to changes made by the act; amending s. 641.31, F.S.; providing that certain step-therapy protocol requirements apply to a pharmacy benefit manager acting on behalf of a health maintenance organization; amending s. 641.314, F.S.; conforming a provision to changes made by the act; providing legislative intent, construction, and severability; providing an appropriation; providing an effective date.

297190

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/28/2023	.	
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	.	
	.	

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

Senate Amendment to Amendment (100780) (with title amendment)

Delete lines 610 - 623
and insert:
(d) Require the pharmacy benefit manager to pass 100 percent of all prescription drug manufacturer rebates, including nonresident manufacturer rebates, received to the pharmacy benefits plan or program, if the contractual arrangement delegates the negotiation of rebates to the pharmacy benefit

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manager, for the sole purpose of offsetting defined cost sharing and reducing premiums of covered persons. Any excess rebate revenue after the pharmacy benefit manager and the pharmacy benefits plan or program have taken all actions required under this paragraph must be used for the sole purpose of offsetting copayments and deductibles of covered persons. This paragraph does not apply to contracts involving Medicaid managed care plans.

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

And the title is amended as follows:

Delete lines 1250 - 1251

and insert:

pharmacy; specifying requirements for certain

555656

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/28/2023	.	
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	.	
	.	

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

Senate Amendment to Amendment (100780)

Delete lines 1179 - 1180

and insert:

Section 21. For the 2023-2024 fiscal year, the sum of $980,705 in recurring funds and $146,820 in nonrecurring funds from the Insurance Regulatory Trust Fund are appropriated to the Office of Insurance Regulation, and 10 full-time equivalent positions with associated salary rate of 644,877 are authorized, for the purpose of implementing this act.

By Senator Brodeur

10-00822D-23 20231550__

A bill to be entitled

An act relating to prescription drugs; providing a short title; amending s. 499.005, F.S.; specifying additional prohibited acts related to the Florida Drug and Cosmetic Act; amending s. 499.012, F.S.; providing that prescription drug manufacturer and nonresident prescription drug manufacturer permitholders are subject to specified requirements; creating s. 499.026, F.S.; defining terms; requiring certain drug manufacturers to notify the Department of Business and Professional Regulation of reportable drug price increases on a specified form on the effective date of such increase; providing requirements for the form; providing construction; requiring such manufacturers to submit certain reports to the department by a specified date each year; providing requirements for the reports; authorizing the department to request certain additional information from the manufacturer before approving the report; requiring the department to submit the forms and reports to the Agency for Health Care Administration to be posted on the agency's website; prohibiting manufacturers from claiming a public records exemption for trade secrets for any information provided in such notifications or reports; providing that department employees remain protected from liability for releasing the forms and reports as public records; authorizing the department, in consultation with the agency, to adopt rules; providing for emergency rulemaking; amending s.

10-00822D-23 20231550__

624.307, F.S.; requiring the Division of Consumer Services of the Department of Financial Services to designate an employee as the primary contact for consumer complaints involving pharmacy benefit managers; requiring the division to refer certain complaints to the Office of Insurance Regulation; amending s. 624.490, F.S.; revising the definition of the term "pharmacy benefit manager"; amending s. 626.88, F.S.; revising the definition of the term "administrator"; defining the term "pharmacy benefit manager"; amending s. 626.8805, F.S.; providing a grandfathering provision for certain pharmacy benefit managers operating as administrators; providing a penalty for certain persons who do not hold a certificate of authority to act as an administrator on or after a specified date; providing additional requirements for pharmacy benefit managers applying for a certificate of authority to act as an administrator; exempting pharmacy benefit managers for certain fees; amending s. 626.8814, F.S.; requiring pharmacy benefit managers to identify certain ownership affiliations to the office; requiring pharmacy benefit managers to report any change in such information to the office within a specified timeframe; creating s. 626.8825, F.S.; defining terms; providing requirements for certain contracts between a pharmacy benefit manager and a pharmacy benefits plan or program or a participating pharmacy; specifying requirements for certain administrative appeal

procedures that such contracts with participating pharmacies must include; requiring pharmacy benefit managers to submit reports on submitted appeals to the office every 90 days; creating s. 626.8827, F.S.; specifying prohibited practices for pharmacy benefit managers; creating s. 626.8828, F.S.; authorizing the office to investigate administrators that are pharmacy benefit managers and certain applicants; requiring the office to review certain referrals and investigate them under certain circumstances; providing for biennial reviews of pharmacy benefit managers; authorizing the office to conduct additional examinations; requiring the office to conduct an examination under certain circumstances; providing procedures and requirements for such examinations; defining the terms "contracts" and "knowing and willful"; specifying provisions that apply to such investigations and examinations; providing recordkeeping requirements for pharmacy benefit managers; authorizing the office to order the production of such records and other specified information; authorizing the office to take statements under oath; requiring pharmacy benefit managers and applicants subjected to an investigation or examination to pay the associated expenses; specifying covered expenses; providing for collection of such expenses; providing for the deposit of certain moneys into the Insurance Regulatory Trust Fund; authorizing the office to pay examiners, investigators, and other

persons from such fund; providing administrative penalties; providing grounds for administrative action against a certificate of authority; amending s. 626.89, F.S.; requiring pharmacy benefit managers to notify the office of specified complaints, settlements, or discipline within a specified timeframe; requiring pharmacy benefit managers to annually submit a certain attestation statement to the office; amending s. 627.42393, F.S.; providing that certain step-therapy protocol requirements apply to a pharmacy benefit manager acting on behalf of a health insurer; amending ss. 627.64741 and 627.6572, F.S.; conforming provisions to changes made by the act; amending s. 641.31, F.S.; providing that certain step-therapy protocol requirements apply to a pharmacy benefit manager acting on behalf of a health maintenance organization; amending s. 641.314, F.S.; conforming a provision to changes made by the act; amending s. 624.491, F.S.; conforming a cross-reference; providing legislative intent, construction, and severability; providing an appropriation; providing an effective date.

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

Section 1. This act may be cited as the "Prescription Drug Reform Act."

Section 2. Subsection (29) is added to section 499.005, Florida Statutes, to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(29) Failure to accurately complete and timely submit reportable drug price increase forms and reports as required under this part and rules adopted thereunder.

Section 3. Subsection (16) is added to section 499.012, Florida Statutes, to read:

499.012 Permit application requirements.—

(16) A permit for a prescription drug manufacturer or a nonresident prescription drug manufacturer is subject to the requirements of s. 499.026.

Section 4. Section 499.026, Florida Statutes, is created to read:

499.026 Notification of manufacturer prescription drug price increases.—

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

(a) "Course of therapy" means the recommended daily dose units of a prescription drug pursuant to its prescribing label for 30 days or the recommended daily dose units of a prescription drug pursuant to its prescribing label for a normal course of treatment which is less than 30 days.

(b) "Manufacturer" means a person holding a prescription drug manufacturer permit or a nonresident prescription drug manufacturer permit under s. 499.01.

(c) "Prescription drug" has the same meaning as in s. 499.003 and includes biological products but is limited to those prescription drugs and biological products intended for human use.

(d) "Reportable drug price increase" means, for a prescription drug with a wholesale acquisition cost of at least $100 for a course of therapy before the effective date of an increase:

1. Any increase of 15 percent or more of the wholesale acquisition cost during the preceding 12-month period; or

2. Any increase of 40 percent or more of the wholesale acquisition cost during the preceding 3 calendar years.

(e) "Wholesale acquisition cost" means, with respect to a prescription drug or biological product, the manufacturer's list price for the prescription drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data.

(2) On the effective date of a manufacturer's reportable drug price increase, the manufacturer must provide notification of each reportable drug price increase to the department on a form prescribed by the department. The form must require the manufacturer to specify all of the following:

(a) The proprietary and nonproprietary names of the prescription drug, as applicable.

(b) The wholesale acquisition cost before the reportable drug price increase.

(c) The dollar amount of the reportable drug price increase.

(d) The percentage amount of the reportable drug price increase from the wholesale acquisition cost before the

reportable drug price increase.

(e) A statement regarding whether a change or improvement in the prescription drug necessitates the reportable drug price increase. If so, the manufacturer must describe the change or improvement.

(f) The intended uses of the prescription drug.

This subsection does not prohibit a manufacturer from notifying other parties, such as pharmacy benefit managers, of a drug price increase before the effective date of the drug price increase.

(3) By April 1 of each year, each manufacturer shall submit a report to the department on a form prescribed by the department. A report is not deemed to be submitted until approved by the department. At a minimum, the report must include all of the following:

(a) A list of all prescription drugs affected by a reportable drug price increase during the previous calendar year and both the dollar amount of each reportable drug price increase and the percentage increase of each reportable drug price increase relative to the previous wholesale acquisition cost of the prescription drug. The prescription drugs shall be identified using their proprietary names and nonproprietary names, as applicable.

(b) If more than one form has been filed under this section for previous reportable drug price increases, the percentage increase of the prescription drug from the earliest form filed to the most recent form filed.

(c) The intended uses of each prescription drug listed in

the report and whether the prescription drug manufacturer benefits from market exclusivity for such drug.

(d) The length of time the prescription drug has been available for purchase.

(e) A complete description of the factors contributing to each reportable drug price increase. The factors must be provided with such specificity as to explain the need or justification for each reportable drug price increase. The department may request additional information from a manufacturer relating to the need or justification of any reportable drug price increase before approving the manufacturer's report.

(f) Any action that the manufacturer has filed to extend a patent report after the first extension has been granted.

(4)(a) The department shall submit all forms and reports submitted by manufacturers to the Agency for Health Care Administration, to be posted on the agency's website pursuant to s. 408.062.

(b) A manufacturer may not claim a public records exemption for a trade secret under s. 119.0715 for any information required by the department under this section. Department employees remain protected from liability for release of forms and reports pursuant to s. 119.0715(4).

(5) The department, in consultation with the Agency for Health Care Administration, shall adopt rules to implement this section.

(a) The department shall adopt necessary emergency rules pursuant to s. 120.54(4) to implement this section. If an emergency rule adopted under this section is held to be

unconstitutional or an invalid exercise of delegated legislative authority and becomes void, the department may adopt an emergency rule pursuant to this section to replace the rule that has become void. If the emergency rule adopted to replace the void emergency rule is also held to be unconstitutional or an invalid exercise of delegated legislative authority and becomes void, the department shall follow the nonemergency rulemaking procedures of the Administrative Procedure Act to replace the rule that has become void.

(b) For emergency rules adopted under this section, the department need not make the findings required under s. 120.54(4)(a). Emergency rules adopted under this section are also exempt from:

1. Sections 120.54(3)(b) and 120.541. Challenges to emergency rules adopted under this section are subject to the time schedules provided in s. 120.56(5).

2. Section 120.54(4)(c), and remain in effect until replaced by rules adopted under the nonemergency rulemaking procedures of the Administrative Procedure Act.

Section 5. Paragraph (a) of subsection (10) of section 624.307, Florida Statutes, is amended, and paragraph (b) of that subsection is republished, to read:

624.307 General powers; duties.—

(10)(a) The Division of Consumer Services shall perform the following functions concerning products or services regulated by the department or office:

1. Receive inquiries and complaints from consumers.

2. Prepare and disseminate information that the department deems appropriate to inform or assist consumers.

3. Provide direct assistance to and advocacy for consumers who request such assistance or advocacy.

4. With respect to apparent or potential violations of law or applicable rules committed by a person or entity licensed by the department or office, report apparent or potential violations to the office or to the appropriate division of the department, which may take any additional action it deems appropriate.

5. Designate an employee of the division as the primary contact for consumers on issues relating to sinkholes.

6. Designate an employee of the division as the primary contact for consumers on issues relating to pharmacy benefit managers. The division must refer to the office any consumer complaint that alleges conduct that may constitute a violation of part VII of chapter 626 or for which a pharmacy benefit manager does not respond in accordance with paragraph (b).

(b) Any person licensed or issued a certificate of authority by the department or the office shall respond, in writing, to the division within 20 days after receipt of a written request for documents and information from the division concerning a consumer complaint. The response must address the issues and allegations raised in the complaint and include any requested documents concerning the consumer complaint not subject to attorney-client or work-product privilege. The division may impose an administrative penalty for failure to comply with this paragraph of up to $2,500 per violation upon any entity licensed by the department or the office and $250 for the first violation, $500 for the second violation, and up to $1,000 for the third or subsequent violation upon any individual

licensed by the department or the office.

Section 6. Subsection (1) of section 624.490, Florida Statutes, is amended to read:

624.490 Registration of pharmacy benefit managers.—

(1) As used in this section, the term "pharmacy benefit manager" has the same meaning as in s. 626.88 ~~means a person or entity doing business in this state which contracts to administer prescription drug benefits on behalf of a health insurer or a health maintenance organization to residents of this state~~.

Section 7. Subsection (1) of section 626.88, Florida Statutes, is amended, and subsection (6) is added to that section, to read:

626.88 Definitions.—For the purposes of this part, the term:

(1) "Administrator" means ~~is~~ any person who directly or indirectly solicits or effects coverage of, collects charges or premiums from, or adjusts or settles claims on residents of this state in connection with authorized commercial self-insurance funds or with insured or self-insured programs which provide life or health insurance coverage or coverage of any other expenses described in s. 624.33(1); ~~or~~ any person who, through a health care risk contract as defined in s. 641.234 with an insurer or health maintenance organization, provides billing and collection services to health insurers and health maintenance organizations on behalf of health care providers; or a pharmacy benefit manager. The term does not include~~, other than~~ any of the following ~~persons~~:

(a) An employer or wholly owned direct or indirect

subsidiary of an employer, on behalf of such employer's employees or the employees of one or more subsidiary or affiliated corporations of such employer.

(b) A union on behalf of its members.

(c) An insurance company which is either authorized to transact insurance in this state or is acting as an insurer with respect to a policy lawfully issued and delivered by such company in and pursuant to the laws of a state in which the insurer was authorized to transact an insurance business.

(d) A health care services plan, health maintenance organization, professional service plan corporation, or person in the business of providing continuing care, possessing a valid certificate of authority issued by the office, and the sales representatives thereof, if the activities of such entity are limited to the activities permitted under the certificate of authority.

(e) An entity that is affiliated with an insurer and that only performs the contractual duties, between the administrator and the insurer, of an administrator for the direct and assumed insurance business of the affiliated insurer. The insurer is responsible for the acts of the administrator and is responsible for providing all of the administrator's books and records to the insurance commissioner, upon a request from the insurance commissioner. For purposes of this paragraph, the term "insurer" means a licensed insurance company, health maintenance organization, prepaid limited health service organization, or prepaid health clinic.

(f) A nonresident entity licensed in its state of domicile as an administrator if its duties in this state are limited to

the administration of a group policy or plan of insurance and no more than a total of 100 lives for all plans reside in this state.

(g) An insurance agent licensed in this state whose activities are limited exclusively to the sale of insurance.

(h) A person appointed as a managing general agent in this state, whose activities are limited exclusively to the scope of activities conveyed under such appointment.

(i) An adjuster licensed in this state whose activities are limited to the adjustment of claims.

(j) A creditor on behalf of such creditor's debtors with respect to insurance covering a debt between the creditor and its debtors.

(k) A trust and its trustees, agents, and employees acting pursuant to such trust established in conformity with 29 U.S.C. s. 186.

(l) A trust exempt from taxation under s. 501(a) of the Internal Revenue Code, a trust satisfying the requirements of ss. 624.438 and 624.439, or any governmental trust as defined in s. 624.33(3), and the trustees and employees acting pursuant to such trust, or a custodian and its agents and employees, including individuals representing the trustees in overseeing the activities of a service company or administrator, acting pursuant to a custodial account which meets the requirements of s. 401(f) of the Internal Revenue Code.

(m) A financial institution which is subject to supervision or examination by federal or state authorities or a mortgage lender licensed under chapter 494 who collects and remits premiums to licensed insurance agents or authorized insurers

concurrently or in connection with mortgage loan payments.

(n) A credit card issuing company which advances for and collects premiums or charges from its credit card holders who have authorized such collection if such company does not adjust or settle claims.

(o) A person who adjusts or settles claims in the normal course of such person's practice or employment as an attorney at law and who does not collect charges or premiums in connection with life or health insurance coverage.

(p) A person approved by the department who administers only self-insured workers' compensation plans.

(q) A service company or service agent and its employees, authorized in accordance with ss. 626.895-626.899, serving only a single employer plan, multiple-employer welfare arrangements, or a combination thereof.

(r) Any provider or group practice, as defined in s. 456.053, providing services under the scope of the license of the provider or the member of the group practice.

(s) Any hospital providing billing, claims, and collection services solely on its own and its physicians' behalf and providing services under the scope of its license.

(t) A corporation not for profit whose membership consists entirely of local governmental units authorized to enter into risk management consortiums under s. 112.08.

A person who provides billing and collection services to health insurers and health maintenance organizations on behalf of health care providers shall comply with the provisions of ss. 627.6131, 641.3155, and 641.51(4).

(6) "Pharmacy benefit manager" means a person or entity doing business in this state which contracts to administer prescription drug benefits on behalf of a pharmacy benefits plan or program as defined in s. 626.8825. The term includes, but is not limited to, a person or entity that performs one or more of the following services:

(a) Pharmacy claims processing.

(b) Administration or management of pharmacy discount card programs.

(c) Managing pharmacy networks or pharmacy reimbursement.

(d) Paying or managing claims for pharmacist services provided to covered persons.

(e) Developing or managing a clinical formulary, including utilization management or quality assurance programs.

(f) Pharmacy rebate administration.

(g) Managing patient compliance, therapeutic intervention, or generic substitution programs.

Section 8. Present subsections (3) through (6) of section 626.8805, Florida Statutes, are redesignated as subsection (4) through (7), respectively, a new subsection (3) and subsection (8) are added to that section, and subsection (1) and present subsection (3) of that section are amended, to read:

626.8805 Certificate of authority to act as administrator.—

(1) It is unlawful for any person to act as or hold himself or herself out to be an administrator in this state without a valid certificate of authority issued by the office pursuant to ss. 626.88-626.894. A pharmacy benefit manager that is registered with the office under s. 624.490 as of June 30, 2023, may continue to operate until January 1, 2024, as an

administrator without a certificate of authority and is not in violation of the requirement to possess a valid certificate of authority as an administrator during that timeframe. To qualify for and hold authority to act as an administrator in this state, an administrator must otherwise be in compliance with this code and with its organizational agreement. The failure of any person, excluding a pharmacy benefit manager, to hold such a certificate while acting as an administrator shall subject such person to a fine of not less than $5,000 or more than $10,000 for each violation. A person who, on or after January 1, 2024, does not hold a certificate of authority to act as an administrator while operating as a pharmacy benefit manager is subject to a fine of $10,000 per violation per day.

(3) An applicant that is a pharmacy benefit manager must also submit all of the following:

(a) A complete biographical statement on forms prescribed by the commission, an independent investigation report, and fingerprints obtained pursuant to chapter 624, of all of the individuals referred to in paragraph (2)(c).

(b) A self-disclosure of any administrative, civil, or criminal complaints, settlements, or discipline of the applicant, or any of the applicant's affiliates, which relate to a violation of the insurance laws, including pharmacy benefit manager laws, in any state.

(c) A statement attesting to compliance with the network requirements in s. 626.8825 beginning January 1, 2024.

(4)(a) The applicant shall make available for inspection by the office copies of all contracts relating to services provided by the administrator to insurers or other persons using the

services of the administrator.

(b) An applicant that is a pharmacy benefit manager shall also make available for inspection by the office:

1. Copies of all contract templates with any pharmacy as defined in s. 465.003; and

2. Copies of all subcontracts to support its operations.

(8) A pharmacy benefit manager is exempt from fees associated with the initial application and the annual filing fees in s. 626.89.

Section 9. Section 626.8814, Florida Statutes, is amended to read:

626.8814 Disclosure of ownership or affiliation.—

(1) Each administrator shall identify to the office any ownership interest or affiliation of any kind with any insurance company responsible for providing benefits directly or through reinsurance to any plan for which the administrator provides administrative services.

(2) Pharmacy benefit managers shall also identify to the office any ownership affiliation of any kind with any pharmacy which, either directly or indirectly, through one or more intermediaries:

(a) Has an investment or ownership interest in a pharmacy benefit manager holding a certificate of authority issued under this part;

(b) Shares common ownership with a pharmacy benefit manager holding a certificate of authority issued under this part; or

(c) Has an investor or a holder of an ownership interest which is a pharmacy benefit manager holding a certificate of authority issued under this part.

(3) A pharmacy benefit manager shall report any change in information required by subsection (2) to the office in writing within 60 days after the change occurs.

Section 10. Section 626.8825, Florida Statutes, is created to read:

626.8825 Pharmacy benefit manager transparency and accountability.—

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

(a) "Adjudication transaction fee" means a fee charged by the pharmacy benefit manager to the pharmacy for electronic claim submissions.

(b) "Affiliated pharmacy" means a pharmacy that, either directly or indirectly through one or more intermediaries:

1. Has an investment or ownership interest in a pharmacy benefit manager holding a certificate of authority issued under this part;

2. Shares common ownership with a pharmacy benefit manager holding a certificate of authority issued under this part; or

3. Has an investor or a holder of an ownership interest which is a pharmacy benefit manager holding a certificate of authority issued under this part.

(c) "Brand name or generic effective rate" means the contractual rate set forth by a pharmacy benefit manager for the reimbursement of covered brand name or generic drugs, calculated using the total payments in the aggregate, by drug type, during the performance period. The effective rates are typically calculated as a discount from industry benchmarks, such as average wholesale price or wholesale acquisition cost.

(d) "Covered person" means a person covered by,

participating in, or receiving the benefit of a pharmacy benefits plan or program.

(e) "Direct and indirect remuneration fees" means price concessions that are paid to the pharmacy benefit manager by the pharmacy retrospectively and that cannot be calculated at the point of sale. The term may also include discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, upfront payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies, or similar entities.

(f) "Dispensing fee" means a fee intended to cover reasonable costs associated with providing the drug to a covered person. This cost includes the pharmacist's services and the overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.

(g) "Effective rate guarantee" means the minimum ingredient cost reimbursement a pharmacy benefit manager guarantees it will pay for pharmacist services during the applicable measurement period.

(h) "Erroneous claims" means pharmacy claims submitted in error, including, but not limited to, unintended, incorrect, fraudulent, or test claims.

(i) "Incentive payment" means a retrospective monetary payment made as a reward or recognition by the pharmacy benefits plan or program or pharmacy benefit manager to a pharmacy for meeting or exceeding predefined pharmacy performance metrics as related to quality measure, such as Healthcare Effectiveness Data and Information Set measures.

(j) "Maximum allowable cost appeal pricing adjustment" means a retrospective positive payment adjustment made to a pharmacy by the pharmacy benefits plan or program or by the pharmacy benefit manager pursuant to an approved maximum allowable cost appeal request submitted by the same pharmacy to dispute the amount reimbursed for a drug based on the pharmacy benefit manager's listed maximum allowable cost price.

(k) "Monetary recoupments" means rescinded or recouped payments from a pharmacy or provider by the pharmacy benefits plan or program or by the pharmacy benefit manager.

(l) "Network" means a pharmacy or group of pharmacies that agree to provide pharmacist services to covered persons on behalf of a pharmacy benefits plan or program or a group of pharmacy benefits plans or programs in exchange for payment for such services. The term includes a pharmacy that generally dispenses outpatient prescription drugs to covered persons or dispenses particular types of prescription drugs, provides pharmacist services to particular types of covered persons, or dispenses prescriptions in particular health care settings, including networks of specialty, institutional, or long-term care facilities.

(m) "Network reconciliation offsets" means a process during annual payment reconciliation between a pharmacy benefit manager and a pharmacy which allows the pharmacy benefit manager to offset an amount for overperformance or underperformance of contractual guarantees across guaranteed line items, channels, networks, or payers, as applicable.

(n) "Participation contract" means any agreement between a pharmacy benefit manager and pharmacy for the provision and

reimbursement of pharmacist services and any exhibits, attachments, amendments, or addendums to such agreement.

(o) "Pass-through pricing model" means a payment model used by a pharmacy benefit manager in which the payments made by the pharmacy benefits plan or program to the pharmacy benefit manager for the covered outpatient drugs are:

1. Equivalent to the payments the pharmacy benefit manager makes to a dispensing pharmacy or provider for such drugs, including any contracted professional dispensing fee between the pharmacy benefit manager and its network of pharmacies. Such dispensing fee would be paid if the pharmacy benefits plan or program was making the payments directly.

2. Passed through in their entirety by the pharmacy benefits plan or program or by the pharmacy benefit manager to the pharmacy or provider that dispenses the drugs, and the payments are made in a manner that is not offset by any reconciliation.

(p) "Pharmacist" means a pharmacist as defined in s. 465.003.

(q) "Pharmacist services" means products, goods, and services or any combination of products, goods, and services provided as part of the practice of the profession of pharmacy as defined in s. 465.003 or otherwise covered by a pharmacy benefits plan or program.

(r) "Pharmacy" means a pharmacy as defined in s. 465.003.

(s) "Pharmacy benefit manager" has the same meaning as in s. 626.88.

(t) "Pharmacy benefits plan or program" means a plan or program that pays for, reimburses, covers the cost of, or

provides access to discounts on pharmacist services provided by one or more pharmacies to covered persons who reside in, are employed by, or receive pharmacist services from this state. The term includes, but is not limited to, health maintenance organizations, health insurers, self-insured employer health plans, discount card programs, and government-funded health plans, including the Statewide Medicaid Managed Care program established pursuant to part IV of chapter 409 and the state group insurance program pursuant to part I of chapter 110.

(u) "Rebate" means all payments that accrue to a pharmacy benefit manager or its pharmacy benefits plan or program client, directly or indirectly, from a pharmaceutical manufacturer, including, but not limited to, discounts, administration fees, credits, incentives, or penalties associated directly or indirectly in any way with claims administered on behalf of a pharmacy benefits plan or program client.

(v) "Spread pricing" is the practice in which a pharmacy benefit manager charges a pharmacy benefits plan or program a different amount for pharmacist services than the amount the pharmacy benefit manager reimburses a pharmacy for such pharmacist services.

(w) "Usual and customary price" means the amount charged to cash customers for a pharmacist service exclusive of sales tax or other amounts claimed.

(2) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A PHARMACY BENEFITS PLAN OR PROGRAM.—In addition to any other requirements in the Florida Insurance Code, all contractual arrangements executed, amended, adjusted, or renewed on or after July 1, 2023, which are applicable to pharmacy benefits covered

on or after January 1, 2024, between a pharmacy benefit manager and a pharmacy benefits plan or program must:

(a) Use a pass-through pricing model, remaining consistent with the prohibition in paragraph (3)(c).

(b) Exclude terms that allow for the direct or indirect engagement in the practice of spread pricing unless the pharmacy benefit manager passes along the entire amount of such difference to the pharmacy benefits plan or program as allowable under paragraph (a).

(c) Ensure that funds received in relation to providing services for a pharmacy benefits plan or program or a pharmacy are received by the pharmacy benefit manager in trust for the pharmacy benefits plan or program or pharmacy, as applicable, and are used or distributed only pursuant to the pharmacy benefit manager's contract with the pharmacy benefits plan or program or with the pharmacy or as otherwise required by applicable law.

(d) Include network adequacy requirements that meet or exceed the Medicare Part D program standards for convenient access to network pharmacies set forth in 42 C.F.R. s. 423.120, and that:

1. Do not limit a network to solely include affiliated pharmacies;

2. Require a pharmacy benefit manager to offer a provider contract to licensed pharmacies physically located on the physical site of providers within the pharmacy benefits plan's or program's geographic service area which have been specifically designated as essential providers by the Agency for Health Care Administration pursuant to s. 409.975(1)(a), and

Florida cancer hospitals that meet the criteria in s. 409.975(1)(b), regardless of the pharmacy benefits plan's or program's geographic service area, solely for the administration or dispensing of covered prescription drugs, including biological products, that are administered through infusions, intravenously injected, inhaled during a surgical procedure, or a covered parenteral drug, as part of onsite outpatient care;

3. Do not require a covered person to receive a prescription drug by United States mail, common carrier, local courier, third-party company or delivery service, or pharmacy direct delivery. This subparagraph does not prohibit a pharmacy benefit manager from operating mail order or delivery programs on an opt-in basis at the sole discretion of a covered person;

4. Prohibit a requirement for a covered person to receive pharmacist services from an affiliated pharmacy or an affiliated health care provider for the in-person administration of covered prescription drugs; offering or implementing pharmacy networks that require or incentivize a covered person to use an affiliated pharmacy or an affiliated health care provider for the in-person administration of covered prescription drugs; or advertising, marketing, or promoting an affiliated pharmacy to covered persons. Subject to the foregoing, a pharmacy benefit manager may include an affiliated pharmacy in communications to covered persons regarding network pharmacies and prices, provided that the pharmacy benefit manager includes information, such as links to all nonaffiliated network pharmacies, in such communications and that the information provided is accurate and of equal prominence. This paragraph may not be construed to prohibit a pharmacy benefit manager from entering into an

agreement with an affiliated pharmacy to provide pharmacist services to covered persons.

(e) Prohibit the ability of a pharmacy benefit manager to condition participation in one pharmacy network on participation in any other pharmacy network or penalize a pharmacy for exercising its prerogative not to participate in a specific pharmacy network.

(f) Prohibit a pharmacy benefit manager from instituting a network that requires a pharmacy to meet accreditation standards inconsistent with or more stringent than applicable federal and state requirements for licensure and operation as a pharmacy in this state.

(3) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A PARTICIPATING PHARMACY.—In addition to other requirements in the Florida Insurance Code, a participation contract executed, amended, adjusted, or renewed on or after July 1, 2023, that applies to pharmacist services on or after January 1, 2024, between a pharmacy benefit manager and one or more pharmacies or pharmacists, must include, in substantial form, terms that ensure compliance with all of the following requirements, and which, except to the extent not allowed by law, shall supersede any contractual terms in the participation contract to the contrary:

(a) At the time of adjudication for electronic claims or the time of reimbursement for non-electronic claims, the pharmacy benefit manager shall provide the pharmacy with a remittance, including such detailed information as is necessary for the pharmacy or pharmacist to identify the reimbursement schedule for the specific network applicable to the claim and

which is the basis used by the pharmacy benefit manager to calculate the amount of reimbursement paid. This information must include, but is not limited to, the applicable network reimbursement ID or plan ID as defined in the most current version of the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, or its nationally recognized successor industry guide. The office shall adopt rules to implement this paragraph.

(b) The pharmacy benefit manager must ensure that any basis of reimbursement information is communicated to a pharmacy in accordance with the NCPDP Telecommunication Standard Implementation Guide, or its nationally recognized successor industry guide, when performing reconciliation for any effective rate guarantee, and that such basis of reimbursement information communicated is accurate, corresponds with the applicable network rate, and may be relied upon by the pharmacy.

(c) A prohibition of financial clawbacks or reconciliation offsets. A pharmacy benefit manager may not recoup direct or indirect remuneration fees, dispensing fees, brand name or generic effective rate adjustments through reconciliation, or any other monetary recoupments as related to discounts, multiple network reconciliation offsets, adjudication transaction fees, and any other instance when a fee may be recouped from a pharmacy. For purposes of this section, the terms "financial clawbacks" or "reconciliation offsets" do not include:

1. Any incentive payments provided by the pharmacy benefit manager to a network pharmacy for meeting or exceeding predefined quality measures, such as Healthcare Effectiveness Data and Information Set measures; recoupment due to an

erroneous claim, fraud, waste, or abuse; a claim adjudicated in error; a maximum allowable cost appeal pricing adjustment; or an adjustment made as part of a pharmacy audit pursuant to s. 624.491.

2. Any recoupment that is returned to the state for programs in chapter 409 or the state group insurance program in s. 110.123.

(d) A pharmacy benefit manager may not unilaterally change the terms of any participation contract.

(e) The pharmacy benefit manager must provide a pharmacy, upon its request, a list of pharmacy benefits plans or programs in which the pharmacy is a part of the network. Updates to the list must be communicated to the pharmacy within 7 days. The pharmacy benefit manager may not restrict the pharmacy or pharmacist from disclosing this information to the public.

(f) The pharmacy benefit manager must ensure that the Electronic Remittance Advice contains claim level payment adjustments in accordance with American National Standards Institute Accredited Standard Committee, X12 format, and must include or be accompanied by the appropriate level of detail for the pharmacy to reconcile any debits or credits, including, but not limited to, pharmacy NCPDP or NPI identifier, date of service, prescription number, refill number, adjustment code, if applicable, and transaction amount.

(g) The pharmacy benefit manager shall provide a reasonable administrative appeal procedure to allow a pharmacy or pharmacist to challenge the maximum allowable cost pricing information and the reimbursement made under the maximum allowable cost for a specific drug as being below the

acquisition cost available to the challenging pharmacy or pharmacist.

1. The administrative appeal procedure must include a telephone number and e-mail address, or a website, for the purpose of submitting the administrative appeal. The appeal may be submitted directly to the pharmacy benefit manager or through a pharmacy service administration organization. The pharmacy or pharmacist must be given at least 30 business days after a maximum allowable cost update or after an adjudication for an electronic claim or reimbursement for a non-electronic claim to file the administrative appeal.

2. The pharmacy benefit manager must respond to the administrative appeal within 30 business days after receipt of the appeal.

3. If the appeal is upheld, the pharmacy benefit manager must:

a. Update the maximum allowable cost pricing information to at least the acquisition cost available to the pharmacy;

b. Permit the pharmacy or pharmacist to reverse and rebill the claim in question;

c. Provide to the pharmacy or pharmacist the national drug code on which the increase or change is based; and

d. Make the increase or change effective for each similarly situated pharmacy or pharmacist who is subject to the applicable maximum allowable cost pricing information.

4. If the appeal is denied, the pharmacy benefit manager must provide to the pharmacy or pharmacist the national drug code and the name of the national or regional pharmaceutical wholesalers operating in this state which have the drug

currently in stock at a price below the maximum allowable cost pricing information.

5. If the drug with the national drug code provided by the pharmacy benefit manager is not available below the acquisition cost to the pharmacy or pharmacist from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of drugs for resale, the pharmacy benefits manager must adjust the maximum allowable cost pricing information above the acquisition cost to the pharmacy or pharmacist and permit the pharmacy or pharmacist to reverse and rebill each claim affected by the pharmacy's or pharmacist's inability to procure the drug at a cost that is equal to or less than the previously challenged maximum allowable cost.

6. Every 90 days, a pharmacy benefit manager shall report to the office the total number of appeals received and denied in the preceding 90-day period for each specific drug for which an appeal was submitted pursuant to this paragraph.

Section 11. Section 626.8827, Florida Statutes, is created to read:

626.8827 Pharmacy benefit manager prohibited practices.—In addition to other prohibitions in this part, a pharmacy benefit manager may not do any of the following:

(1) Prohibit, restrict, or penalize in any way a pharmacy or pharmacist from disclosing to any person any information that the pharmacy or pharmacist deems appropriate, including, but not limited to, information regarding any of the following:

(a) The nature of treatment, risks, or alternatives thereto.

(b) The availability of alternate treatment, consultations,

or tests.

(c) The decision of utilization reviewers or similar persons to authorize or deny pharmacist services.

(d) The process used to authorize or deny pharmacist services or benefits.

(e) Information on financial incentives and structures used by the pharmacy benefits plan or program.

(f) Information that may reduce the costs of pharmacist services.

(g) Whether the cost-sharing obligation exceeds the retail price for a covered prescription drug and the availability of a more affordable alternative drug, pursuant to s. 465.0244.

(2) Prohibit, restrict, or penalize in any way a pharmacy or pharmacist from disclosing information to the office, the Agency for Health Care Administration, Department of Management Services, law enforcement, or state and federal governmental officials, provided that the recipient of the information represents it has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential; and before disclosure of information designated as confidential, the pharmacist or pharmacy marks as confidential any document in which the information appears or requests confidential treatment for any oral communication of the information.

(3) Communicate at the point-of-sale, or otherwise require, a cost-sharing obligation for the covered person in an amount that exceeds the lesser of:

(a) The applicable cost-sharing amount under the applicable pharmacy benefits plan or program; or

(b) The usual and customary price, as defined in s. 626.8825, of the pharmacist services.

(4) Transfer or share records relative to prescription information containing patient-identifiable or prescriber-identifiable data to an affiliated pharmacy for any commercial purpose other than the limited purposes of facilitating pharmacy reimbursement, formulary compliance, or utilization review on behalf of the applicable pharmacy benefits plan or program.

(5) Fail to make any payment due to a pharmacy for an adjudicated claim with a date of service before the effective date of a pharmacy's termination from a pharmacy benefit network unless payments are withheld because of actual fraud on the part of the pharmacy or except as otherwise required by law.

(6) Terminate the contract of, penalize, or disadvantage a pharmacist or pharmacy due to a pharmacist or pharmacy:

(a) Disclosing information about pharmacy benefit manager practices in accordance with this act;

(b) Exercising any of its prerogatives under this part; or

(c) Sharing any portion, or all, of the pharmacy benefit manager contract with the office pursuant to a complaint or a query regarding whether the contract is in compliance with this act.

(7) Fail to comply with the requirements in s. 626.8825.

Section 12. Section 626.8828, Florida Statutes, is created to read:

626.8828 Investigations and examinations of pharmacy benefit managers; expenses; penalties.—

(1) The office may investigate administrators who are pharmacy benefit managers and applicants for authorization as

provided in ss. 624.307 and 624.317. The office must review any referral made pursuant to s. 624.307(10) and must investigate any referral that, as determined by the Commissioner of Insurance Regulation or his or her designee, reasonably indicates a possible violation of this part.

(2)(a) The office shall examine the business and affairs of each pharmacy benefit manager at least biennially. The biennial examination of each pharmacy benefit manager must be a systematic review for the purpose of determining the pharmacy benefit manager's compliance with all provisions of this part and all other laws or rules applicable to pharmacy benefit managers and must include a detailed review of the pharmacy benefit manager's compliance with ss. 626.8825 and 626.8827. The first 2-year cycle for conducting biennial reviews begins July 1, 2023. By January 1 of the year following a 2-year cycle, the office must deliver to the Governor, the President of the Senate, and the Speaker of the House of Representatives a report summarizing the results of the biennial examinations during the most recent 2-year cycle which includes detailed descriptions of any violations committed by each pharmacy benefit manager and detailed reporting of actions taken by the office against each pharmacy benefit manager for such violations.

(b) The office also may conduct additional examinations as often as it deems advisable or necessary for the purpose of ascertaining compliance with this part and any other laws or rules applicable to pharmacy benefit managers or applicants for authorization.

(c) If a referral made pursuant to s. 624.307(10) reasonably indicates a pattern or practice of violations of this

part by a pharmacy benefit manager, the office must begin an examination of the pharmacy benefit manager or include findings related to such referral within an ongoing examination.

(d) Based on the findings of an examination that a pharmacy benefit manager or an applicant for authorization has exhibited a pattern or practice of knowing and willful violations of s. 626.8825 or s. 626.8827, the office may, pursuant to chapter 120, order a pharmacy benefit manager to file all contracts between the pharmacy benefit manager and pharmacies or pharmacy benefits plans or programs and any policies, guidelines, rules, protocols, standard operating procedures, instructions, or directives that govern or guide the manner in which the pharmacy benefit manager or applicant conducts business related to such knowing and willful violations for review and inspection for the following 36-month period. Such documents are public records and are not trade secrets or otherwise exempt from s. 119.07(1). As used in this section, the term:

1. "Contracts" means any contract to which s. 626.8825 is applicable.

2. "Knowing and willful" means any act of commission or omission which is committed intentionally, as opposed to accidentally, and which is committed with knowledge of the act's unlawfulness or with reckless disregard as to the unlawfulness of the act.

(e) Examinations may be conducted by an independent professional examiner under contract to the office, in which case payment must be made directly to the contracted examiner by the pharmacy benefit manager examined in accordance with the rates and terms agreed to by the office and the examiner.

(3) In making investigations and examinations of pharmacy benefit managers and applicants for authorization, the office and such pharmacy benefit manager is subject to all of the following provisions:

(a) Section 624.318, as to the conduct of examinations.

(b) Section 624.319, as to examination and investigation reports.

(c) Section 624.321, as to witnesses and evidence.

(d) Section 624.322, as to compelled testimony.

(e) Section 624.324, as to hearings.

(f) Section 624.34, as to fingerprinting.

(g) Any other provision of chapter 624 applicable to the investigation or examination of a licensee under this part.

(4)(a) A pharmacy benefit manager must maintain an accurate record of all contracts and records with all pharmacies and pharmacy benefits plans or programs for the duration of the contract, and for 5 years thereafter. Such contracts must be made available to the office and kept in a form accessible to the office.

(b) The office may order any pharmacy benefit manager or applicant to produce any records, books, files, contracts, advertising and solicitation materials, or other information and may take statements under oath to determine whether the pharmacy benefit manager or applicant is in violation of the law or is acting contrary to the public interest.

(5)(a) Notwithstanding s. 624.307(3), each pharmacy benefit manager and applicant for authorization must pay to the office the expenses of the examination or investigation. Such expenses include actual travel expenses, reasonable living expense

allowance, compensation of the examiner, investigator, or other person making the examination or investigation, and necessary costs of the office directly related to the examination or investigation. Such travel expense and living expense allowances are limited to those expenses necessarily incurred on account of the examination or investigation and shall be paid by the examined pharmacy benefit manager or applicant together with compensation upon presentation by the office to such pharmacy benefit manager or applicant of such charges and expenses after a detailed statement has been filed by the examiner and approved by the office.

(b) All moneys collected from pharmacy benefit managers and applicants for authorization pursuant to this subsection shall be deposited into the Insurance Regulatory Trust Fund, and the office may make deposits from time to time into such fund from moneys appropriated for the operation of the office.

(c) Notwithstanding s. 112.061, the office may pay to the examiner, investigator, or person making such examination or investigation out of such trust fund the actual travel expenses, reasonable living expense allowance, and compensation in accordance with the statement filed with the office by the examiner, investigator, or other person, as provided in paragraph (a).

(6) In addition to any other enforcement authority available to the office, the office shall impose an administrative fine of $5,000 for each violation of s. 626.8825 or s. 626.8827. Each instance of a violation of such sections by a pharmacy benefit manager against each individual pharmacy or prescription benefits plan or program constitutes a separate

violation. Notwithstanding any other provision of law, there is no limitation on aggregate fines issued pursuant to this section. The proceeds from any administrative fine shall be deposited into the General Revenue Fund.

(7) Failure by a pharmacy benefit manager to pay expenses incurred or administrative fines imposed under this section is grounds for the denial, suspension, or revocation of its certificate of authority.

Section 13. Section 626.89, Florida Statutes, is amended, to read:

626.89 Annual financial statement and filing fee; notice of change of ownership; pharmacy benefit manager filings.—

(1) Each authorized administrator shall annually file with the office a full and true statement of its financial condition, transactions, and affairs within 3 months after the end of the administrator’s fiscal year or within such extension of time as the office for good cause may have granted. The statement must be for the preceding fiscal year and must be in such form and contain such matters as the commission prescribes and must be verified by at least two officers of the administrator.

(2) Each authorized administrator shall also file an audited financial statement performed by an independent certified public accountant. The audited financial statement must ~~shall~~ be filed with the office within 5 months after the end of the administrator’s fiscal year and be for the preceding fiscal year. An audited financial statement prepared on a consolidated basis must include a columnar consolidating or combining worksheet that must be filed with the statement and must comply with the following:

(a) Amounts shown on the consolidated audited financial statement must be shown on the worksheet;

(b) Amounts for each entity must be stated separately; and

(c) Explanations of consolidating and eliminating entries must be included.

(3) At the time of filing its annual statement, the administrator shall pay a filing fee in the amount specified in s. 624.501 for the filing of an annual statement by an insurer.

(4) In addition, the administrator shall immediately notify the office of any material change in its ownership.

(5) A pharmacy benefit manager shall also notify the office within 15 days after any administrative, civil, or criminal complaints, settlements, or discipline of the pharmacy benefit manager or any of its affiliates which relate to a violation of the insurance laws, including pharmacy benefit laws in any state.

(6) A pharmacy benefit manager shall also annually submit to the office a statement attesting to its compliance with the network requirements of s. 626.8825.

(7) The commission may by rule require all or part of the statements or filings required under this section to be submitted by electronic means in a computer-readable form compatible with the electronic data format specified by the commission.

Section 14. Subsection (5) is added to section 627.42393, Florida Statutes, to read:

627.42393 Step-therapy protocol.—

(5) This section applies to a pharmacy benefit manager acting on behalf of a health insurer.

Section 15. Subsections (2), (3), and (4) of section 627.64741, Florida Statutes, are amended to read:

627.64741 Pharmacy benefit manager contracts.—

(2) In addition to the requirements of part VII of chapter 626, a contract between a health insurer and a pharmacy benefit manager must require that the pharmacy benefit manager:

(a) Update maximum allowable cost pricing information at least every 7 calendar days.

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

~~(3) A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from limiting a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.~~

~~(4) A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from requiring an insured to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:~~

~~(a) The applicable cost-sharing amount; or~~

~~(b) The retail price of the drug in the absence of prescription drug coverage.~~

Section 16. Subsections (2), (3), and (4), of section 627.6572, Florida Statutes, are amended to read:

627.6572 Pharmacy benefit manager contracts.—

(2) In addition to the requirements of part VII of chapter 626, a contract between a health insurer and a pharmacy benefit manager must require that the pharmacy benefit manager:

(a) Update maximum allowable cost pricing information at least every 7 calendar days.

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

~~(3) A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from limiting a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.~~

~~(4) A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from requiring an insured to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:~~

~~(a) The applicable cost-sharing amount; or~~

~~(b) The retail price of the drug in the absence of prescription drug coverage.~~

Section 17. Paragraph (e) is added to subsection (46) of section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(46)

(e) This subsection applies to a pharmacy benefit manager acting on behalf of a health maintenance organization.

Section 18. Subsections (2), (3), and (4) of section 641.314, Florida Statutes, are amended to read:

641.314 Pharmacy benefit manager contracts.—

(2) In addition to the requirements of part VII of chapter 626, a contract between a health maintenance organization and a pharmacy benefit manager must require that the pharmacy benefit manager:

(a) Update maximum allowable cost pricing information at least every 7 calendar days.

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

~~(3) A contract between a health maintenance organization and a pharmacy benefit manager must prohibit the pharmacy benefit manager from limiting a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.~~

~~(4) A contract between a health maintenance organization and a pharmacy benefit manager must prohibit the pharmacy benefit manager from requiring a subscriber to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:~~

~~(a) The applicable cost-sharing amount; or~~

~~(b) The retail price of the drug in the absence of prescription drug coverage.~~

Section 19. Subsection (1) of section 624.491, Florida

Statutes, is amended to read:

624.491 Pharmacy audits.—

(1) A health insurer or health maintenance organization providing pharmacy benefits through a major medical individual or group health insurance policy or a health maintenance contract, respectively, must comply with the requirements of this section when the health insurer or health maintenance organization or any person or entity acting on behalf of the health insurer or health maintenance organization, including, but not limited to, a pharmacy benefit manager as defined in s. 626.88 ~~s. 624.490(1)~~, audits the records of a pharmacy licensed under chapter 465. The person or entity conducting such audit must:

(a) Except as provided in subsection (3), notify the pharmacy at least 7 calendar days before the initial onsite audit for each audit cycle.

(b) Not schedule an onsite audit during the first 3 calendar days of a month unless the pharmacist consents otherwise.

(c) Limit the duration of the audit period to 24 months after the date a claim is submitted to or adjudicated by the entity.

(d) In the case of an audit that requires clinical or professional judgment, conduct the audit in consultation with, or allow the audit to be conducted by, a pharmacist.

(e) Allow the pharmacy to use the written and verifiable records of a hospital, physician, or other authorized practitioner, which are transmitted by any means of communication, to validate the pharmacy records in accordance

with state and federal law.

(f) Reimburse the pharmacy for a claim that was retroactively denied for a clerical error, typographical error, scrivener's error, or computer error if the prescription was properly and correctly dispensed, unless a pattern of such errors exists, fraudulent billing is alleged, or the error results in actual financial loss to the entity.

(g) Provide the pharmacy with a copy of the preliminary audit report within 120 days after the conclusion of the audit.

(h) Allow the pharmacy to produce documentation to address a discrepancy or audit finding within 10 business days after the preliminary audit report is delivered to the pharmacy.

(i) Provide the pharmacy with a copy of the final audit report within 6 months after the pharmacy's receipt of the preliminary audit report.

(j) Calculate any recoupment or penalties based on actual overpayments and not according to the accounting practice of extrapolation.

Section 20. (1) This act establishes requirements for pharmacy benefit managers as defined in s. 624.490, Florida Statutes, including, without limitation, pharmacy benefit managers in their performance of services for or otherwise on behalf of a pharmacy benefits plan or program providing coverage pursuant to Titles XVIII, XIX, or XXI of the Social Security Act, 42 U.S.C. ss. 1395 et seq., 1396 et seq., and 1397aa et seq., known as Medicare, Medicaid, or any other similar coverage under a state or Federal Government funded health plan, including the Statewide Medicaid Managed Care program established pursuant to part IV of chapter 409, Florida

Statutes, and the state group insurance program pursuant to part I of chapter 110, Florida Statutes.

(2) This act is not intended, nor may it be construed, to conflict with existing, relevant federal law.

(3) If any provision of this act or its application to any person or circumstances is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 21. The sum of $1.5 million is hereby appropriated to the Office of Insurance Regulation to implement this act.

Section 22. This act shall take effect July 1, 2023.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Committee on Agriculture, Environment, and General Government, *Chair*
Health Policy, *Vice Chair*
Appropriations
Appropriations Committee on Health and Human Services
Children, Families, and Elder Affairs
Community Affairs
Regulated Industries
Rules

JOINT COMMITTEE:
Joint Legislative Auditing Committee

SENATOR JASON BRODEUR
10th District

March 10, 2023

The Honorable Colleen Burton
Chair, Committee on Health Policy
318 Senate Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Chair Burton,

I respectfully request that **Senate Bill 1550**, **Prescription Drugs**, be placed on the agenda of the Health Policy Committee meeting to be considered at your earliest convenience.

If you have any questions or concerns, please do not hesitate to reach out to me or my office.

Sincerely,

Jason Brodeur

Senator Jason Brodeur – District 10

CC: Allen Brown – Staff Director
Anhar Al-Asadi – Administrative Assistant
Daniel Looke – Deputy Staff Director

REPLY TO:
❒ 110 Timberlachen Circle, Suite 1012, Lake Mary, Florida 32746 (407) 333-1802
❒ 405 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5010

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

KATHLEEN PASSIDOMO
President of the Senate

DENNIS BAXLEY
President Pro Tempore

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3/27/23
Meeting Date

Senate Health Policy
Committee

1550
Bill Number or Topic

100780
Amendment Barcode (if applicable)

Name Katie Scanlon

Phone (863) 688-1188

Address 3300 Publix Corporate Parkway
Street

Email katie.scanlon@publix.com

Lakeland FL 33811
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3-27-23
Meeting Date

Health Policy
Committee

1550
Bill Number or Topic

100780
Amendment Barcode (if applicable)

Name Kevin Duane

Phone 904 765 3531

Address 7307 N Main St
Street

Email Kevin@PanamaRX.com

Jacksonville FL 32208
City State Zip

Reset Form

Speaking: [X] For [ ] Against [ ] Information **OR** Waive Speaking: [ ] In Support [ ] Against

PLEASE CHECK ONE OF THE FOLLOWING:

[X] I am appearing without compensation or sponsorship.

[ ] I am a registered lobbyist, representing:

[ ] I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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Health Policy
Committee

1550
Bill Number or Topic

100780
Amendment Barcode (if applicable)

Name Ken Komorny, VP of Pharmacy at Moffitt

Phone 8137454644

Address 12902 Magnolia Drive
Street

Email kenneth.komorny@moffitt.org

Tampa FL 33612
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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Health Policy
Committee

1550
Bill Number or Topic

100780 and bill as amended
Amendment Barcode (if applicable)

Name Justin Senior

Phone 850-528-9159

Address 125 S. Gadsden St.
Street

Email justin@snhaf.net

Tallahassee FL 32301
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** **Waive Speaking:** ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
Safety Net Hospital Alliance

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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SB 1550
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100780
Amendment Barcode (if applicable)

Name Clay Meenan

Phone 682-276-5245

Address 306 E College Ave
Street

Email claym@fha.org

Tallahassee FL 32312
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
Florida Hospital Association

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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Amendment Barcode (if applicable)

Name Barney Bishop

Phone 850.510.9922

Address 1454 Vieux Carre Dr.
Street

Email Barney@BarneyBishop.com

Tall FL 32308
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
SPAR - Small Business Pharmacies

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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Committee

1550
Bill Number or Topic

Amendment Barcode (if applicable)

Name Jesse Brashear

Phone 3524763538

Address 206 W. Dampier St.
Street

Email jesse@brashearspharmacy.com

Inverness FL 34450
City *State* *Zip*

Speaking: [X] For [ ] Against [ ] Information **OR** Waive Speaking: [ ] In Support [ ] Against

PLEASE CHECK ONE OF THE FOLLOWING:

[X] I am appearing without compensation or sponsorship.

[ ] I am a registered lobbyist, representing:

[ ] I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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1552
Bill Number or Topic

Amendment Barcode (if applicable)

Name Danny Jackson

Phone 850-294-4025

Address 310 Woodland DR
Street

Email dannyjacksonrph@gmail.com

Monticello FL 32344
City State Zip

Speaking: ☒ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☒ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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Committee

1550
Bill Number or Topic

Amendment Barcode (if applicable)

Name DR. Bob Levin

Phone 727.643.5850

Address 1831 N Belcher Rd
Street

Email rwlevin1@MSN.com

Clearwater FL 33765
City State Zip

Speaking: ☒ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☒ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

Florida Society of Rheumatology

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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Health Policy
Committee

[redacted] 1550
Bill Number or Topic

Amendment Barcode (if applicable)

Name DR Paresh Patel

Phone

Address Florida Cancer Specialist
Street

Email ppatel@flcancer.com

Tallahassee, FL 32308
City State Zip

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

Florida Society of Clinical Oncologist

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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Committee

Amendment Barcode (if applicable)

Name Corinna Strayer

Phone 850 524 7468

Address 527 Vinnedge Ride
Street

Email corinnastrayer@gmail.com

Tallahassee FL 32303
City State Zip

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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Committee

Amendment Barcode (if applicable)

Name Loretta Boesing

Phone 573-430-9494

Address 224 Cypress St
Street

Email

Park Hills MO 63601
City State Zip

Speaking: ☒ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☒ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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Committee

Amendment Barcode (if applicable)

Name Elis Brashear

Phone 352-634-5173

Address 206 W Dampier St.
Street

Email elis@brashearspharmacy.com

Inverness FL 34450
City State Zip

Speaking: [X] For [ ] Against [ ] Information **OR** Waive Speaking: [ ] In Support [ ] Against

PLEASE CHECK ONE OF THE FOLLOWING:

[X] I am appearing without compensation or sponsorship.

[ ] I am a registered lobbyist, representing:

[ ] I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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Committee

SB1550
Bill Number or Topic

Amendment Barcode (if applicable)

Name Connor Rose

Phone 859-797-1820

Address 400 Redding Road #11
Street

Email crose@pcmanet.org

Lexington KY 40517
City State Zip

Speaking: ☐ For ☑ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☑ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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Bill Number or Topic

Amendment Barcode (if applicable)

Name Clay Meeran

Phone 682-276-5245

Address 306 E College Ave
Street

Email ClayM@Pha.org

Tallahassee FL 32312
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing: Florida Hospital Association

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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Bill Number or Topic

Amendment Barcode (if applicable)

Name JAKE FARMER

Phone 352 359 6835

Address 605 Wavery Rd
Street

Email Jake.farmer@walgreens.com

Tallahassee FL 32312
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
Walgreens

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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Bill Number or Topic

Amendment Barcode (if applicable)

Name Chris Nyland

Phone 904-233-3051

Address 4427 Merschel St
Street

Email nylandlaw@aol.com

Jacksonville FL 32210
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:

Florida Gastroenterology Society

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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Amendment Barcode (if applicable)

Name Jeff Kottkamp

Phone

Address
Street

Email

Tallahassee
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:
Small Business Pharmacies Aligned for Reform

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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Committee

Amendment Barcode (if applicable)

Name Helen Sairany

Phone 850 544 5899

Address 2350 Phillips Rd.
Street

Email hsairany@pharmview.com

Tallahasee FL 32308
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☒ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☒ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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Bill Number or Topic

Amendment Barcode (if applicable)

Name AARP - Ivonne Fernandez

Phone 954-850-7262

Address 215 S Monroe Street - 605
Street

Email ifernandez@aarp.org

Tallahassee FL
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** **Waive Speaking:** ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:

AARP

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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Bill Number or Topic

Amendment Barcode (if applicable)

Name Jarrod Fowler

Phone 850-224-6496

Address 1430 Piedmont Dr. E
Street

Tallahassee FL 32308
City *State* *Zip*

Email jfowler@flmedical.org

Speaking: ☐ For ☐ Against ☐ Information **OR** **Waive Speaking:** ☒ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☒ I am a registered lobbyist, representing: Florida Medical Association

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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1550
Bill Number or Topic

Amendment Barcode (if applicable)

Name Jonathan Chapman

Phone 850-755-3318

Address 2340 Hansen Lane
Street

Email jchapman@fachc.org

Tallahassee FL 32301
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☒ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☒ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

FL Assoc of Community Health centers

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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SB 1550
Bill Number or Topic

Amendment Barcode (if applicable)

Name Bill Mincy, PPSC

Phone (850) 322-7740

Address 124 Marriott Drive, Suite 204
Street

Email bill.mincy@ppsconline.com

Tallahassee FL 32301
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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Bill Number or Topic

Amendment Barcode (if applicable)

Name Greg Black

Phone 8505098022

Address PO Box 838
Street

Email Greg@WaypointStrat.com

Tallahassee FL 32302
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
National Association of Chain Drug Stores

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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Committee

SB 1550
Bill Number or Topic

Amendment Barcode (if applicable)

Name Joseph Salzverg ("Saul's-Verg")

Phone 850-577-9090

Address 301 S Bronough Street, Suite 600
Street

Email joseph.salzverg@gray-robinson.com

TLH FL 32301
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
General Counsel: Florida Society of Health-System Pharmacists

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3/27/2023
Meeting Date

1550
Bill Number or Topic

Committee

Amendment Barcode (if applicable)

Name Anna Pawelczyk
Eastwood Pharmacy

Phone 850-877-7108

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Street

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Tallahassee FL 32308
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

The Florida Senate

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3/27/2023
Meeting Date

1550
Bill Number or Topic

Committee

Amendment Barcode (if applicable)

Name John McDonald

Phone 850-559-6668

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Street

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City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

3/27/2023
Meeting Date

HEALTH POLICY
Committee

SENATE BILL 1550
Bill Number or Topic

Amendment Barcode (if applicable)

Name ZACH HOOVER

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ORLANDO FL 32806
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** **Waive Speaking:** ☒ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☒ I am a registered lobbyist, representing:
ORLANDO HEALTH

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 1552
INTRODUCER:	Health Policy Committee and Senator Brodeur
SUBJECT:	Public Records/Pharmacy Benefit Managers
DATE:	March 29, 2023 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Brown	HP	**Fav/CS**
2.			FP	
3.				

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1552 extends the current public records exemptions that are applicable to administrators under the Florida Insurance Code (FIC) found in ss. 624.319 and 626.884, F.S., to pharmacy benefit managers (PBMs) which will be a new class of administrators if SB 1550, or similar legislation, is enacted. Additional examination and investigation authority specific to PBMs is provided in SB 1550, and statutory reference to those reports and related work papers is also included in the exemptions provided in CS/SB 1552.

The exemptions are subject to the Open Government Sunset Review Act and will stand repealed on October 2, 2028, unless reviewed and reenacted by the Legislature.

The bill provides a statement of public necessity as required by the State Constitution.

Because the bill creates a new public records exemption, it requires a two-thirds vote of the members present and voting in each house of the Legislature for final passage.

The bill provides the effective date is the same date that SB 1550, or similar legislation, if adopted, takes effect. The effective date provided in SB 1550 is July 1, 2023.

II. Present Situation:

Access to Public Records - Generally

The Florida Constitution provides that the public has the right to inspect or copy records made or received in connection with official governmental business.[1] The right to inspect or copy applies to the official business of any public body, officer, or employee of the state, including all three branches of state government, local governmental entities, and any person acting on behalf of the government.[2]

Additional requirements and exemptions related to public records are found in various statutes and rules, depending on the branch of government involved. For instance, s.11.0431, F.S., provides public access requirements for legislative records. Relevant exemptions are codified in s. 11.0431(2)-(3), F.S., and adopted in the rules of each house of the legislature.[3] Florida Rule of Judicial Administration 2.420 governs public access to judicial branch records.[4] Lastly, ch. 119, F.S., known as the Public Records Act, provides requirements for public records held by executive agencies.

Executive Agency Records – The Public Records Act

The Public Records Act provides that all state, county and municipal records are open for personal inspection and copying by any person, and that providing access to public records is a duty of each agency.[5]

Section 119.011(12), F.S., defines "public records" to include:

> All documents, papers, letters, maps, books, tapes, photographs, films, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connections with the transaction of official business by any agency.

The Florida Supreme Court has interpreted this definition to encompass all materials made or received by an agency in connection with official business that are used to "perpetuate, communicate, or formalize knowledge of some type."[6]

---

[1] FLA. CONST. art. I, s. 24(a).
[2] *Id*.
[3] *See* Rule 1.48, *Rules and Manual of the Florida Senate*, (2022-2024) and Rule 14.1, *Rules of the Florida House of Representatives*, Edition 2, (2022-2024)
[4] *State v. Wooten*, 260 So. 3d 1060 (Fla. 4th DCA 2018).
[5] Section 119.01(1), F.S. Section 119.011(2), F.S., defines "agency" as "any state, county, district, authority, or municipal officer, department, division, board, bureau, commission, or other separate unit of government created or established by law including, for the purposes of this chapter, the Commission on Ethics, the Public Service Commission, and the Office of Public Counsel, and any other public or private agency, person, partnership, corporation, or business entity acting on behalf of any public agency."
[6] *Shevin v. Byron, Harless, Schaffer, Reid and Assoc., Inc*., 379 So. 2d 633, 640 (Fla. 1980).

The Florida Statutes specify conditions under which public access to public records must be provided. The Public Records Act guarantees every person's right to inspect and copy any public record at any reasonable time, under reasonable conditions, and under supervision by the custodian of the public record.[7] A violation of the Public Records Act may result in civil or criminal liability.[8]

The Legislature may exempt public records from public access requirements by passing a general law by a two-thirds vote of both the House and the Senate.[9] The exemption must state with specificity the public necessity justifying the exemption and must be no broader than necessary to accomplish the stated purpose of the exemption.[10]

General exemptions from the public records requirements are contained in the Public Records Act.[11] Specific exemptions often are placed in the substantive statutes relating to a particular agency or program.[12]

When creating a public records exemption, the Legislature may provide that a record is "exempt" or "confidential and exempt." There is a difference between records the Legislature has determined to be exempt from the Public Records Act and those which the Legislature has determined to be exempt from the Public Records Act *and confidential*.[13] Records designated as "confidential and exempt" are not subject to inspection by the public and may only be released under the circumstances defined by statute.[14] Records designated as "exempt" may be released at the discretion of the records custodian under certain circumstances.[15]

Open Government Sunset Review Act

The provisions of s. 119.15, F.S., known as the Open Government Sunset Review Act[16] (the Act), prescribe a legislative review process for newly created or substantially amended[17] public records or open meetings exemptions, with specified exceptions.[18] The Act requires the repeal of

[7] Section 119.07(1)(a), F.S.
[8] Section 119.10, F.S. Public records laws are found throughout the Florida Statutes, as are the penalties for violating those laws.
[9] FLA. CONST. art. I, s. 24(c).
[10] *Id*. *See, e.g.*, *Halifax Hosp. Medical Center v. News-Journal Corp.*, 724 So. 2d 567 (Fla. 1999) (holding that a public meetings exemption was unconstitutional because the statement of public necessity did not define important terms and did not justify the breadth of the exemption); *Baker County Press, Inc. v. Baker County Medical Services, Inc.*, 870 So. 2d 189 (Fla. 1st DCA 2004) (holding that a statutory provision written to bring another party within an existing public records exemption is unconstitutional without a public necessity statement).
[11] *See, e.g.*, s. 119.071(1)(a), F.S. (exempting from public disclosure examination questions and answer sheets of examinations administered by a governmental agency for the purpose of licensure).
[12] *See, e.g.*, s. 213.053(2)(a), F.S. (exempting from public disclosure information contained in tax returns received by the Department of Revenue).
[13] *WFTV, Inc. v. The Sch. Bd. of Seminole County*, 874 So. 2d 48, 53 (Fla. 5th DCA 2004).
[14] *Id*.
[15] *Williams v. City of Minneola*, 575 So. 2d 683 (Fla. 5th DCA 1991).
[16] Section 119.15, F.S.
[17] An exemption is considered to be substantially amended if it is expanded to include more records or information or to include meetings as well as records. Section 119.15(4)(b), F.S.
[18] Section 119.15(2)(a) and (b), F.S., provides that exemptions required by federal law or applicable solely to the Legislature or the State Court System are not subject to the Open Government Sunset Review Act.

such exemption on October 2nd of the fifth year after creation or substantial amendment, unless the Legislature reenacts the exemption.[19]

The Act provides that a public records or open meetings exemption may be created or maintained only if it serves an identifiable public purpose and is no broader than is necessary.[20] An exemption serves an identifiable purpose if it meets one of the following purposes *and* the Legislature finds that the purpose of the exemption outweighs open government policy and cannot be accomplished without the exemption:

- It allows the state or its political subdivisions to effectively and efficiently administer a governmental program, and administration would be significantly impaired without the exemption;[21]
- It protects sensitive, personal information, the release of which would be defamatory, cause unwarranted damage to the good name or reputation of the individual, or would jeopardize the individual's safety. If this public purpose is cited as the basis of an exemption, however, only personal identifying information is exempt;[22] or
- It protects information of a confidential nature concerning entities, such as trade or business secrets.[23]

The Act also requires specified questions to be considered during the review process.[24] In examining an exemption, the Act directs the Legislature to question the purpose and necessity of reenacting the exemption.

Public Necessity Statement and Two-thirds Vote Requirement

If the exemption is continued and expanded, then a public necessity statement and a two-thirds vote for passage are required.[25] If the exemption is continued without substantive changes or if the exemption is continued and narrowed, then a public necessity statement and a two-thirds vote for passage are *not* required. If the Legislature allows an exemption to expire, the previously exempt records will remain exempt unless otherwise provided by law.[26]

Pharmacy Benefit Managers as Administrators

[19] Section 119.15(3), F.S.
[20] Section 119.15(6)(b), F.S.
[21] Section 119.15(6)(b)1., F.S.
[22] Section 119.15(6)(b)2., F.S.
[23] Section 119.15(6)(b)3., F.S.
[24] Section 119.15(6)(a), F.S. The specified questions are:
- What specific records or meetings are affected by the exemption?
- Whom does the exemption uniquely affect, as opposed to the general public?
- What is the identifiable public purpose or goal of the exemption?
- Can the information contained in the records or discussed in the meeting be readily obtained by alternative means? If so, how?
- Is the record or meeting protected by another exemption?
- Are there multiple exemptions for the same type of record or meeting that it would be appropriate to merge?

[25] *See generally* s. 119.15, F.S.
[26] Section 119.15(7), F.S.

Pharmacy benefit managers (PBMs) are companies that manage prescription drug benefits on behalf of pharmacy benefit plans or programs (health insurers, Medicare Part D drug plans, large employers, state health plans, and other payers).[27] Key PBM functions may include administration and management of prescription drug benefits; developing and maintaining formularies; negotiating discounts and rebates between payers and pharmaceutical manufacturers; providing access to a contracted pharmacy network; real-time pharmacy claims processing; and performing utilization management, retroactive claims review, prior authorization and other medication management programs.[28]

Pharmacy benefit managers that contract to administer prescription drug benefits on behalf of a health insurer or health maintenance organization to residents of Florida have been required to register with the Office of Insurance Regulation (OIR) pursuant to s. 624.490, F.S., since 2019. A $5 fee is paid at the time of registration and no specific regulation of PBM practices is addressed under Florida law.

CS/SB 1550, if enacted, will regulate all PBMs as administrators under the FIC.

III. Effect of Proposed Changes:

CS/SB 1552 provides the same public records exemptions to PBMs that currently exist for administrators under the FIC by amending and reenacting two statutes in which the exemptions are found. SB 1550, or similar legislation, if enacted, will require PBMs to become administrators. In addition, because additional examination and investigation provisions relating to PBMs are created in SB 1550, the bill extends the confidentiality and public records exemptions to these new provisions, unless otherwise provided in statute.[29]

Section 1. The records that are made confidential and exempt in s. 624.319, F.S., are examination reports, until filed; investigation reports, until the investigation is completed or ceases to be active; and the related work papers. Portions of these documents may remain confidential and exempt if disclosure would:

- Jeopardize the integrity of another active examination or investigation;
- Impair the safety or financial soundness of the licensee, affiliated party, or insured;
- Reveal person financial, medical, or health information;
- Reveal the identity of a confidential source;
- Defame or cause unwarranted damage to the good name or reputation of an individual or jeopardize the safety of an individual;
- Reveal examination techniques or procedures; or
- Reveal information received from another governmental entity of the National Association of Insurance Commissioners, which is confidential or exempt when held by that entity.

[27]The Commonwealth Fund, Pharmacy Benefit Managers and Their Role in Drug Spending, (April 22, 2019) available at: https://www.commonwealthfund.org/sites/default/files/2019-04/Explainer_PBMs_1.pdf (last visited Mar 21, 2023).
[28] U.S. Pharmacist, State PBM Regulations Protecting Community Pharmacies, (August 16, 2022) *US Pharm. 2022;47(8):21-25* available at: https://www.uspharmacist.com/article/state-pbm-regulations-protecting-community-pharmacies (last visited Mar. 21, 2023).
[29] Section 12 of SB 1550 creates s. 626.8828, Florida Statutes. Section 626.8828(2)(d), provides that documents obtained pursuant to an expanded examination or investigation predicated upon a pattern or practice of knowing and willful violations of s. 626.8825 or s. 626.8827, are public records and are not trade secrets or otherwise exempt from s. 119.07(1), F.S.

Section 2. The records that are made confidential and exempt in s. 626.884, F.S., are books and records of all transactions among the administrator, insurers, and insured persons maintained by an administrator that are made available to the OIR for examination, audit, and inspection. This section of law is reenacted to include PBMs as a new class of administrator.

CS/SB 1552 includes technical updates to the two statutory sections to reference s. 24(a), Art. I of the State Constitution. The provisions making certain information confidential and exempt from the public records law were in the FIC prior to adoption of s. 24(a), Art. I of the State Constitution in 1992. The adopted Constitutional language includes a grandfather provision, "All laws that are in effect on July 1, 1993 that limit public access to records … shall remain in force … until they are repealed."

The bill provides for review and repeal of both ss. 624.319 and 624.884, F.S., which provide the new exemptions, unless saved from repeal through reenactment by the Legislature by October 2, 2028, in accordance with the Open Government Sunset Review Act.

Section 3. The bill contains statements of public necessity explaining why the documents need to be made confidential and exempt.

The first statement provides that as a new class of administrator, PBMs need to be subject to the exemptions that currently exist for administrators, unless otherwise provided in statute, to protect their confidential information and business and professional good name or reputation in a like manner. Also, both the Department of Financial Services and the OIR have responsibility for examining and investigating administrators under the FIC, and the exemptions are needed to ensure that disclosure of certain information relating to examinations and investigations of PBMs would not jeopardize the integrity of investigations or reveal information that is received from another regulatory entity which is confidential or exempt when held by that entity.

The bill also contains a statement of public necessity for making the trade secret information contained in the books and records of PBMs confidential and exempt. This statement provides that the Legislature recognizes that the release of trade secret information of a PBM, as with any administrator, could destroy the value of a business's proprietary information and cause financial loss to the business by giving its competitors an unfair advantage and weakening its position in the marketplace.

Section 4. This bill's effective date is the same date that SB 1550 or similar legislation takes effect, if adopted, and becomes a law. SB 1550 provides an effective date of July 1, 2023.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

Vote Requirement

Article I, s. 24(c) of the State Constitution requires a two-thirds vote of the members present and voting for final passage of a bill creating or expanding an exemption to the public records requirements. This bill creates a new public records exemption pertaining to PBMs; therefore, it requires a two-thirds vote.

Public Necessity Statement

Article I, s. 24(c) of the State Constitution requires a bill creating or expanding an exemption to the public records requirements to state with specificity the public necessity justifying the exemption. Section 3 includes public necessity statements that support the exemptions.

Breadth of Exemption

Article I, s. 24(c), of the State Constitution requires an exemption to the public records requirements to be no broader than necessary to accomplish the stated purpose of the law. The purpose of the law is to protect examination and investigation reports, related work papers, and information in books and records applicable to PBMs, which is a new class of Administrator in the same manner as other Administrators under the FIC. The exemption does not appear to be broader than necessary to accomplish the purpose of the law.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 624.319 and 626.884.

IX. Additional Information:

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

CS by Health Policy on March 27, 2023:
The CS narrows the public necessity statement in Section 3 of the bill to address the need for confidentiality of the documents "in accordance with s. 624.319, F.S.," rather than permanently. That section protects examination and investigation reports and related documents until the report is filed or the investigation concludes, with some exceptions.

The effective date of the bill is tied to the same date that SB 1550 or similar legislation takes effect, if adopted and becomes law.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/28/2023	.	
	.	
	.	
	.	

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

Senate Amendment

Delete lines 190 - 196

and insert:

Statutes, and s. 24(a), Article I of the State Constitution in accordance with s. 624.319, Florida Statutes. Administrators who are pharmacy benefit managers are subject to additional records production, examination, and investigation provisions, and those applicable work papers and examinations and investigation reports are to be made confidential and exempt from s.

795932

119.07(1), Florida Statutes, and s. 24(a), Article I of the State Constitution in accordance with s. 624.319, Florida Statutes. As a new class of administrators,

626324

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/28/2023	.	
	.	
	.	
	.	

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

Senate Amendment

Delete line 236
and insert:
SB 1550 or similar legislation takes effect, if such legislation

By Senator Brodeur

10-02226-23 20231552__

A bill to be entitled

An act relating to public records; amending s. 624.319, F.S.; providing an exemption from public records requirements for examination and investigation reports and work papers relating to pharmacy benefit managers; providing for future legislative review and repeal of the exemption; reenacting and amending s. 626.884, F.S.; expanding a public records exemption for the books and records of administrators held by the Office of Insurance Regulation for purposes of examination, audit, and inspection to incorporate the inclusion of pharmacy benefit managers as administrators under the Florida Insurance Code; providing for future legislative review and repeal of the exemption; providing statements of public necessity; providing a contingent effective date.

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

Section 1. Section 624.319, Florida Statutes, is amended to read:

624.319 Examination and investigation reports.—

(1) The department or office or its examiner shall make a full and true written report of each examination. The examination report shall contain only information obtained from examination of the records, accounts, files, and documents of or relative to the insurer examined or from testimony of individuals under oath, together with relevant conclusions and recommendations of the examiner based thereon. The department or

10-02226-23 20231552__

office must ~~shall~~ furnish a copy of the examination report to the insurer examined at least ~~not less than~~ 30 days before ~~prior to~~ filing the examination report in its office. If such insurer so requests in writing within such 30-day period, the department or office must ~~shall~~ grant a hearing with respect to the examination report and may ~~shall~~ not ~~so~~ file the examination report until after the hearing and after such modifications have been made therein as the department or office deems proper.

(2) The examination report so filed is admissible in evidence in any action or proceeding brought by the department or office against the person examined, or against its officers, employees, or agents. In all other proceedings, the admissibility of the examination report is governed by the evidence code. The department or office or its examiners may testify and offer other proper evidence as to information secured or matters discovered during the course of an examination, regardless of whether a written report of the examination has been made, furnished, or filed in the department or office. The production of documents during the course of an examination or investigation does not constitute a waiver of the attorney-client or work-product privilege.

(3)(a)1. Examination reports, until filed, are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

2. Investigation reports are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the investigation is completed or ceases to be active.

3. For purposes of this subsection, an investigation is active while it is being conducted by the department or office

with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings. An investigation does not cease to be active if the department or office is proceeding with reasonable dispatch and has a good faith belief that action could be initiated by the department or office or other administrative or law enforcement agency. After an investigation is completed or ceases to be active, portions of the investigation report relating to the investigation remain confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution if disclosure would:

a. Jeopardize the integrity of another active investigation;

b. Impair the safety and financial soundness of the licensee or affiliated party;

c. Reveal personal financial information;

d. Reveal the identity of a confidential source;

e. Defame or cause unwarranted damage to the good name or reputation of an individual or jeopardize the safety of an individual; or

f. Reveal investigative techniques or procedures.

(b)1. For purposes of this paragraph, "work papers" means the records of the procedures followed, the tests performed, the information obtained and the conclusions reached in an examination or investigation performed under this section or ss. 624.316, 624.3161, 624.317, ~~and~~ 624.318, and 626.8828. Work papers include planning documentation, work programs, analyses, memoranda, letters of confirmation and representation, abstracts of company documents, and schedules or commentaries prepared or obtained in the course of such examination or investigation.

2.a. Work papers held by the department or office are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the examination report is filed or until the investigation is completed or ceases to be active.

b. Information received from another governmental entity or the National Association of Insurance Commissioners, which is confidential or exempt when held by that entity, for use by the department or office in the performance of its examination or investigation duties pursuant to this section or ss. 624.316, 624.3161, 624.317, ~~and~~ 624.318, and 626.8828 is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

c. This exemption applies to work papers and such information held by the department or office before, on, or after the effective date of this exemption.

3. Confidential and exempt work papers and information may be disclosed to:

a. Another governmental entity, if disclosure is necessary for the receiving entity to perform its duties and responsibilities; and

b. The National Association of Insurance Commissioners.

4. After an examination report is filed or an investigation is completed or ceases to be active, portions of work papers may remain confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution if disclosure would:

a. Jeopardize the integrity of another active examination or investigation;

b. Impair the safety or financial soundness of the licensee, affiliated party, or insured;

c. Reveal personal financial, medical, or health information;

d. Reveal the identity of a confidential source;

e. Defame or cause unwarranted damage to the good name or reputation of an individual or jeopardize the safety of an individual;

f. Reveal examination techniques or procedures; or

g. Reveal information that is confidential or exempt under sub-subparagraph 2.b.

(c) Lists of insurers or regulated companies are confidential and exempt from s. 119.07(1) if:

1. The financial solvency, condition, or soundness of such insurers or regulated companies is being monitored by the office;

2. The list is prepared to internally coordinate regulation by the office of the financial solvency, condition, or soundness of the insurers or regulated companies; and

3. The office determines that public inspection of such list could impair the financial solvency, condition, or soundness of such insurers or regulated companies.

(4) After the examination report has been filed pursuant to subsection (1), the department or office may publish the results of any such examination in one or more newspapers published in this state whenever it deems it to be in the public interest.

(5) After the examination report of an insurer has been filed pursuant to subsection (1), an affidavit must ~~shall~~ be filed with the office, within ~~not more than~~ 30 days after the report has been filed, on a form furnished by the office and signed by the officer of the company in charge of the insurer's

business in this state, stating that she or he has read the report and that the recommendations made in the report will be considered within a reasonable time.

(6) This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2028, unless reviewed and save from repeal through reenactment by the Legislature.

Section 2. Section 626.884, Florida Statutes, is reenacted and amended to read:

626.884 Maintenance of records by administrator; access; confidentiality.—

(1) Every administrator shall maintain in such administrator's principal administrative office for the duration of the written agreement and for 5 years thereafter adequate books and records of all transactions among such administrator, insurers, and insured persons. Such books and records shall be maintained in accordance with prudent standards of insurance recordkeeping.

(2) The office shall have access to books and records maintained by the administrator for the purpose of examination, audit, and inspection. Information contained in such books and records is confidential and exempt from ~~the provisions of~~ s. 119.07(1) and s. 24(a), Art. I of the State Constitution if the disclosure of such information would reveal a trade secret as defined in s. 688.002. However, the office may use such information in any proceeding instituted against the administrator.

(3) The insurer shall retain the right of continuing access to books and records maintained by the administrator sufficient

to permit the insurer to fulfill all of its contractual obligations to insured persons, subject to any restrictions in the written agreement pertaining to the proprietary rights of the parties in such books and records.

(4) This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2028, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 3. (1) The Legislature finds that it is a public necessity that the information contained in examination and investigation reports and work papers relating to examinations and investigations of pharmacy benefit managers, who are now considered administrators, as defined in s. 626.88, Florida Statutes, for purposes of regulation under the Florida Insurance Code, be made confidential and exempt from s. 119.07(1), Florida Statutes, and s. 24(a), Article I of the State Constitution. Administrators who are pharmacy benefit managers are subject to additional records production, examination, and investigation provisions, and those applicable work papers and examinations and investigation reports are to be made confidential and exempt from s. 119.07(1), Florida Statutes, and s. 24(a), Article I of the State Constitution. As a new class of administrators, pharmacy benefit managers need to be subject to the exemptions that currently exist for administrators, unless otherwise provided in statute, in order to protect their confidential information and business and professional good name or reputation in a like manner. Additionally, the Department of Financial Services and the Office of Insurance Regulation, both of which are responsible for examinations and investigations of

administrators under the Florida Insurance Code, need to ensure that disclosure of such information would not jeopardize the integrity of another active investigation, reveal the identity of a confidential source, reveal investigative techniques or procedures, or reveal information that is received from another governmental entity or the National Association of Insurance Commissioners which is confidential or exempt when held by that entity. For these reasons, the Legislature finds that it is a public necessity that such information be made confidential and exempt from public records requirements.

(2) The Legislature finds that it is a public necessity that the trade secret information contained in the books and records of pharmacy benefit managers, who are now considered administrators, as defined in s. 626.88, Florida Statutes, for purposes of regulation under the Florida Insurance Code, which are held by the Office of Insurance Regulation in relation to examinations, audits, or inspections of pharmacy benefit managers be made confidential and exempt from s. 119.07(1), Florida Statutes, and s. 24(a), Article I of the State Constitution. The Legislature recognizes that the release of trade secret information could destroy the value of a business's proprietary information and cause financial loss to the business by giving its competitors an unfair advantage and weakening its position in the marketplace. As a new class of administrators, pharmacy benefit managers need to be subject to the exemptions that currently exist for administrators, unless otherwise provided in statute, in order to protect their trade secret information. For these reasons, the Legislature finds that it is a public necessity to make such trade secret information

contained in the books and records of pharmacy benefit managers confidential and exempt from public records requirements.

Section 4. This act shall take effect on the same date that SB ___ or similar legislation takes effect, if such legislation is adopted in the same legislative session or an extension thereof and becomes a law.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Committee on Agriculture, Environment, and General Government, *Chair*
Health Policy, *Vice Chair*
Appropriations
Appropriations Committee on Health and Human Services
Children, Families, and Elder Affairs
Community Affairs
Regulated Industries
Rules

JOINT COMMITTEE:
Joint Legislative Auditing Committee

SENATOR JASON BRODEUR
10th District

March 10, 2023

The Honorable Colleen Burton
Chair, Committee on Health Policy
318 Senate Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Chair Burton,

I respectfully request that **Senate Bill 1552**, **Public Records/Pharmacy Benefit Managers**, be placed on the agenda of the Health Policy Committee meeting to be considered at your earliest convenience.

If you have any questions or concerns, please do not hesitate to reach out to me or my office.

Sincerely,

Jason Brodeur

Senator Jason Brodeur – District 10

CC: Allen Brown – Staff Director
Anhar Al-Asadi – Administrative Assistant
Daniel Looke – Deputy Staff Director

REPLY TO:
❒ 110 Timberlachen Circle, Suite 1012, Lake Mary, Florida 32746 (407) 333-1802
❒ 405 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5010

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

KATHLEEN PASSIDOMO
President of the Senate

DENNIS BAXLEY
President Pro Tempore

CourtSmart Tag Report

Room: KB 412 **Case No.:** - **Type:**
Caption: Senate Committee on Health Policy **Judge:**

Started: 3/27/2023 3:04:26 PM
Ends: 3/27/2023 4:58:14 PM Length: 01:53:49

3:04:25 PM Chair Brodeur calls meeting to order
3:04:35 PM Roll Call
3:05:05 PM Quorum is present
3:05:10 PM Take up Tab 4 SB 514 Private Instructional Personnel
3:06:09 PM Chair Brodeur recognizes Senator Hooper to explain bill
3:06:57 PM Chair Brodeur recognizes Senator Hooper to close
3:07:14 PM Roll Call SB 514
3:07:18 PM Vote recorded
3:07:50 PM Take up Tab 1 SB 140 Fees/Professional Counselors Licensure Compact
3:07:57 PM Chair Brodeur recognizes Senator Rodriguez to explain bill
3:08:41 PM Public Appearance by Corinne Mixon of FL Mental Health Counselors Association
3:08:48 PM Chair Brodeur recognizes Senator Rodriguez to close
3:08:55 PM Roll Call SB 140
3:09:25 PM Vote recorded
3:09:29 PM Take up Tab 2 SB 1506 Department of Health
3:09:40 PM Chair Brodeur recognizes Senator Rodriguez to explain bill
3:10:05 PM Take up amendment barcode 771024 by Senator Rodriguez
3:10:17 PM Chair Brodeur recognizes Senator Rodriguez to explain amendment barcode 771024
3:10:23 PM Action on amendment recorded
3:11:10 PM Take up amendment barcode 974128 by Senator Rodriguez
3:11:21 PM Chair Brodeur recognizes Senator Rodriguez to explain amendment barcode 974128
3:11:35 PM Public Appearance by Theresa Bulger of various organizations
3:12:29 PM Public Appearance by Stephen Winn of Florida Hearing Society
3:12:38 PM Question by Senator Book
3:12:45 PM Answer by Senator Rodriguez
3:13:11 PM Action on amendment recorded, back on bill
3:13:28 PM Public Appearance by Theresa Bulger of various organizations
3:13:41 PM Chair Brodeur recognizes Senator Rodriguez to close on bill
3:13:55 PM Roll Call SB 1506
3:14:03 PM Vote recorded
3:14:28 PM Take up Tab 6 SB 454 Physician Assistant Licensure
3:14:42 PM Chair Brodeur recognizes Senator Avila to explain bill
3:16:01 PM Take up amendment barcode 333290
3:17:01 PM Chair Brodeur recognizes Senator Avila to explain amendment barcode 333290
3:17:18 PM Action on amendment recorded, back on bill
3:17:49 PM Public Appearance by Monica Rodriguez of Miami Dade College
3:18:06 PM Public Appearance by Corinne Mixon of Florida Academy of PA's
3:18:12 PM Chair Brodeur recognizes Senator Avila to close
3:18:18 PM Roll Call SB 454
3:18:26 PM vote recorded
3:18:30 PM Chair Brodeur passes gavel to Senator Albritton
3:19:12 PM Take up Tab 7 SB 1232 Telehealth Prescribing
3:19:20 PM Chair Albritton recognizes Senator Brodeur to explain bill
3:20:06 PM Take up amendment barcode 536114
3:20:19 PM Chair Albritton recognizes Senator Book to explain amendment barcode 536114
3:20:56 PM Question by Senator Brodeur
3:21:01 PM Answer by Senator Book
3:21:18 PM Question by Senator Harrell
3:21:44 PM Answer by Senator Book
3:21:49 PM Comment by Senator Brodeur
3:22:01 PM Comment by Senator Book
3:22:10 PM Chair Albritton recognizes Senator Book to close

3:22:31 PM Action on amendment recorded
3:23:16 PM Take up amendment barcode 132784
3:23:31 PM Chair Albritton recognizes Senator Book to explain amendment barcode 132784
3:23:51 PM Comment by Senator Brodeur
3:24:00 PM Chair Albritton recognizes Senator Book to close
3:24:17 PM Action on amendment recorded, back on bill
3:24:27 PM Public Appearance by Zach Hoover of Orlando Health
3:24:41 PM Public Appearance by Chris Nuland of Florida Chapter, American College of Physicians
3:24:52 PM Public Appearance by Clay Meenan of Florida Hospital Association
3:24:58 PM Public Appearance by Justin Senior of SNHAF
3:25:03 PM Public Appearance by Ivvone Fernandez of AARP
3:25:11 PM Public Appearance by Ellen Anderson of Moffitt Cancer Center
3:25:14 PM Public Appearance by Jarrod Fowler of Florida Medical Association
3:25:15 PM Chair Albritton recognizes Senator Brodeur to close on bill
3:25:50 PM Roll Call SB 1232
3:26:00 PM Vote recorded
3:26:30 PM Take up Tab 8 SB 344 Physician Certifications of Medical Use of Marijuana
3:27:11 PM Take up amendment barcode 958848
3:27:27 PM Chair Albritton Recognizes Senator Brodeur to explain amendment barcode 958848
3:28:28 PM Questions by Senator Davis
3:28:31 PM Answer by Senator Brodeur
3:28:50 PM Action on amendment recorded, back on bill
3:29:51 PM Public Appearance by Jody James of FL Cannabis Action Network
3:31:01 PM Public Appearance by Dr. Ajay Desai
3:33:17 PM Question by Senator Harrell
3:34:00 PM Answer by Senator Brodeur
3:35:00 PM Public Appearance by Bob Lotane
3:37:11 PM Question by Senator Harrell
3:37:13 PM Answer by Senator Brodeur
3:37:38 PM Chair Albritton recognizes Senator Brodeur to close
3:38:15 PM Roll Call SB 344
3:38:26 PM Vote recorded
3:38:30 PM Chair Albritton Passes gavel back to Vice Chair Brodeur
3:39:14 PM Take up Tab 3 SB 612 Prevention of Blood Clots
3:39:25 PM Chair Brodeur recognizes Senator Yarborough to explain bill
3:40:10 PM Take up amendment 558772
3:41:09 PM Chair recognizes Senator Yarborough to explain amendment barcode 558772
3:41:20 PM Action on amendment recorded, back on bill
3:41:29 PM Public Appearance by Doug Adkins
3:43:10 PM Public Appearance by Janet Adkins
3:45:30 PM Public Appearance by Chris Nuland of Florida Society of Thoracic and Cardiovascular Surgeons
3:45:36 PM Public Appearance by Theresa Bulger of Deaf Kids Can
3:45:45 PM Chair Brodeur recognizes Senator Yarborough to close on bill
3:46:06 PM Roll Call SB 612
3:46:37 PM Vote recorded
3:46:41 PM Take up Tab 5 SB 1596 Provider Accountability
3:46:56 PM Chair Brodeur recognizes Senator Garcia to explain bill
3:47:53 PM Take up amendment 584094
3:48:08 PM Chair recognizes Senator Garcia to explain amendment barcode 584094
3:49:37 PM Question by Senator Davis
3:51:30 PM Answer by Senator Garcia
3:51:40 PM Question by Senator Book
3:51:45 PM Answer by Senator Garcia
3:53:20 PM Public Appearance by Chris Nuland
3:54:17 PM Question by Senator Harrell
3:55:17 PM Answer by Chris Nuland
3:55:30 PM Comment by Senator Harrell
3:56:15 PM Action on amendment recorded, back on bill
3:56:36 PM Public Appearance by Kim Smoak
3:56:51 PM Public Appearance by Ivvone Fernandez of AARP
3:56:58 PM Public Appearance by Patrick Steele of AHCA
3:57:18 PM Comment by Senator Harrell

3:58:23 PM Comment by Senator Osgood
3:58:51 PM Comment by Senator Davis
4:00:40 PM Chair recognizes Senator Garcia to close
4:00:49 PM Roll Call SB 1596
4:00:59 PM Vote recorded
4:01:07 PM Chair Brodeur passes gavel to Chair Albritton
4:02:07 PM Take up Tab 9 SB 1550 Prescription Drugs
4:02:17 PM Take up amendment barcode 100780
4:02:33 PM Chair Albritton recognizes Senator Brodeur to explain amendment barcode 100780
4:07:11 PM Take up amendment to amendment barcode 555656
4:07:20 PM Chair Albritton passes gavel to Senator Burton
4:07:22 PM Chair Burton recognizes Senator Brodeur to explain amendment barcode 555656
4:07:36 PM Action on amendment recorded
4:07:47 PM Take up amendment to amendment barcode 297190
4:08:05 PM Chair Burton recognizes Senator Brodeur to explain amendment barcode 297190
4:08:15 PM Action on amendment recorded
4:08:26 PM Back on amendment barcode 100780
4:08:53 PM Public appearance by Ken Komorny of Moffit
4:11:34 PM Question by Senator Book
4:12:01 PM Public Appearance by Justin Senior of Safety Net Hospital Alliance
4:12:22 PM Public appearance by Kevin Duane
4:15:21 PM Question by Senator Book
4:16:22 PM Public Appearance by Katie Scanlon of Publix
4:16:46 PM Public Appearance by Clay Meenan of Florida Hospital Association
4:18:16 PM Comment by Senator Harrell
4:18:34 PM Chair Burton recognizes Senator Brodeur to close on amendment barcode 100780
4:18:47 PM Action on amendment recorded, back on bill
4:18:55 PM Question by Senator Davis
4:20:39 PM Answer by Senator Brodeur
4:22:51 PM Public Appearance by Connor Rose
4:24:45 PM Question by Senator Garcia
4:26:03 PM Answer by Connor Rose
4:26:25 PM Public Appearance by Elis Brashear
4:29:02 PM Public Appearance by Loretta Boesing
4:32:24 PM Public Appearance by Corrina Strayer
4:33:28 PM Public Appearance by Dr. Paresh Patel of Florida Society of Clinical Oncologist
4:38:25 PM Public Appearance by Dr. Bob Levin of Florida Society of Rheumatology
4:43:45 PM Public Appearance by Danny Jackson
4:46:28 PM Public Appearance by Jesse Brashear
4:47:53 PM Public Appearance by Barney Bishop of SPAR
4:48:31 PM Public Appearances
4:49:47 PM Chair recognizes Senator Brodeur to close on bill
4:51:59 PM Roll Call SB 1550
4:52:58 PM Vote recorded
4:53:34 PM Take up Tab 10 SB 1552 Public Records/ Pharmacy Benefit Managers
4:53:49 PM Chair Burton recognizes Senator Brodeur to explain bill
4:54:02 PM Take up amendment barcode 795932
4:54:31 PM Chair Burton recognizes Senator Brodeur to explain amendment barcode 795932
4:54:40 PM Action on amendment recorded
4:54:50 PM Take up amendment barcode 626324
4:54:59 PM Chair Burton recognizes Senator Brodeur to explain amendment barcode 626324
4:55:08 PM Action on amendment recorded, back on bill
4:55:17 PM Chair Burton recognizes Senator Brodeur to close
4:55:26 PM Roll Call SB 1552
4:55:30 PM Vote recorded
4:57:43 PM Senator Burgess moves
4:57:52 PM Meeting Adjourned