Tab 1	SB 126 b	y Bradley; Si	milar to H 00101 Prescription	on Hearing Aids	
883970	–A S	WD	HP, Bradley	Delete L.13 - 35:	02/17 03:41 PM
Tab 2	SB 152 b	y Davis; Iden	tical to H 00103 Protection	from Surgical Smoke	
Tab 3	SB 264 by Harrell; Identical to H 00721 Step-therapy Protocols				
Tab 4	SB 342 by Harrell; Identical to H 00527 Public Records/Agency for Health Care Administration				
Tab 5	SB 294 b	y Harrell; Sin	nilar to H 00689 Collaborati	ve Pharmacy Practice for Chron	ic Health Conditions

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY Senator Burton, Chair Senator Harrell, Vice Chair

MEETING DATE: Tuesday, February 18, 2025

TIME: 1:45—3:45 p.m.

PLACE: Pat Thomas Committee Room, 412 Knott Building

MEMBERS: Senator Burton, Chair; Senator Harrell, Vice Chair; Senators Berman, Calatayud, Davis, Gaetz,

Leek, Osgood, Passidomo, and Trumbull

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and L NO. and INTRODUCER SENATE COMMITTEE ACTIONS	
1	SB 126 Bradley (Similar H 101)	distribution of prescription hearing aids to consumers	
		HP 02/18/2025 Favorable CM RC	
2	SB 152 Davis (Identical H 103)	Protection from Surgical Smoke; Requiring hospitals and ambulatory surgical centers to, by a specified date, adopt and implement policies requiring the use of smoke evacuation systems during certain surgical procedures, etc. HP 02/18/2025 Favorable	Favorable Yeas 10 Nays 0
		AHS RC	
3	SB 264 Harrell	Step-therapy Protocols; Defining the term "serious mental illness"; requiring the Agency for Health Care Administration to approve drug products for Medicaid recipients for the treatment of serious mental illness without step-therapy prior authorization under certain circumstances; directing the agency to include rate impacts resulting from the act in certain rates that become effective on a specified date, etc.	Favorable Yeas 9 Nays 0
		HP 02/18/2025 Favorable AHS FP	

Health Policy Tuesday, February 18, 2025, 1:45—3:45 p.m.

ГАВ	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	SB 342 Harrell (Identical H 527)	Public Records/Agency for Health Care Administration; Providing an exemption from public records requirements for the personal identifying and location information of certain current or former personnel of the Agency for Health Care Administration and the names and personal identifying and location information of the spouses and children of such personnel; providing for future legislative review and repeal of the exemption; providing a statement of public necessity, etc. HP 02/18/2025 Favorable GO RC	Favorable Yeas 9 Nays 0
5	SB 294 Harrell (Similar H 689)	Collaborative Pharmacy Practice for Chronic Health Conditions; Revising the definition of the term "chronic health condition" to exclude specified heart conditions for purposes of collaborative pharmacy practice for chronic health conditions, etc. HP 02/18/2025 Favorable AHS RC	Favorable Yeas 9 Nays 0

S-036 (10/2008) Page 2 of 2

The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

	Prepared By: The Professional Staff of the Committee on Health Policy					
BILL:	SB 126					
INTRODUCER:	Senator Bradley					
SUBJECT:	Prescription Hearing Aids					
DATE:	February 1	7, 2025	REVISED:			
ANAL	YST	STAFF	DIRECTOR	REFERENCE		ACTION
1. Smith		Brown		HP	Favorable	
2				CM		
3.				RC		

I. Summary:

SB 126 authorizes the sale and distribution of prescription hearing aids to consumers through the mail if a licensed hearing aid specialist or a licensed audiologist conducts required testing procedures before the sale.

The bill provides an effective date of July 1, 2025.

II. Present Situation:

Hearing Aids

Federal Regulations

The Food and Drug Administration (FDA) Reauthorization Act of 2017 (FDARA), s. 709, ¹ directed the FDA to establish a category of over-the-counter (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. 800,² 801,³ and 874.⁴ The FDA's new rule establishes a new category for OTC hearing aids. An OTC hearing aid is an air-

¹21 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 Feb. 14, 2025).

² 21 CFR 800.30, available at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-800#800.30 (last visited Feb. 14, 2025).

³ 21 CFR 801.60 - 63, available at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-801/subpart-C (last visited Feb. 14, 2025).

⁴ 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 Feb. 14, 2025).

conduction hearing aid that does not require implantation or other surgical intervention and is intended for use by a person aged 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, 2022.⁵

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 OTC hearing aids, a licensed person may service, market, sell, dispense, provide customer support for, or distribute OTC hearing aids.

Florida Regulations

In Florida, there are currently 1,289 licensed hearing aid specialists, and 1,654 licensed audiologists.⁶ In 2023, Florida's practice acts for hearing aid specialists and audiologists were amended to distinguish between prescription hearing aids and OTC hearing aids and conform to the new FDA rules.⁷ Under Florida law, prescription hearing aids are dispensed by hearing aid specialists and audiologists who are subject to DOH regulation under the Board of Hearing Aid Specialist (BHAS) and Board of Speech-Language Pathology and Audiology (BSLPA).⁸ Under Florida law, selling or distributing prescription hearing aids through the mail to the ultimate consumer is unlawful and is punishable as a misdemeanor of the second degree.⁹

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. Both hearing aid specialists and audiologists may provide services through telehealth within this state. Out-of-state hearing aid specialists and audiologists may register to provide services through telehealth to patients located in this state. 11

⁵ 21 CFR 800.30, available at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-800#800.30 (last visited Feb. 14, 2025).

⁶ Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long Range Plan, 2023 - 2024*, available at https://mgawebteam.com/annualreports/2324/ (last visited Feb. 14, 2025).

⁷ Laws of Fla. 2023-71.

⁸ See Part II, ch. 484 and Part I, ch. 468, respectively.

⁹ Sections 468.1265 and 484.054, F.S.

¹⁰ Section 456.47, F.S.

¹¹ *Id*.

Hearing Aid Specialists

Under s. 484.041, F.S., hearing aid specialists may dispense prescription 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. ¹²

Hearing aid specialists are licensed and regulated by the BHAS.¹³ 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:
 - o 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 practicing¹⁴ in such capacity for at least 12 months; or
 - o 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:
 - o 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.

Effective July 1, 2025, an applicant for licensure must also submit to a background screening test in accordance with s. 456.0135, F.S.

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. ¹⁵ Licensed audiologists may 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. ¹⁶ 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;

¹² Section 484.041(3)(a), F.S.

¹³ Section 484.042, F.S.

¹⁴ See Fla. Admin. Code R. 64B6-2.002 (2025), 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.

¹⁵ Section 468.1125(6)(a), F.S.

¹⁶ Section 468.1125(6)(b), F.S.

 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.¹⁷

Audiologists are licensed and regulated by the BSLPA.¹⁸ 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.¹⁹
 - Applicants who earned a doctoral degree from an approved program after January 1, 2008, must complete 75 semester hours.
 - o 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 of clinical work experience.
- Passed the licensure examination no more than three years prior to the date of the application.²⁰

Effective July 1, 2025, an applicant for licensure must also submit to a background screening test in accordance with s. 456.0135, F.S.

Minimal Procedures and Equipment 21

Florida law requires hearing aid specialists, and audiologists only when indicated, to perform all of the following procedures to be used in the fitting and selling of prescription hearing aids:

- Pure tone audiometric testing by air and bone to determine the type and degree of hearing deficiency.
- Effective masking.
- 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.

¹⁷ *Id*.

¹⁸ Section 468.1135, F.S.

¹⁹ Section 468.1155, F.S.

²⁰ 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.

²¹ Sections 468.12225 and 484.0501, F.S. See also Fla. Admin. Code R. 64B6-6, 64B20-8, and 64B20-9.

A wide range audiometer that meets the specifications of the American National Standards Institute for diagnostic audiometers and a speech audiometer or a master hearing aid must be used by hearing aid specialists, and audiologists only when indicated, in the fitting and selling of prescription hearing aids.

A hearing aid specialist must make a final fitting ensuring physical and operational comfort of the prescription hearing aid. An audiologist must make such a final fitting only when indicated.

Each audiometric test must be made in a testing room that has been certified by the Department of Health and meets certain requirements established in statute and rule. However, this requirement may be waived by a client who has been provided written notice of the benefits and advantages of having the test conducted in a certified testing room.

III. Effect of Proposed Changes:

Sections 1 and 2 of the bill amend ss. 468.1265 and 484.054, F.S., to create an exception that would allow for prescription hearing aids to be sold and distributed to a consumer through the mail if, before the sale, all required testing procedures as outlined in s. 468.1225 or s. 484.0501 are conducted by an audiologist licensed under s. 468.1185 or a hearing aid specialist licensed under s. 484.045, respectively. The two statutory sections are identical.

Under the bill, if a hearing aid specialist or an audiologist (as indicated) fails to complete *all* required testing procedures in each enumerated section, then the practitioner would commit a misdemeanor of the second degree, punishable as provided in s. 775.072 or s. 775.083.

Section 3 of the bill provides an effective date of July 1, 2025.

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:

Under the bill, a hearing aid specialist or audiologist must complete "all required testing procedures *outlined in* s. 468.1225 or s. 484.0501" before the sale of prescription hearing aids distributed through the mail. Section 468.1225(7), F.S., gives rulemaking authority to the Board of Speech-Language Pathology and Audiology, and section 484.0501(7), F.S., gives rulemaking authority to the Board of Hearing Aid Specialists. It is unclear whether a court would interpret the requirements in the respective rules to be included as "required testing procedures outlined in" those sections because the rulemaking authority is derived therein.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

To implement the bill, the Department of Health would need to develop a communication plan to ensure compliance and operational readiness. The department anticipates that this would include updating websites and the Artificial Intelligence chatbot, notifying stakeholder groups, and communicating the statutory changes to staff through training.²²

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends sections 468.1265 and 484.054 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.

²² Department of Health, Senate Bill 126 Legislative Analysis (Feb. 11, 2025) (on file with the Senate Committee on Health Policy).

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

By Senator Bradley

6-00498-25 2025126

A bill to be entitled

An act relating to prescription hearing aids; amending ss. 468.1265 and 484.054, F.S.; authorizing the sale and distribution of prescription hearing aids to consumers through the mail if certain conditions are met before the sale; providing an effective date.

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

Section 1. 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. However, prescription hearing aids may be sold and distributed to a consumer through the mail if, before the sale, all required testing procedures as outlined in s.

468.1225 or s. 484.0501 are conducted by an audiologist licensed under s. 468.1185 or a hearing aid specialist licensed under s.

484.045, respectively. 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 2. 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. However, prescription hearing aids may be sold and distributed to a consumer through the mail if, before

36

6-00498-25

the sale, all required testing procedures as outlined in s.

468.1225 or s. 484.0501 are conducted by an audiologist licensed under s. 468.1185 or a hearing aid specialist licensed under s.

484.045, respectively. Any violation of this section constitutes a misdemeanor of the second degree, punishable as provided in s.

775.082 or s. 775.083.

Section 3. This act shall take effect July 1, 2025.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES: Regulated Industries, Chair
Appropriations Committee on Higher
Education, Vice Chair
Appropriations Committee on Pre-K - 12 Education Criminal Justice Ethics and Elections Fiscal Policy Rules

JOINT COMMITTEES: Joint Committee on Public Counsel Oversight, Alternating Chair

SENATOR JENNIFER BRADLEY

6th District

January 15, 2025

Senator Colleen Burton, Chair Senate Committee on Health Policy 408 Senate Building 404 South Monroe Street Tallahassee, FL 32399-1100

Dear Chair Burton:

I respectfully request that SB 126 be placed on the committee's agenda at your earliest convenience. This bill relates to prescription hearing aids.

Thank you for your consideration.

Sincerely,

Jennifer Bradley

& Bradley

cc: Allen Brown, Staff Director Anhar Al-Asadi, Administrative Assistant

- □ 1845 East West Parkway, Suite 5, Fleming Island, Florida 32003 (904) 278-2085
- ☐ 184 North Marion Avenue, Lake City, Florida 32055 (904) 278-2085
- □ 406 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5006

APPEARANCE RECORD

SB 126

Bill Number or Topic

Meeting Date

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

the meeting
Amendment Barcode (if applicable)
Phone 305 850 3627
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aive Speaking: In Support Against
OLLOWING:
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. 2020-2022 Joint Rules.pdf (flsenate.gov)

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

	The Florida Senate	
	APPEARANCE RECORD	126
	Meeting Date / Deliver both copies of this form to Senate professional staff conducting the meeting	l Bill Number or Topic
Name	Theresa Bulger Phone 850	Amendment Barcode (if applicable) 792 - HEAR
Address		a deaf kids can. or
	Tellehasse, 7 339 City State Zip	
	Speaking: For Against Information OR Waive Speaking:	In Support Against
	PLEASE CHECK ONE OF THE FOLLOWING:	
	appearing without I am a registered lobbyist, representing: ACAD Emy of And plag is to, from of the Deat Sextem and Dest	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. 2020-2022 Joint Rules.pdf (fisenate.gov)

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

The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

	Prepa	red By: The	Professional S	staff of the Committe	e on Health Poli	су
BILL:	SB 152	SB 152				
INTRODUCER:	Senator Davis					
SUBJECT:	Protection from Surgical Smoke					
DATE:	February 1	7, 2025	REVISED:			
ANAL	YST	STAFF	DIRECTOR	REFERENCE		ACTION
1. Looke		Brown		HP	Favorable	
2.			·	AHS		
3.				RC		

I. Summary:

SB 152 requires hospitals and ambulatory surgical centers (ASC) to, by January 1, 2026, adopt and implement policies that require the use of a smoke evacuation system during any surgical procedure that is likely to generate surgical smoke.

The bill provides an effective date of July 1, 2025.

II. Present Situation:

Surgical smoke is produced by the thermal destruction of tissue by the use of lasers or electrosurgical devices. Surgical smoke has been shown to contain toxic gases, vapors and particulates, dead and live cellular material, and viruses.

At high concentrations, such smoke can cause ocular and upper respiratory tract irritation in health care personnel and can create view obstruction for the surgeon. The smoke has been shown to have mutagenic potential.³ Studies have shown that surgical smoke may be associated with complications such as carcinogenicity, toxicity, mutagenicity, irritants, respiratory diseases, spread of pathogenic microorganisms, Human Papillomavirus DNA transfer, Hepatitis B transfer, tumor cell transmission, headache, dizziness, drowsiness, bad hair odor, and runny

¹ The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, *Control of Smoke From Laser/Electric Surgical Procedures*, last updated June 30, 2017, available at https://www.cdc.gov/niosh/docs/hazardcontrol/hc11.html (last visited Feb. 11, 2025).

² *Id.*³ The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, *Control of Smoke From Laser/Electric Surgical Procedures: Engineering Controls Database*, last updated Nov. 16, 2018, available at https://www.cdc.gov/niosh/engcontrols/ecd/detail193.html, (last visited Feb. 11, 2025).

eyes.⁴ Some researchers have suggested that surgical smoke may act as a vector for cancerous cells that may be inhaled.⁵

According to the federal Occupational Safety and Health Administration, recognized controls and work practices for surgical smoke include:

- Using portable local smoke evacuators and room suction systems with in-line filters.
- Keeping the smoke evacuator or room suction hose nozzle inlet within two inches of the surgical site to effectively capture airborne contaminants.
- Having a smoke evacuator available for every operating room where plume is generated.
- Evacuating all smoke, no matter how much is generated.
- Keeping the smoke evacuator "ON" (activated) at all times when airborne particles are produced during all surgical or other procedures.
- Considering all tubing, filters, and absorbers as infectious waste and dispose of them appropriately.
- Using new tubing before each procedure and replace the smoke evacuator filter as recommended by the manufacturer.
- Inspecting smoke evacuator systems regularly to ensure proper functioning.⁶

Additionally, the Joint Commission, a major accrediting organization for hospitals and ambulatory surgical centers, addressed the issue of surgical smoke in its newsletter entitled "Quick Safety Issue 56: Alleviating the Dangers of Surgical Smoke." In the newsletter the Joint Commission recommends that "health care organizations that conduct surgery and other procedures using lasers and other devices that produce surgical smoke should take the following actions to help protect patients and especially staff from the dangers of surgical smoke.

- Implement standard procedures for the removal of surgical smoke and plume through the use of engineering controls, such as smoke evacuators and high filtration masks.
- Use specific insufflators for patients undergoing laparoscopic procedures that lessen the accumulation of methemoglobin buildup in the intra-abdominal cavity. (Surgical smoke is cytotoxic if absorbed into the blood and can cause elevated methemoglobin.) For example, a lapro-shield smoke evacuation device a filter that attaches to a trocar helps clear the field inside the abdomen.
- During laser procedures, use standard precautions, such as those promulgated by the Blood-Borne Pathogen Standard (29 CFR 1910.1030) and the Center for Disease Control and Prevention's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings, to prevent exposure to the aerosolized blood, blood by-products and pathogens contained in surgical smoke plumes.

⁴ Merajikhah A, Imani B, Khazaei S, Bouraghi H. Impact of Surgical Smoke on the Surgical Team and Operating Room Nurses and Its Reduction Strategies: A Systematic Review. Iran J Public Health. 2022 Jan;51(1):27-36. doi: 10.18502/ijph.v51i1.8289. PMID: 35223623; PMCID: PMC8837875. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8837875/, (last visited Feb. 11, 2025).

⁵ United States Department of Labor, Occupational Safety and Health Administration, *Surgical Suite* >> *Smoke Plume*, available at https://www.osha.gov/etools/hospitals/surgical-suite/smoke-plume, (last visited Feb. 11, 2025). ⁶ *Supra* n. 5.

⁷ Available at <u>Quick Safety Issue 56</u>: <u>Alleviating the dangers of surgical smoke | The Joint Commission</u> (last visited Feb. 11, 2025).

• Establish and periodically review policies and procedures for surgical smoke safety and control. Make these policies and procedures available to staff in all areas where surgical smoke is generated.

- Provide surgical team members with initial and ongoing education and competency verification on surgical smoke safety, including the organization's policies and procedures.
- Conduct periodic training exercises to assess surgical smoke precautions and consistent evacuation for the surgical suite or procedural area."

III. Effect of Proposed Changes:

SB 152 creates s. 395.1013, F.S., to require that hospitals and ASCs adopt and implement policies that require the use of a smoke evacuation system during any surgical procedures that is likely to generate surgical smoke. The bill defines:

- "Smoke evacuation system" to mean equipment that effectively captures, filters, and eliminates surgical smoke at the site of origin before the smoke makes contact with the eyes or respiratory tract of occupants in the room; and
- "Surgical smoke" to mean the gaseous byproduct produced by energy-generating devices such as lasers and electrosurgical devices. The term includes, but is not limited to, surgical plume, smoke plume, bio-aerosols, laser-generated airborne contaminants, and lung-damaging dust.

The bill requires hospitals and ASCs to adopt and implement the required policies by January 1, 2026.

The bill provides an effective date of July 1, 2025.

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:

SB 152 may have a negative fiscal impact on a hospital or ASC if the hospital or ASC is required to purchase and maintain equipment in order to meet the requirements of the bill.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 395.1013 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.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

By Senator Davis

5-00188-25 2025152

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A bill to be entitled

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creating s. 395.1013, F.S.; defining the terms "smoke evacuation system" and "surgical smoke"; requiring hospitals and ambulatory surgical centers to, by a specified date, adopt and implement policies requiring the use of smoke evacuation systems during certain

surgical procedures; providing an effective date.

An act relating to protection from surgical smoke;

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

- Section 1. Section 395.1013, Florida Statutes, is created to read:
 - 395.1013 Smoke evacuation systems required.—
 - (1) As used in this section, the term:
- (a) "Smoke evacuation system" means equipment that effectively captures, filters, and eliminates surgical smoke at the site of origin before the smoke makes contact with the eyes or respiratory tract of occupants in the room.
- (b) "Surgical smoke" means the gaseous byproduct produced by energy-generating devices, such as lasers and electrosurgical devices. The term includes, but is not limited to, surgical plume, smoke plume, bio-aerosols, laser-generated airborne contaminants, and lung-damaging dust.
- (2) By January 1, 2026, each licensed facility shall adopt and implement policies that require the use of a smoke evacuation system during any surgical procedure that is likely to generate surgical smoke.
 - Section 2. This act shall take effect July 1, 2025.

THE FLORIDA SENATE



Tallahassee, Florida 32399-1100

COMMITTEES:

COMMITTEES:
Appropriations Committee on Health and Human Services, Vice Chair
Appropriations Committee on Higher Education Commerce and Tourism
Education Pre-K - 12
Fiscal Policy
Health Policy Health Policy Transportation

JOINT COMMITTEE:
Joint Legislative Auditing Committee

SENATOR TRACIE DAVIS Democratic Leader Pro Tempore 5th District

То:	Senator Colleen Burton, Chair Committee on Health Policy
Subject:	Committee Agenda Request
Date:	January 27, 2025
I respectfully i	request that Senate Bill # 152 , relating to surgical smoke, be placed on the: committee agenda at your earliest possible convenience. next committee agenda.
Thank you for	your time and consideration.

Senator Tracie Davis Florida Senate, District 5

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	2/18/2	5	APPEARANCE	RECORE	SBISa
	Meeting Date		Deliver both copies of t	his form to	Bill Number or Topic
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	Committee				Amendment Barcode (if applicable)
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While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022 Joint Rules.pdf (flsenate.gov)

Durses Association

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2/18/2020 Meeting Date

The Florida Senate

APPEARANCE RECORD

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	Committee			Amendment Barcode (if applicable)
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APPEARANCE RECORD

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S-001 (08/10/2021)

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2/19/2019	APPEARANCE RECORD	
Haff Date	Deliver both copies of this form to Senate professional staff conducting the meeting	Bill Number or Topic
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APPEARANCE RECORD

152

Meeting Date
Health Policy
Committee

2/18/25

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	Tallahassee	Florida	32312			
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APPEARANCE RECORD

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Meeting Date

Heath Policy

Committee

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Amendment Barcode (if applicable)

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PLEASE CHECK ONE OF THE FOLLOWING:

I am appearing without compensation or sponsorship.

I am a registered lobbyist, representing:

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

Florida Neurosurgion Society

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SB 152 1/18/2025 APPEARANCE RECORD Bill Number or Topic Meeting Date Deliver both copies of this form to **Health Policy** Senate professional staff conducting the meeting Amendment Barcode (if applicable) Committee 850-222-9075 Megan Fay 124 West Jefferson Street Address Email Street 32301 Tallahassee FL State City OR Waive Speaking: In Support Against For Against Information Speaking: PLEASE CHECK ONE OF THE FOLLOWING: I am not a lobbyist, but received I am a registered lobbyist, am appearing without something of value for my appearance representing: compensation or sponsorship. (travel, meals, lodging, etc.),

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FL Association of Nurse Anesthetists

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S-001 (08/10/2021)

sponsored by:

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 264								
INTRODUCER:	Senator Ha	Senator Harrell							
SUBJECT:	Step-therap	y Protoco	ls						
DATE:	February 1	7, 2025	REVISED:						
ANAL	YST	STAFF	DIRECTOR	REFERENCE		ACTION			
1. Morgan		Brown		HP	Favorable				
2.				AHS					
3.				FP					

I. Summary:

SB 264 creates an exception from step-therapy prior authorization requirements within the Florida Medicaid program for a drug product that is prescribed for the treatment of a serious mental illness, as that term is defined in the bill, or a medication of a similar drug class if prior authorization was previously granted for the prescribed drug and the medication was dispensed to the patient during the previous 12 months.

Upon becoming law, the bill directs the Florida Agency for Health Care Administration (AHCA) to include the bill's rate impact within the Statewide Medicaid Managed Care program rates that take effect October 1, 2025.

The AHCA reports that the bill will have a fiscal impact on the Florida Medicaid program. *See* Section V of this analysis.

Except as otherwise expressly provided, the bill takes effect on October 1, 2025.

II. Present Situation:

The Florida Medicaid Program

Florida Medicaid is the health care safety net for low-income Floridians. The national Medicaid program is a partnership of federal and state governments established to provide coverage for health services for eligible persons. Florida's program is administered by the AHCA and financed through state and federal funds. As of December 2024, the Florida Medicaid program covers over 4.2 million low-income individuals.¹

¹ Florida Agency for Health Care Administration, *Senate Bill 264 Analysis* (Feb. 5, 2025) (on file with Senate Committee on Health Policy).

A Medicaid state plan is an agreement between a state and the federal government describing how the state administers its Medicaid programs. The state plan establishes groups of individuals covered under the Medicaid program, services that are provided, payment methodologies, and other administrative and organizational requirements.²

In order to participate in Medicaid, federal law requires states to cover certain population groups (mandatory eligibility groups) and gives states the flexibility to cover other population groups (optional eligibility groups). States set individual eligibility criteria within federal minimum standards.³ The AHCA may seek an amendment to the state plan as necessary to comply with federal or state laws or to implement program changes.⁴

In Florida, the majority of Medicaid recipients receive their services through a managed care plan contracted with the AHCA under the Statewide Medicaid Managed Care (SMMC) program. The SMMC program has three components: the Managed Medical Assistance (MMA) program, the Long-term Care program, and the Prepaid Dental Health program. Among these three components, Florida's SMMC program offers a health care package covering acute, preventive, behavioral health, prescribed drugs, long-term care, and dental services. The SMMC benefits are authorized by federal authority and are specifically required in ss. 409.973 and 409.98, F.S.⁵

The AHCA contracts with managed care plans on a regional basis to provide services to eligible recipients. The MMA program, which covers most medical and acute care services for managed care plan enrollees, was fully implemented in 2014 and was re-procured for a period beginning December 2018 and ending in 2023.⁶ In 2020, the Legislature extended the allowable term of the SMMC contracts from five to six years.⁷ As a result, the AHCA's previous contracts recently ended in December 2024. On February 1, 2025, the AHCA implemented new SMMC contracts, and the contractual period runs through 2030.⁸

Coverage of Prescribed Drugs

Section 409.91195, F.S., establishes the Pharmaceutical and Therapeutics Committee within the AHCA and tasks it with developing a Florida Medicaid Preferred Drug List (PDL). The Governor appoints the eleven committee members, including five pharmacists, five physicians, and one consumer representative. The committee must meet quarterly and must review all drug classes included in the PDL at least every 12 months. The committee may recommend additions to and deletions from the PDL, such that the PDL provides for medically appropriate

² Medicaid.gov, *Medicaid State Plan Amendments, available at* https://www.medicaid.gov/medicaid-state-plan-amendments/index.html (last visited Feb. 13, 2025).

³ Centers for Disease Control and Prevention, National Center for Health Statistics, *Medicaid, available at* https://www.cdc.gov/nchs/hus/sources-definitions/medicaid.htm (last visited Feb. 13, 2025).

⁴ Supra note 2.

⁵ Supra note 1.

⁶ Agency for Health Care Administration, *Statewide Medicaid Managed Care: Overview, available at* https://ahca.myflorida.com/medicaid/statewide-mc/pdf/mma/SMMC Overview 12042018.pdf (last visited Feb. 13, 2025).

⁷ Chapter 2020-156, s. 44, Laws of Florida

⁸ Florida Agency for Health Care Administration, *Statewide Medicaid Managed Care 3.0 Overview, available at* https://ahca.myflorida.com/content/download/25090/file/Statewide%20Medicaid%20Managed%20Care%20Full%20Deck_0_9172024.pdf (last visited Feb. 13, 2025).

⁹ Section 409.91195(1), F.S.

¹⁰ Section 409.91195(3), F.S.

drug therapies for Medicaid patients which achieve cost savings contained in the General Appropriations Act.¹¹

The committee considers the amount of rebates drug manufacturers are offering if their drug is placed on the PDL.¹² These state-negotiated supplemental rebates, along with federally negotiated rebates, can reduce the per-prescription cost of a brand name drug to below the cost of its generic equivalent.¹³ In 2021, the AHCA reported that Florida collects over \$2 billion per year in federal and supplemental rebates for drugs dispensed to Medicaid recipients. These funds are used to offset the cost of Medicaid services.¹⁴

Medicaid managed care plans are required by the AHCA to provide all prescription drugs listed on the AHCA's PDL. As a result, the managed care plans have not implemented their own planspecific formularies or PDLs. Medicaid managed care plans are required to provide a link to the AHCA's PDL on their websites. ¹⁵ Florida Medicaid covers all Food and Drug Administration (FDA) approved prescription medications. ¹⁶ Those not included on the PDL must be prior approved by Medicaid or the health plans. ¹⁷

The AHCA also manages the federally required Florida Medicaid Drug Utilization Review Board, which meets quarterly and develops and reviews clinical prior authorization criteria, including step-therapy protocols, for certain drugs that are not on the AHCA's Medicaid PDL.¹⁸

Prescribed Drugs Prior Authorization Requirements, Step-Therapy Protocols

Prior authorization means a process by which a health care provider must qualify for payment coverage by obtaining advance approval from an insurer before a specific service is delivered to the patient. Within the Florida Medicaid program, only care, goods, and services that are medically necessary will obtain prior authorization. The AHCA must respond to prior authorization requests for prescribed drugs within 24 hours of receipt of the request. Medicaid managed care plans are contractually required to respond to prior authorization requests for prescribed drugs within 24 hours of receipt of the request. Proceedings of the request.

¹¹ Section 409.91195(4), F.S.

¹² Section 409.91195(7), F.S.

¹³ Supra note 1.

¹⁴ Florida Agency for Health Care Administration, *Senate Bill 534 Analysis* (Nov. 11, 2021) (on file with Senate Committee on Health Policy).

¹⁵ Supra note 1.

¹⁶ Florida Agency for Health Care Administration, *Florida Medicaid Preferred Drug List (Jan. 1, 2025), available at* https://ahca.myflorida.com/content/download/22289/file/December%20P%26T%20PDL%2001.15.2025.pdf (last visited Feb. 13, 2025).

¹⁷ Supra note 1.

¹⁸ *Id*.

¹⁹ Riley, Hannah, Gistia Healthcare, *Making Sense of Prior Authorization, What is it?* (Apr. 21, 2020) *available at* https://f.hubspotusercontent00.net/hubfs/6718559/downloadables/Making%20Sense%20of%20Prior%20Authorization%20What%20is%20it%20">https://f.hubspotusercontent00.net/hubfs/6718559/downloadables/Making%20Sense%20of%20Prior%20Authorization%20What%20is%20it%20">https://f.hubspotusercontent00.net/hubfs/6718559/downloadables/Making%20Sense%20of%20Prior%20Authorization%20What%20is%20it%20">https://f.hubspotusercontent00.net/hubfs/6718559/downloadables/Making%20Sense%20of%20Prior%20Authorization%20What%20it%20">https://f.hubspotusercontent00.net/hubfs/6718559/downloadables/Making%20Sense%20of%20Prior%20Authorization%20What%20it%20">https://f.hubspotusercontent00.net/hubfs/6718559/downloadables/Making%20Sense%20of%20Prior%20Authorization%20What%20it%20">https://f.hubspotusercontent00.net/hubfs/6718559/downloadables/Making%20Sense%20of%20Prior%20Authorization%20What%20It%20">https://f.hubspotusercontent00.net/hubfs/6718559/downloadables/Making%20Sense%20of%20Prior%20Authorization%20What%20It%20">https://f.hubspotusercontent/hubfs/6718559/downloadables/Making%20Sense%20of%20Prior%20Authorization%20What%20">https://f.hubspotusercontent/hubfs/6718559/downloadables/Making%20Sense%20of%20Prior%20Authorization%20What%20">https://f.hubspotusercontent/hubfs/6718559/downloadables/Making%20Sense%20of%20Prior%20Authorization%20What%20">https://f.hubspotusercontent/hubfs/6718559/downloadables/Making%20Sense%20Of%20Prior%20Authorization%20Sense%20Of%20Prior%20Authorization%20Sense%20Of%20Prior%20Authorization%20Sense%20Of%20Prior%20Authorization%20Sense%20Of%20Prior%20Authorization%20Sense%20Of%20Prior%20Authorization%20Sense%20Of%20Prior%20Authorization%20Sense%20Of%20Sense%20Of%20Of%20Of%20Off%20Off%20Off%20Off%20Off%20Off%20Off%20Off%20Off%20Off%20Off%20Off%20Off%20Off%20Off%20Of

²⁰ Supra note 1.

Section 409.912(5)(a)14., F.S., requires the AHCA to implement a step-therapy²¹ prior authorization process for prescribed drugs excluded from the PDL. The recipient must try the prescribed drug on the PDL within the 12 months before a non-PDL drug is approved. However, a non-PDL drug may be approved without meeting the step-therapy prior authorization criteria if the prescribing physician provides additional written medical documentation that the non-PDL product is medically necessary because:²²

- There is not a drug on the PDL to treat the disease or medical condition which is an acceptable clinical alternative;
- The alternative drugs have been ineffective in the treatment of the recipient's disease;
- The drug product or medication of a similar drug class is prescribed for the treatment of schizophrenia or schizotypal or delusional disorders; prior authorization has been granted previously for the prescribed drug; and the medication was dispensed to the patient during the previous 12 months; or
- Based on historical evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective, or the number of doses has been ineffective.

The AHCA must work with the physician to determine the best alternative for the recipient.²³

Regardless of whether a drug is listed on the PDL, a Medicaid managed care plan's prior authorization criteria and protocols related to prescribed drugs cannot be more restrictive than the criteria established by the AHCA for Fee-for-Service Delivery System prior authorizations.²⁴ Medicaid managed care plans must ensure that the prior authorization process for prescribed drugs is readily accessible to health care providers and must provide timely responses to providers.²⁵

Coverage of Prescription Drugs for Serious Mental Illness

Drugs treating serious mental illness accounted for over \$200 million in paid claims in the Medicaid program from October 2023 to September 2024. Antidepressants compose one of the largest drug classes and are responsible for over \$20 million in paid claims per year.²⁶

Tricyclic Antidepressants

As of October 2024, 99.9 percent of the paid claims in this class were for preferred drugs.²⁷ The net cost of non-preferred drugs can be 10 times greater than the net cost of preferred drugs with the same mechanism of action.²⁸

²¹ Step therapy means trying less expensive options before "stepping up" to drugs that cost more. Blue Cross Blue Shield Blue Care Network of Michigan, *How does step therapy work?*, *available at* https://www.bcbsm.com/index/health-insurance-help/faqs/plan-types/pharmacy/what-is-step-therapy.html (last visited Feb. 13, 2025).

²² Section 409.912(5)(a)14, F.S.

 $^{^{23}}$ *Id*.

²⁴ Supra note 1.

²⁵ Section 409.967(2)(c)2, F.S.

²⁶ Supra note 1.

 $^{^{27}}$ Id.

²⁸ Florida Agency for Health Care Administration, *2023 Agency Legislative Bill Analysis: SB 112*, (Feb. 17, 2023) (on file with the Senate Committee on Health Policy).

Selective Serotonin Reuptake Inhibitors (SSRI) Antidepressants

As of October 2024, 99.4 percent of the paid claims in this class were for preferred drugs.²⁹ The cost of non-preferred drugs can be 22 times greater than the cost of preferred drugs within the same therapeutic class.³⁰

Other Antidepressants

As of October 2024, 99.2 percent of the paid claims in this class were for preferred drugs. This class contains oral and injectable antidepressant drugs.³¹ The cost of oral non-preferred drugs can be 17 times greater than the cost of preferred drugs within the review class, which includes all oral antidepressants that are not tricyclic or SSRIs.³²

Antipsychotics

As of October 2024, 98.9 percent of the paid claims in this class were for preferred drugs. PDL compliance results in significant savings annually in the antipsychotic class.³³

The Medicaid PDL includes numerous generic and brand name drugs for the treatment of serious mental illness. If a drug is not on the PDL, the prescriber must obtain prior authorization before dispensing the medication. The AHCA and Medicaid managed care plans are required to respond to prior authorization requests within 24 hours of receipt. Prior authorization requests for mental health medications are reviewed using the Psychotherapeutic Medication Guidelines established by the University of South Florida.³⁴

The AHCA maintains prior authorization criteria and automated edits.³⁵

Prescription Drugs Used in the Treatment of Schizophrenia for Medicaid Recipients

In the 2022 Regular Legislative Session, the Legislature enacted SB 534, which amended s. 409.912, F.S., to create an exception from step-therapy prior authorization requirements within the Florida Medicaid program for a drug product if the prescribing physician provides the AHCA with written medical or clinical documentation that the product is medically necessary. Under SB 534, medical necessity is created when the drug product or a medication of a similar drug class is being prescribed for the treatment of schizophrenia or schizotypal or delusional disorders, prior authorization has previously been granted to the patient for the prescribed drug, and the medication had been dispensed to the patient during the previous 12 months.³⁶

After the step therapy requirement was mitigated by the enactment of SB 534 in 2022 for schizophrenia-related medications, the PDL compliance decreased 0.1 percent in the

²⁹ Supra note 1.

³⁰ Supra note 28.

³¹ Supra note 1.

³² Supra note 28.

³³ Supra note 1.

³⁴ *Id*.

³⁵ *Id*.

³⁶ See Chapter 2022-27, Laws of Florida.

antipsychotic class. This decrease in compliance results in a reduction in collection of manufacturer rebates that offset the cost of Medicaid drug spending.³⁷

III. **Effect of Proposed Changes:**

Section 1 amends s. 409.901, F.S., to create a definition of the term "serious mental illness" pertaining to the Florida Medicaid program. The bill defines that term to mean any of the following psychiatric disorders as defined by the American Psychiatric Association in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition:³⁸

- Bipolar disorders, including hypomanic, manic, depressive, and mixed-feature episodes.
- Depression in childhood or adolescence.
- Major depressive disorders, including single and recurrent depressive episodes.
- Obsessive-compulsive disorders.
- Paranoid personality disorder or other psychotic disorders.
- Schizoaffective disorders, including bipolar or depressive symptoms.
- Schizophrenia.

Section 2 amends s. 409.912(5)(a), F.S., to create an exception from step-therapy prior authorization requirements within the Florida Medicaid program for a drug product that is prescribed for the treatment of a serious mental illness or a medication of a similar drug class if prior authorization was previously granted for the prescribed drug and the medication was dispensed to the patient during the previous 12 months. The bill requires that in cases involving drugs for the treatment of a serious mental illness, the exception must be approved, as opposed to the AHCA being authorized to approve the exception as in current law.

Section 3 amends s. 409.910(20)(a), F.S., to make a conforming change.

Section 4 directs the AHCA, upon the bill becoming law, to include the bill's rate impact within the Statewide Medicaid Managed Care program rates that take effect October 1, 2025.

Section 5 provides an effective date of October 1, 2025, except as otherwise provided.

IV. **Constitutional Issues:**

Municipality/County Mandates Restrictions: Α.

None.

³⁷ Supra note 28.

³⁸ According to the American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR), not the original Fifth Edition, is the Association's latest version of the manual. The Association indicates that "DSM-5-TR features the most current text updates based on scientific literature with contributions from more than 200 subject matter experts. The revised version includes a new diagnosis (prolonged grief disorder), clarifying modifications to the criteria sets for more than 70 disorders, addition of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) symptom codes for suicidal behavior and nonsuicidal self-injury, and updates to descriptive text for most disorders based on extensive review of the literature. In addition, DSM-5-TR includes a comprehensive review of the impact of racism and discrimination on the diagnosis and manifestations of mental disorders. The manual will help clinicians and researchers define and classify mental disorders, which can improve diagnoses, treatment, and research." See https://www.psychiatry.org/psychiatrists/practice/dsm (last visited Feb. 14, 2025).

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 Agency for Health Care Administration (AHCA) reports that:³⁹

- SB 264 will have an operational impact on both the Florida Medicaid fee-for-service delivery system and Statewide Medicaid Managed Care due to changes that will need to be made to all coding related to drugs used to treat serious mental illness.
- In addition to the operational impact, the bill could have adverse impact on the state Medicaid budget. The Florida Medicaid Prescribed Drug List (PDL) includes many effective generic and brand-name medications with robust federal rebates and additional supplemental rebates offered by drug manufacturers, resulting in reduced cost to the Florida Medicaid program. If numerous prescribing physicians elect to prescribe drugs that are not on the PDL under the bill, it may lead to an increase in net drug cost in therapeutic classes related to serious mental illness. The AHCA estimates a significant overall fiscal increase to the Florida Medicaid program of up to \$50 million per year could be possible due to utilization changes and potential loss of supplemental rebates.
- After the enactment of SB 534 (2022) on July 1, 2022, the Florida Medicaid program observed a relative decrease in the amount of rebates collected for the treatment of schizophrenia. A substantial decrease in rebates relative to the large number of drugs used to treat serious mental illness could be expected if SB 264 takes effect as written. In 2023, the AHCA projected that antipsychotics alone would result in the

³⁹ Supra note 1.

collection of over \$13 million in rebates during the 2022-2023 fiscal year, with a total spend of more than \$70 million.⁴⁰ The loss of rebates for a class this size could increase the overall cost of pharmacy spending in the Florida Medicaid program.

In terms of numbers, the AHCA indicates that the fiscal impact of the bill could be significant. According to the fiscal year 2020-2021 data, the Florida Medicaid program spent over \$117 million on medications for the treatment of serious mental illness. If numerous prescribing physicians elect to prescribe drugs that are not on the PDL, and the bill's provisions are applied, it may lead to an increase in drug cost in therapeutic classes related to serious mental illness due to the loss of the AHCA's bargaining power in terms of negotiating rebates. Every one-percent loss in the rate of PDL compliance could generate a \$1.1 million increase in Florida Medicaid program expenses. The extent of such noncompliance under the bill is unknown. According to the bill is unknown.

The bill could also mitigate costs to the Florida Medicaid program or other state expenditures in indirect ways. For example, if Medicaid recipients needing certain drugs for serious mental illness experience a delay in access to those drugs due to the steptherapy protocol, such delay could lead to the need for other costly treatments, such as the costs of involuntary evaluation during a mental health crisis. The bill could mitigate the need for those other costly treatments. Such impact is also indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill's list of psychiatric disorders as defined by the American Psychiatric Association in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5), includes "paranoid personality disorder or other psychotic disorders." The DSM-5 categorizes the following disorders under Schizophrenia and "other psychotic disorders":⁴⁴

- Schizotypal (Personality) Disorder;
- Delusional Disorder;
- Brief Psychotic Disorder;
- Schizophreniform Disorder;
- Schizophrenia;
- Schizoaffective Disorder;
- Substance/Medication-Induced Psychotic Disorder;
- Psychotic Disorder Due to Another Medical Condition;
- Catatonia;
- Other Specified Schizophrenia Spectrum and Other Psychotic Disorder; and

⁴⁰ Supra note 28.

⁴¹ Supra note 1.

⁴² Supra note 28.

⁴³ See s. 394.463, F.S., within the Florida Mental Health Act.

⁴⁴ Wiregrass Georgia Technical College, *DSM-5: Schizophrenia Spectrum and Other Psychotic Disorders, available at* https://wiregrass.libguides.com/c.php?g=1044445&p=7583272 (last visited Feb. 14, 2025).

BILL: SB 264 Page 9

• Unspecified Schizophrenia Spectrum and Other Psychotic Disorder.

With the exception of schizophrenia and schizoaffective disorder, the bill includes these disorders by reference to the DSM-5 as "other psychotic disorders" but does not list them by name. It's possible that the DSM-5 might someday classify other disorders as psychotic disorders that do not appear in this list.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.901, 409.912, and 409.910.

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.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

By Senator Harrell

31-00834-25 2025264

A bill to be entitled

An act relating to step-therapy protocols; amending s. 409.901, F.S.; defining the term "serious mental illness"; amending s. 409.912, F.S.; requiring the Agency for Health Care Administration to approve drug products for Medicaid recipients for the treatment of serious mental illness without step-therapy prior authorization under certain circumstances; amending s. 409.910, F.S.; conforming a cross-reference; directing the agency to include rate impacts resulting from the act in certain rates that become effective on a specified date; providing effective dates.

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

2.6

Section 1. Present subsections (27) and (28) of section 409.901, Florida Statutes, are redesignated as subsections (28) and (29), respectively, and a new subsection (27) is added to that section, to read:

409.901 Definitions; ss. 409.901-409.920.—As used in ss. 409.901-409.920, except as otherwise specifically provided, the term:

- (27) "Serious mental illness" means any of the following psychiatric disorders as defined by the American Psychiatric Association in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition:
- (a) Bipolar disorders, including hypomanic, manic, depressive, and mixed-feature episodes.
 - (b) Depression in childhood or adolescence.

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(c) Major depressive disorders, including single and recurrent depressive episodes.

- (d) Obsessive-compulsive disorders.
- (e) Paranoid personality disorder or other psychotic disorders.
- (f) Schizoaffective disorders, including bipolar or depressive symptoms.
 - (g) Schizophrenia.

Section 2. Paragraph (a) of subsection (5) of section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.-The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician's opinion of the correct diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. s. 438.114. Such confirmation or second opinion shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the

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inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider's professional peers or the national guidelines of a provider's professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid singlesource-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards,

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appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers are not entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

- (5)(a) The agency shall implement a Medicaid prescribed-drug spending-control program that includes the following components:
- 1. A Medicaid preferred drug list, which shall be a listing of cost-effective therapeutic options recommended by the Medicaid Pharmacy and Therapeutics Committee established pursuant to s. 409.91195 and adopted by the agency for each therapeutic class on the preferred drug list. At the discretion of the committee, and when feasible, the preferred drug list should include at least two products in a therapeutic class. The agency may post the preferred drug list and updates to the list on an Internet website without following the rulemaking procedures of chapter 120. Antiretroviral agents are excluded from the preferred drug list. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day

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supply unless the drug products' smallest marketed package is greater than a 34-day supply, or the drug is determined by the agency to be a maintenance drug, in which case a 100-day maximum supply may be authorized. The agency may seek any federal waivers necessary to implement these cost-control programs and to continue participation in the federal Medicaid rebate program, or alternatively to negotiate state-only manufacturer rebates. The agency may adopt rules to administer this subparagraph. The agency shall continue to provide unlimited contraceptive drugs and items. The agency must establish procedures to ensure that:

- a. There is a response to a request for prior authorization by telephone or other telecommunication device within 24 hours after receipt of a request for prior authorization; and
- b. A 72-hour supply of the drug prescribed is provided in an emergency or when the agency does not provide a response within 24 hours as required by sub-subparagraph a.
- 2. A provider of prescribed drugs is reimbursed in an amount not to exceed the lesser of the actual acquisition cost based on the Centers for Medicare and Medicaid Services National Average Drug Acquisition Cost pricing files plus a professional dispensing fee, the wholesale acquisition cost plus a professional dispensing fee, the state maximum allowable cost plus a professional dispensing fee, or the usual and customary charge billed by the provider.
- 3. The agency shall develop and implement a process for managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The management process may include, but is not limited to,

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comprehensive, physician-directed medical-record reviews, claims analyses, and case evaluations to determine the medical necessity and appropriateness of a patient's treatment plan and drug therapies. The agency may contract with a private organization to provide drug-program-management services. The Medicaid drug benefit management program shall include initiatives to manage drug therapies for HIV/AIDS patients, patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending. The agency <u>must shall</u> enroll any Medicaid recipient in the drug benefit management program if he or she meets the specifications of this provision and is not enrolled in a Medicaid health maintenance organization.

4. The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, credentialing, or similar criteria. The agency shall give special consideration to rural areas in determining the size and location of pharmacies included in the Medicaid pharmacy network. A pharmacy credentialing process may include criteria such as a pharmacy's full-service status, location, size, patient educational programs, patient consultation, disease management services, and other characteristics. The agency may impose a moratorium on Medicaid pharmacy enrollment if it is determined that it has a sufficient number of Medicaidparticipating providers. The agency must allow dispensing practitioners to participate as a part of the Medicaid pharmacy network regardless of the practitioner's proximity to any other entity that is dispensing prescription drugs under the Medicaid program. A dispensing practitioner must meet all credentialing

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requirements applicable to his or her practice, as determined by the agency.

- 5. The agency shall develop and implement a program that requires Medicaid practitioners who issue written prescriptions for medicinal drugs to use a counterfeit-proof prescription pad for Medicaid prescriptions. The agency shall require the use of standardized counterfeit-proof prescription pads by prescribers who issue written prescriptions for Medicaid recipients. The agency may implement the program in targeted geographic areas or statewide.
- 6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients to provide rebates of at least 15.1 percent of the average manufacturer price for the manufacturer's generic products. These arrangements <u>must shall</u> require that if a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs at a level below 15.1 percent, the manufacturer must provide a supplemental rebate to the state in an amount necessary to achieve a 15.1-percent rebate level.
- 7. The agency may establish a preferred drug list as described in this subsection, and, pursuant to the establishment of such preferred drug list, negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act and at no less than 14 percent of the average manufacturer price as defined in 42 U.S.C. s. 1936 on the last day of a quarter unless the federal or supplemental rebate, or both, equals or exceeds 29 percent. There is no upper limit on the supplemental rebates the agency may negotiate. The agency may determine that specific products, brand-name or

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generic, are competitive at lower rebate percentages. Agreement to pay the minimum supplemental rebate percentage guarantees a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug list. However, a pharmaceutical manufacturer is not quaranteed placement on the preferred drug list by simply paying the minimum supplemental rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates. The agency may contract with an outside agency or contractor to conduct negotiations for supplemental rebates. For the purposes of this section, the term "supplemental rebates" means cash rebates. Value-added programs as a substitution for supplemental rebates are prohibited. The agency may seek any federal waivers to implement this initiative.

- 8.a. The agency may implement a Medicaid behavioral drug management system. The agency may contract with a vendor that has experience in operating behavioral drug management systems to implement this program. The agency may seek federal waivers to implement this program.
- b. The agency, in conjunction with the Department of Children and Families, may implement the Medicaid behavioral drug management system that is designed to improve the quality of care and behavioral health prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid behavioral drugs. The program may include the following

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elements:

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(I) Provide for the development and adoption of best practice guidelines for behavioral health-related drugs such as antipsychotics, antidepressants, and medications for treating bipolar disorders and other behavioral conditions; translate them into practice; review behavioral health prescribers and compare their prescribing patterns to a number of indicators that are based on national standards; and determine deviations from best practice guidelines.

- (II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.
- (III) Assess Medicaid beneficiaries who are outliers in their use of behavioral health drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of behavioral health drugs.
- (IV) Alert prescribers to patients who fail to refill prescriptions in a timely fashion, are prescribed multiple same-class behavioral health drugs, and may have other potential medication problems.
- (V) Track spending trends for behavioral health drugs and deviation from best practice guidelines.
- (VI) Use educational and technological approaches to promote best practices, educate consumers, and train prescribers in the use of practice guidelines.
 - (VII) Disseminate electronic and published materials.
 - (VIII) Hold statewide and regional conferences.
 - (IX) Implement a disease management program with a model

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quality-based medication component for severely mentally ill individuals and emotionally disturbed children who are high users of care.

- 9. The agency shall implement a Medicaid prescription drug management system.
- a. The agency may contract with a vendor that has experience in operating prescription drug management systems in order to implement this system. Any management system that is implemented in accordance with this subparagraph must rely on cooperation between physicians and pharmacists to determine appropriate practice patterns and clinical guidelines to improve the prescribing, dispensing, and use of drugs in the Medicaid program. The agency may seek federal waivers to implement this program.
- b. The drug management system must be designed to improve the quality of care and prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid prescription drugs. The program must:
- (I) Provide for the adoption of best practice guidelines for the prescribing and use of drugs in the Medicaid program, including translating best practice guidelines into practice; reviewing prescriber patterns and comparing them to indicators that are based on national standards and practice patterns of clinical peers in their community, statewide, and nationally; and determine deviations from best practice guidelines.
- (II) Implement processes for providing feedback to and educating prescribers using best practice educational materials

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and peer-to-peer consultation.

- (III) Assess Medicaid recipients who are outliers in their use of a single or multiple prescription drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of prescription drugs.
- (IV) Alert prescribers to recipients who fail to refill prescriptions in a timely fashion, are prescribed multiple drugs that may be redundant or contraindicated, or may have other potential medication problems.
- 10. The agency may contract for drug rebate administration, including, but not limited to, calculating rebate amounts, invoicing manufacturers, negotiating disputes with manufacturers, and maintaining a database of rebate collections.
- 11. The agency may specify the preferred daily dosing form or strength for the purpose of promoting best practices with regard to the prescribing of certain drugs as specified in the General Appropriations Act and ensuring cost-effective prescribing practices.
- 12. The agency may require prior authorization for Medicaid-covered prescribed drugs. The agency may priorauthorize the use of a product:
 - a. For an indication not approved in labeling;
 - b. To comply with certain clinical guidelines; or
- c. If the product has the potential for overuse, misuse, or abuse.

The agency may require the prescribing professional to provide information about the rationale and supporting medical evidence

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for the use of a drug. The agency shall post prior authorization, step-edit criteria and protocol, and updates to the list of drugs that are subject to prior authorization on the agency's Internet website within 21 days after the prior authorization and step-edit criteria and protocol and updates are approved by the agency. For purposes of this subparagraph, the term "step-edit" means an automatic electronic review of certain medications subject to prior authorization.

- 13. The agency, in conjunction with the Pharmaceutical and Therapeutics Committee, may require age-related prior authorizations for certain prescribed drugs. The agency may preauthorize the use of a drug for a recipient who may not meet the age requirement or may exceed the length of therapy for use of this product as recommended by the manufacturer and approved by the Food and Drug Administration. Prior authorization may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug.
- 14. The agency shall implement a step-therapy prior authorization approval process for medications excluded from the preferred drug list. Medications listed on the preferred drug list must be used within the previous 12 months before the alternative medications that are not listed. The step-therapy prior authorization may require the prescriber to use the medications of a similar drug class or for a similar medical indication unless contraindicated in the Food and Drug Administration labeling. The trial period between the specified steps may vary according to the medical indication. The step-therapy approval process must shall be developed in accordance

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with the committee as stated in s. 409.91195(7) and (8). A drug product may be approved or, in the case of a drug product for the treatment of a serious mental illness, must be approved without meeting the step-therapy prior authorization criteria if 353 the prescribing physician provides the agency with additional written medical or clinical documentation that the product is medically necessary because:

- There is not a drug on the preferred drug list to treat the disease or medical condition which is an acceptable clinical alternative:
- b. The alternatives have been ineffective in the treatment of the beneficiary's disease;
- c. The drug product or medication of a similar drug class is prescribed for the treatment of a serious mental illness schizophrenia or schizotypal or delusional disorders; prior authorization has been granted previously for the prescribed drug; and the medication was dispensed to the patient during the previous 12 months; or
- d. Based on historical evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective, or the number of doses have been ineffective.

The agency shall work with the physician to determine the best alternative for the patient. The agency may adopt rules waiving the requirements for written clinical documentation for specific drugs in limited clinical situations.

15. The agency shall implement a return and reuse program for drugs dispensed by pharmacies to institutional recipients, which includes payment of a \$5 restocking fee for the

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implementation and operation of the program. The return and reuse program <u>must</u> shall be implemented electronically and in a manner that promotes efficiency. The program must permit a pharmacy to exclude drugs from the program if it is not practical or cost-effective for the drug to be included and must provide for the return to inventory of drugs that cannot be credited or returned in a cost-effective manner. The agency shall determine <u>whether</u> <u>if</u> the program has reduced the amount of Medicaid prescription drugs which are destroyed on an annual basis and <u>whether</u> <u>if</u> there are additional ways to ensure more prescription drugs are not destroyed which could safely be reused.

Section 3. Paragraph (a) of subsection (20) of section 409.910, Florida Statutes, is amended to read:

409.910 Responsibility for payments on behalf of Medicaideliqible persons when other parties are liable.—

(20) (a) Entities providing health insurance as defined in s. 624.603, health maintenance organizations and prepaid health clinics as defined in chapter 641, and, on behalf of their clients, third-party administrators, pharmacy benefits managers, and any other third parties, as defined in $\underline{s. 409.901(28)} \ \underline{s.} \ 409.901(27)$, which are legally responsible for payment of a claim for a health care item or service as a condition of doing business in this the state or providing coverage to residents of this state, shall provide such records and information as are necessary to accomplish the purpose of this section, unless such requirement results in an unreasonable burden.

Section 4. The Agency for Health Care Administration is directed to include the rate impact of this act in the Medicaid

managed medical assistance program and long-term care managed care program rates that become effective on October 1, 2025.

This section shall take effect upon this act becoming a law.

Section 5. 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 October 1,

413 2025.

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THE FLORIDA SENATE



Tallahassee, Florida 32399-1100

COMMITTEES:

Appropriations Committee on Higher Education, *Chair*Health Policy, *Vice Chair*Appropriations
Appropriations Committee on Health and Human Services
Children, Families, and Elder Affairs
Education Postsecondary
Environment and Natural Resources

SENATOR GAYLE HARRELL

31st District

February 4, 2025

Senator Burton 408 Senate Office Building Tallahassee, FL 32399

Dear Chair Burton,

I respectfully request that SB 264 –Step Therapy Protocols be placed on the next available agenda for the Health Policy Committee.

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

Thank you,

Senator Gayle Harrell

Senate District 31

Layle

Cc: Allen Brown, Staff Director

Anhar Al-Asadi, Committee Administrative Assistant

APPEARANCE RECORD

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

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2/18/2025		APPE	APPEARANCE RECORD			
Meeting Date Health Policy		De	Deliver both copies of this form to Senate professional staff conducting the meeting			er or Topic
	Committee				Amendment Barc	code (if applicable)
Name	Carali McLean			850-67 Phone	71-4445	
Address				_ Emailexecut	tivedirector@nam	iflorida.org
	Ocala	FL	34478	_		Reset Form
	Speaking: For	State Against Informa	zip tion OR w	aive Speaking:	In Support	ainst
		PLEASE CH	HECK ONE OF THE	FOLLOWING:		
	n appearing without npensation or sponsorship.		a registered lobbyist, esenting:		I am not a lobbyist something of value (travel, meals, lodg sponsored by:	e for my appearance

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. 2020-2022 Joint Rules, pdf (flsenate.gov)

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APPEARANCE RECORD

SB 264

Mooting Data

02/18/2025

Bill Number or Topic

	Meeting Date	Delive	er both copies of this f	form to	bili Number of Topic
H	lealth Policy		sional staff conductin		
	Committee				Amendment Barcode (if applicable)
Name	E. Ivonne Fe	rnandez- AARP		Phone _	954-850-7262
Address	205 S. Monro	e Street		Email _	ifernandez@aarp.org
	Tallahassee	FL	32301		
	City	State	Zip		
	Speaking: For	Against Informatio	n OR w	Vaive Speak	ting: In Support Against
		PLEASE CHE	CK ONE OF THE	FOLLOWIN	lG:
	n appearing without npensation or sponsorship.	represer	egistered lobbyist, nting:		I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.),
		AARP			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. 2020-2022 Joint Rules.pdf (flsenate.gov)

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The Florida Senate **APPEARANCE RECORD**

2/18/25

Bill Number or Topic	

264

Sena	te Health Policy	Deliver I Senate profession	ooth copies of this for onal staff conducting t		Bill Number of Topic
	Committee				Amendment Barcode (if applicable)
Name	Leslie Dughi			Phone	
Address	119 S Monroe	e, Suite 200		_{Email} Le	eslie.Dughi@MHDfirm.com
	Street		00004		
	Tallahassee	FL	32301		
	City	State	Zip		
	Speaking: For	Against Information	OR Wa	ive Speaking	g: 🚺 In Support 🔲 Against
		PLEASE CHEC	K ONE OF THE F	OLLOWING:	
	n appearing without npensation or sponsorship.	I am a regi representi	istered lobbyist, ng:		I am not a lobbyist, but received something of value for my appearance
		Florida Ps	sychiatric Soc	iety	(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. 2020-2022 Joint Rules.pdf (flsenate.gov)

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The Florida Senate APPEARANCE RECORD Bill Number or Topic Meeting Date Deliver both copies of this form to Senate professional staff conducting the meeting Amendment Barcode (if applicable) Committee Street In Support Waive Speaking: Against Information

DI	FACE	CHECK	ONIE	OF THE FA	DLLOWING:
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I am appearing without compensation or sponsorship. am a registered lobbyist,

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

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. 2020-2022 Joint Rules.pdf (flsenate.gov)

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APPEARANCE RECORD

SB 264

February 18, 2025

Meeting Date Health Policy			Deliver both copies of this foorofessional staff conducting	Bill Number or Topic	
Tiodic	Committee				Amendment Barcode (if applicable)
Name	Chris Lyon			Phone	-222-5702
Address	106 East Colle	ge Avenue, Suite	1500	_{Email} clyo	n@llw-law.com
	Street			_	
	Tallahassee	FL	32301		
	City	State	Zip		
	Speaking: For	Against Inform	aation OR W	aive Speaking:	In Support Against
produce and even a result of the		PLEASE C	CHECK ONE OF THE I	FOLLOWING:	
	n appearing without npensation or sponsorship.	rep	n a registered lobbyist, resenting: a Osteopathic M ciation	edical	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. 2020-2022 Joint Rules.pdf (flsenate.gov)

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APPEARANCE RECORD

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February 18, 2025

Meeting Date Health Policy			Deliver both copies of this form to Senate professional staff conducting the meeting		Bill Number or Topic
Name	Committee Barney Bisho	p III		Phone	Amendment Barcode (if applicable) 850-510-9922
Address	1454 Vieux C	arre Drive		Email	Barney@BarneyBishop.com
	Tallahassee	FL	32308		
	City	State	Zip		
	Speaking: For	Against Information	on OR Wa	ive Spea	aking: In Support Against
		PLEASE CHE	CK ONE OF THE F	OLLOWI	ING:
	n appearing without npensation or sponsorship.	represe	Small Business	•	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. 2020-2022 Joint Rules.pdf (flsenate.gov)

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

The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

	Prepa	red By: The	Professional S	taff of the Committe	e on Health Poli	су	
BILL:	SB 342						
INTRODUCER:	Senator Harrell						
SUBJECT:	Public Rec	ords/Agen	cy for Health	Care Administra	tion		
DATE:	February 1	7, 2025	REVISED:				
ANAL	YST	STAFF	DIRECTOR	REFERENCE		ACTION	
1. Smith		Brown		HP	Favorable		
2.				GO			
3.				RC			

I. Summary:

SB 342 exempts from public inspection and copying requirements the personal identifying and location information of current and former Agency for Health Care Administration personnel whose duties include the investigation of complaints filed against health care facilities, the investigation of Medicaid fraud, abuse, or waste, or the inspection of health care facilities licensed or certified by the agency. The exemption also applies to the spouses and children of such personnel.

The bill has no impact on state revenues or state expenditures.

The bill provides an effective date of October 1, 2025.

II. Present Situation:

Access to Public Records - Generally

The State 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

¹ FLA. CONST. art. I, s. 24(a).

⁷ LA. CONST. art. 1, 8, 24(a)

² Id. See also, Sarasota Citizens for Responsible Gov't v. City of Sarasota, 48 So. 3d 755, 762-763 (Fla. 2010).

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:

[a]ll 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."

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. 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

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).

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).

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. 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. Records designated as "exempt" may be released at the discretion of the records custodian under certain circumstances.

Open Government Sunset Review Act

The provisions of s. 119.15, F.S., known as the Open Government Sunset Review Act¹⁶ (the Act), prescribe a legislative review process for newly created or substantially amended¹⁷ public records or open meetings exemptions, with specified exceptions.¹⁸ The Act requires the repeal of such exemption on October 2 of the fifth year after its 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. An exemption serves an identifiable purpose if the Legislature finds that the purpose of the exemption outweighs open government policy and cannot be accomplished without the exemption and it meets one of the following purposes:

- 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

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.

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.

• 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.

If the exemption is continued and expanded, then a public necessity statement and a two-thirds vote for passage are again 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

Florida Agency for Health Care Administration

Health Care Policy and Oversight

The Agency for Health Care Administration (AHCA) is created in s. 20.42, F.S. It is the chief health policy and planning entity for the state and is responsible for, among other things, health facility licensure, inspection, and regulatory enforcement. It licenses or certifies and regulates over 30 different types of health care providers, including hospitals, nursing homes, assisted living facilities, and home health agencies. In total, the AHCA licenses, certifies, regulates, or provides exemptions for more than 50,000 providers.²⁷

Generally applicable provisions of health care provider licensure, including facility inspections and complaints, are addressed in the Health Care Licensing Procedures Act in part II of ch. 408, F.S. Additional chapters or sections in the Florida Statutes provide specific licensure or regulatory requirements pertaining to health care providers in this state.²⁸

Section 408.10, F.S., requires the AHCA to make a toll-free telephone number available to the public for the purpose of handling consumer complaints about the quality of care provided in Florida's health care facilities. The AHCA currently accepts complaints through its hotline and on its website through Licensed Health Care Facility Complaint and Unlicensed Health Care

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?

²³ Section 119.15(6)(b)3., F.S.

²⁵ See generally s. 119.15, F.S.

²⁶ Section 119.15(7), F.S.

²⁷ See the Agency for Health Care Administration, Health Care Policy and Oversight https://ahca.myflorida.com/health-care-policy-and-oversight (last visited Feb.13, 2025).

²⁸ See s. 408.802, F.S., for the health care provider types and applicable licensure statutes.

Facility Complaint forms.²⁹ The AHCA's Complaint Administration Unit receives and processes complaints about the quality of care provided in Florida's health care facilities.

Section 408.811, F.S., outlines procedures for authorized AHCA personnel to inspect health care providers and businesses suspected of operating without a license. An authorized AHCA officer or employee may make or cause to be made any inspection or investigation deemed necessary by the AHCA to determine the state of compliance with the law and applicable rules. Inspections are generally unannounced, with re-licensure inspections occurring biennially, unless otherwise specified. Providers with a strong regulatory record may be exempt from routine inspections, but at least 10 percent of these providers will still be inspected by the AHCA. Inspections by recognized certifying organizations may substitute for state inspections. Providers must produce requested records for inspection at no cost. If deficiencies are found, they must be corrected within 30 days, and a plan of correction must be submitted within 10 days, if required. Providers must maintain public records of inspection reports for at least three years, and these reports must be made available to clients and prospective clients upon request.

Office of Medicaid Program Integrity

The AHCA is also responsible for the administration of the Florida Medicaid program, authorized under Title XIX of the Social Security Act. 30 This authority includes establishing and maintaining a Medicaid state plan approved by the Centers for Medicare & Medicaid Services (CMS) and maintaining any Medicaid waivers needed to operate the Florida Medicaid program as directed by the Legislature.³¹

The Medicaid program is funded with both state and federal tax dollars, and both the states and the federal government have an interest in curbing and investigating Medicaid fraud and recovering overpayments made by the government for improper services. Medicaid fraud means an intentional deception or misrepresentation made by a health care provider or a Medicaid recipient with the knowledge that the deception could result in some unauthorized benefit to him or herself or some other person.³²

Most providers who commit Medicaid fraud fall into one or more of these categories:

- Billing for patients who did not really receive services,
- Billing for a service and/or equipment that wasn't provided,
- Billing for items and services that the patient no longer needs,
- Overcharging for equipment or services,
- Concealing ownership or associations in a related company,
- Paying a "kickback" in exchange for a referral for medical services or equipment,
- Billing more than once for the same service,

²⁹ See the Agency for Health Care Administration, Complaint Administration Unit https://ahca.myflorida.com/health-carepolicy-and-oversight/bureau-of-field-operations/complaint-administration-unit (last visited Feb.13, 2025).

³⁰ Section 409.902, F.S.

³¹ Medicaid.gov, Medicaid State Plan Amendments, available at https://www.medicaid.gov/medicaid/medicaid-state-planamendments/index.html (last visited Feb. 13, 2025).

³² See the Agency for Health Care Administration, Medicaid Fraud: Protect Your Tax Dollars https://ahca.myflorida.com/agency-administration/office-of-inspector-general/medicaid-fraud-protect-your-tax-dollars (last visited Feb.13, 2025).

- Using false credentials such as diplomas, licenses or certifications, or
- Ordering tests or prescriptions that the patient does not need.³³

The AHCA's Office of Medicaid Program Integrity audits and investigates providers suspected of overbilling or defrauding Florida's Medicaid program, recovers overpayments, issues administrative sanctions, and refers cases of suspected fraud for criminal investigation.³⁴

III. Effect of Proposed Changes:

Section 1 creates sub-subparagraph z. under section 119.071(4)(d)1., F.S., to exempt the following information from the public inspection and copying requirements of s. 119.07(1) and s. 24(a), Art. I of the State Constitution:

- The home addresses, telephone numbers, dates of birth, and photographs of current or former personnel of the AHCA whose duties include the investigation of complaints filed against health care facilities, the investigation of Medicaid fraud, abuse, or waste, or the inspection of health care facilities licensed or certified by the agency;
- The names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such personnel; and
- The names and locations of schools and day care facilities attended by the children of such personnel.

These exemptions are subject to the Open Government Sunset Review Act and will stand repealed on October 2, 2030, unless reviewed and saved from repeal through reenactment by the Legislature.

At present, the agency estimates that a total of 421 current investigative staff positions would be included in this exemption. This number is fluid and will change over time due to new hires and staff changes.³⁵

Section 2 of the bill provides, as required by the State Constitution, a statement of public necessity. It states that the release of such personal identifying and location information might place the AHCA's current or former personnel and their family members in danger of physical and emotional harm from disgruntled individuals who have contentious reactions to actions carried out by such personnel or whose business or professional practices have come under scrutiny as a result of such investigations and AHCA actions.

Under the bill, the Legislature finds that the potential for harm outweighs any public benefit that may be derived from the disclosure of such personal identifying and location information.

Section 3 of the bill provides an effective date of October 1, 2025.

³³ Id.

³⁴ *See* the Agency for Health Care Administration, Office of Medicaid Program Integrity https://ahca.myflorida.com/health-care-policy-and-oversight/office-of-medicaid-program-integrity (last visited Feb.13, 2025).

³⁵ Agency for Health Care Administration, Senate Bill 342 Legislative Analysis (Feb. 12, 2025) (on file with the Senate Committee on Health Policy).

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 enacts a new exemption. Thus, the bill requires a two-thirds vote to be enacted.

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 2 of the bill contains a statement of public necessity for the exemption.

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 current and former agency personnel, and their spouse and children, from physical and emotional harm. This bill exempts only their personal identifying and location information from the public records requirements. The exemption does not appear to be broader than necessary to accomplish the purpose of the law.

C. S	State	Tax or	Fee	Increases:

None.

D. 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 119.071 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.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

By Senator Harrell

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A bill to be entitled

An act relating to public records; amending s. 119.071, F.S.; providing an exemption from public records requirements for the personal identifying and location information of certain current or former personnel of the Agency for Health Care Administration and the names and personal identifying and location information of the spouses and children of such personnel; providing for future legislative review and repeal of the exemption; providing a statement of public necessity; providing an effective date.

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

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Section 1. Paragraph (d) of subsection (4) of section 119.071, Florida Statutes, is amended to read:

119.071 General exemptions from inspection or copying of public records.—

- (4) AGENCY PERSONNEL INFORMATION. -
- (d) 1. For purposes of this paragraph, the term:
- a. "Home addresses" means the dwelling location at which an individual resides and includes the physical address, mailing address, street address, parcel identification number, plot identification number, legal property description, neighborhood name and lot number, GPS coordinates, and any other descriptive property information that may reveal the home address.
- b. "Judicial assistant" means a court employee assigned to the following class codes: 8140, 8150, 8310, and 8320.
 - c. "Telephone numbers" includes home telephone numbers,

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personal cellular telephone numbers, personal pager telephone numbers, and telephone numbers associated with personal communications devices.

- 2.a. The home addresses, telephone numbers, dates of birth, and photographs of active or former sworn law enforcement personnel or of active or former civilian personnel employed by a law enforcement agency, including correctional and correctional probation officers, personnel of the Department of Children and Families whose duties include the investigation of abuse, neglect, exploitation, fraud, theft, or other criminal activities, personnel of the Department of Health whose duties are to support the investigation of child abuse or neglect, and personnel of the Department of Revenue or local governments whose responsibilities include revenue collection and enforcement or child support enforcement; the names, home addresses, telephone numbers, photographs, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- b. The home addresses, telephone numbers, dates of birth, and photographs of current or former nonsworn investigative personnel of the Department of Financial Services whose duties include the investigation of fraud, theft, workers' compensation coverage requirements and compliance, other related criminal activities, or state regulatory requirement violations; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such

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personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

- c. The home addresses, telephone numbers, dates of birth, and photographs of current or former nonsworn investigative personnel of the Office of Financial Regulation's Bureau of Financial Investigations whose duties include the investigation of fraud, theft, other related criminal activities, or state regulatory requirement violations; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- d. The home addresses, telephone numbers, dates of birth, and photographs of current or former firefighters certified in compliance with s. 633.408; the names, home addresses, telephone numbers, photographs, dates of birth, and places of employment of the spouses and children of such firefighters; and the names and locations of schools and day care facilities attended by the children of such firefighters are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- e. The home addresses, dates of birth, and telephone numbers of current or former justices of the Supreme Court, district court of appeal judges, circuit court judges, and county court judges and current judicial assistants; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of current or former

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justices and judges and current judicial assistants; and the names and locations of schools and day care facilities attended by the children of current or former justices and judges and current judicial assistants are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution. This sub-subparagraph 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.

- f. The home addresses, telephone numbers, dates of birth, and photographs of current or former state attorneys, assistant state attorneys, statewide prosecutors, or assistant statewide prosecutors; the names, home addresses, telephone numbers, photographs, dates of birth, and places of employment of the spouses and children of current or former state attorneys, assistant state attorneys, statewide prosecutors, or assistant statewide prosecutors; and the names and locations of schools and day care facilities attended by the children of current or former state attorneys, assistant state attorneys, statewide prosecutors, or assistant state attorneys, statewide prosecutors, or assistant statewide prosecutors are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- g. The home addresses, dates of birth, and telephone numbers of general magistrates, special magistrates, judges of compensation claims, administrative law judges of the Division of Administrative Hearings, and child support enforcement hearing officers; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of general magistrates, special magistrates, judges of compensation claims, administrative law judges of the Division

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of Administrative Hearings, and child support enforcement hearing officers; and the names and locations of schools and day care facilities attended by the children of general magistrates, special magistrates, judges of compensation claims, administrative law judges of the Division of Administrative Hearings, and child support enforcement hearing officers are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

- h. The home addresses, telephone numbers, dates of birth, and photographs of current or former human resource, labor relations, or employee relations directors, assistant directors, managers, or assistant managers of any local government agency or water management district whose duties include hiring and firing employees, labor contract negotiation, administration, or other personnel-related duties; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- i. The home addresses, telephone numbers, dates of birth, and photographs of current or former code enforcement officers; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
 - j. The home addresses, telephone numbers, places of

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employment, dates of birth, and photographs of current or former guardians ad litem, as defined in s. 39.01; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such persons; and the names and locations of schools and day care facilities attended by the children of such persons are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

- k. The home addresses, telephone numbers, dates of birth, and photographs of current or former juvenile probation officers, juvenile probation supervisors, detention superintendents, assistant detention superintendents, juvenile justice detention officers I and II, juvenile justice detention officer supervisors, juvenile justice residential officers, juvenile justice residential officer supervisors I and II, juvenile justice counselors, juvenile justice counselor supervisors, human services counselor administrators, senior human services counselor administrators, rehabilitation therapists, and social services counselors of the Department of Juvenile Justice; the names, home addresses, telephone numbers, dates of birth, and places of employment of spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- 1. The home addresses, telephone numbers, dates of birth, and photographs of current or former public defenders, assistant public defenders, criminal conflict and civil regional counsel, and assistant criminal conflict and civil regional counsel; the names, home addresses, telephone numbers, dates of birth, and

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places of employment of the spouses and children of current or former public defenders, assistant public defenders, criminal conflict and civil regional counsel, and assistant criminal conflict and civil regional counsel; and the names and locations of schools and day care facilities attended by the children of current or former public defenders, assistant public defenders, criminal conflict and civil regional counsel, and assistant criminal conflict and civil regional counsel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

- m. The home addresses, telephone numbers, dates of birth, and photographs of current or former investigators or inspectors of the Department of Business and Professional Regulation; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such current or former investigators and inspectors; and the names and locations of schools and day care facilities attended by the children of such current or former investigators and inspectors are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- n. The home addresses, telephone numbers, and dates of birth of county tax collectors; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such tax collectors; and the names and locations of schools and day care facilities attended by the children of such tax collectors are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- o. The home addresses, telephone numbers, dates of birth, and photographs of current or former personnel of the Department of Health whose duties include, or result in, the determination

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or adjudication of eligibility for social security disability benefits, the investigation or prosecution of complaints filed against health care practitioners, or the inspection of health care practitioners or health care facilities licensed by the Department of Health; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

- p. The home addresses, telephone numbers, dates of birth, and photographs of current or former impaired practitioner consultants who are retained by an agency or current or former employees of an impaired practitioner consultant whose duties result in a determination of a person's skill and safety to practice a licensed profession; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such consultants or their employees; and the names and locations of schools and day care facilities attended by the children of such consultants or employees are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- q. The home addresses, telephone numbers, dates of birth, and photographs of current or former emergency medical technicians or paramedics certified under chapter 401; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such emergency medical technicians or paramedics; and the names and locations of schools and day care facilities attended by the

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children of such emergency medical technicians or paramedics are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

- r. The home addresses, telephone numbers, dates of birth, and photographs of current or former personnel employed in an agency's office of inspector general or internal audit department whose duties include auditing or investigating waste, fraud, abuse, theft, exploitation, or other activities that could lead to criminal prosecution or administrative discipline; the names, home addresses, telephone numbers, dates of birth, and places of employment of spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- s. The home addresses, telephone numbers, dates of birth, and photographs of current or former directors, managers, supervisors, nurses, and clinical employees of an addiction treatment facility; the home addresses, telephone numbers, photographs, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution. For purposes of this sub-subparagraph, the term "addiction treatment facility" means a county government, or agency thereof, that is licensed pursuant to s. 397.401 and provides substance abuse prevention, intervention, or clinical treatment, including any licensed service component described in s. 397.311(27).

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t. The home addresses, telephone numbers, dates of birth, and photographs of current or former directors, managers, supervisors, and clinical employees of a child advocacy center that meets the standards of s. 39.3035(2) and fulfills the screening requirement of s. 39.3035(3), and the members of a Child Protection Team as described in s. 39.303 whose duties include supporting the investigation of child abuse or sexual abuse, child abandonment, child neglect, and child exploitation or to provide services as part of a multidisciplinary case review team; the names, home addresses, telephone numbers, photographs, dates of birth, and places of employment of the spouses and children of such personnel and members; and the names and locations of schools and day care facilities attended by the children of such personnel and members are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

- u. The home addresses, telephone numbers, places of employment, dates of birth, and photographs of current or former staff and domestic violence advocates, as defined in s. 90.5036(1)(b), of domestic violence centers certified by the Department of Children and Families under chapter 39; the names, home addresses, telephone numbers, places of employment, dates of birth, and photographs of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- v. The home addresses, telephone numbers, dates of birth, and photographs of current or former inspectors or investigators of the Department of Agriculture and Consumer Services; the

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names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of current or former inspectors or investigators; and the names and locations of schools and day care facilities attended by the children of current or former inspectors or investigators are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution. This sub-subparagraph 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.

The home addresses, telephone numbers, dates of birth, and photographs of current county attorneys, assistant county attorneys, deputy county attorneys, city attorneys, assistant city attorneys, and deputy city attorneys; the names, home addresses, telephone numbers, photographs, dates of birth, and places of employment of the spouses and children of current county attorneys, assistant county attorneys, deputy county attorneys, city attorneys, assistant city attorneys, and deputy city attorneys; and the names and locations of schools and day care facilities attended by the children of current county attorneys, assistant county attorneys, deputy county attorneys, city attorneys, assistant city attorneys, and deputy city attorneys are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution. This exemption does not apply to a county attorney, assistant county attorney, deputy county attorney, city attorney, assistant city attorney, or deputy city attorney who qualifies as a candidate for election to public office. This sub-subparagraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand

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repealed on October 2, 2029, unless reviewed and saved from repeal through reenactment by the Legislature.

- x. The home addresses, telephone numbers, dates of birth, and photographs of current or former commissioners of the Florida Gaming Control Commission; the names, home addresses, telephone numbers, dates of birth, photographs, and places of employment of the spouses and children of such current or former commissioners; and the names and locations of schools and day care facilities attended by the children of such current or former commissioners are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution. This sub-subparagraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2029, unless reviewed and saved from repeal through reenactment by the Legislature.
- y. The home addresses, telephone numbers, dates of birth, and photographs of current clerks of the circuit court, deputy clerks of the circuit court, and clerk of the circuit court personnel; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of current clerks of the circuit court, deputy clerks of the circuit court, and clerk of the circuit court personnel; and the names and locations of schools and day care facilities attended by the children of current clerks of the circuit court, deputy clerks of the circuit court, and clerk of the circuit court personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution. This sub-subparagraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2029, unless reviewed and

31-00870-25 2025342

saved from repeal through reenactment by the Legislature.

- z. The home addresses, telephone numbers, dates of birth, and photographs of current or former personnel of the Agency for Health Care Administration whose duties include the investigation of complaints filed against health care facilities, the investigation of Medicaid fraud, abuse, or waste, or the inspection of health care facilities licensed or certified by the agency; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution. This sub-subparagraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2030, unless reviewed and saved from repeal through reenactment by the Legislature.
- 3. An agency that is the custodian of the information specified in subparagraph 2. and that is not the employer of the officer, employee, justice, judge, or other person specified in subparagraph 2. must maintain the exempt status of that information only if the officer, employee, justice, judge, other person, or employing agency of the designated employee submits a written and notarized request for maintenance of the exemption to the custodial agency. The request must state under oath the statutory basis for the individual's exemption request and confirm the individual's status as a party eligible for exempt status.
- 4.a. A county property appraiser, as defined in s. 192.001(3), or a county tax collector, as defined in s.

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192.001(4), who receives a written and notarized request for maintenance of the exemption pursuant to subparagraph 3. must comply by removing the name of the individual with exempt status and the instrument number or Official Records book and page number identifying the property with the exempt status from all publicly available records maintained by the property appraiser or tax collector. For written requests received on or before July 1, 2021, a county property appraiser or county tax collector must comply with this sub-subparagraph by October 1, 2021. A county property appraiser or county tax collector may not remove the street address, legal description, or other information identifying real property within the agency's records so long as a name or personal information otherwise exempt from inspection and copying pursuant to this section is not associated with the property or otherwise displayed in the public records of the agency.

- b. Any information restricted from public display, inspection, or copying under sub-subparagraph a. must be provided to the individual whose information was removed.
- 5. An officer, an employee, a justice, a judge, or other person specified in subparagraph 2. may submit a written request for the release of his or her exempt information to the custodial agency. The written request must be notarized and must specify the information to be released and the party authorized to receive the information. Upon receipt of the written request, the custodial agency must release the specified information to the party authorized to receive such information.
- 6. The exemptions in this paragraph apply to information held by an agency before, on, or after the effective date of the

31-00870-25 2025342

exemption.

7. Information made exempt under this paragraph may be disclosed pursuant to s. 28.2221 to a title insurer authorized pursuant to s. 624.401 and its affiliates as defined in s. 624.10; a title insurance agent or title insurance agency as defined in s. 626.841(1) or (2), respectively; or an attorney duly admitted to practice law in this state and in good standing with The Florida Bar.

- 8. The exempt status of a home address contained in the Official Records is maintained only during the period when a protected party resides at the dwelling location. Upon conveyance of real property after October 1, 2021, and when such real property no longer constitutes a protected party's home address as defined in sub-subparagraph 1.a., the protected party must submit a written request to release the removed information to the county recorder. The written request to release the removed information must be notarized, must confirm that a protected party's request for release is pursuant to a conveyance of his or her dwelling location, and must specify the Official Records book and page, instrument number, or clerk's file number for each document containing the information to be released.
- 9. Upon the death of a protected party as verified by a certified copy of a death certificate or court order, any party can request the county recorder to release a protected decedent's removed information unless there is a related request on file with the county recorder for continued removal of the decedent's information or unless such removal is otherwise prohibited by statute or by court order. The written request to

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31-00870-25 2025342

release the removed information upon the death of a protected party must attach the certified copy of a death certificate or court order and must be notarized, must confirm the request for release is due to the death of a protected party, and must specify the Official Records book and page number, instrument number, or clerk's file number for each document containing the information to be released. A fee may not be charged for the release of any document pursuant to such request.

Section 2. The Legislature finds that it is a public necessity that the home addresses, telephone numbers, dates of birth, and photographs of current or former personnel of the Agency for Health Care Administration whose duties include the investigation of complaints filed against health care facilities, the investigation of Medicaid fraud, abuse, or waste, or the inspection of health care facilities licensed or certified by the agency; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel be made exempt from s. 119.07(1), Florida Statutes, and s. 24(a), Article I of the State Constitution. The Legislature finds that the release of such personal identifying and location information might place the agency's current or former personnel and their family members in danger of physical and emotional harm from disgruntled individuals who have contentious reactions to actions carried out by such personnel or whose business or professional practices have come under scrutiny as a result of such investigations and agency actions. The Legislature further finds that the harm that may result from

31-00870-25 2025342 465 the release of such personal identifying and location information outweighs any public benefit that may be derived 466 from the disclosure of the information. 467 Section 3. This act shall take effect October 1, 2025. 468

THE FLORIDA SENATE



Tallahassee, Florida 32399-1100

COMMITTEES:

Appropriations Committee on Higher Education, *Chair*Health Policy, *Vice Chair*Appropriations
Appropriations Committee on Health and Human Services
Children, Families, and Elder Affairs
Education Postsecondary
Environment and Natural Resources

SENATOR GAYLE HARRELL

31st District

February 7, 2025

Senator Burton 408 Senate Office Building Tallahassee, FL 32399

Dear Chair Burton,

I respectfully request that SB 342 – Public Records for AHCA be placed on the next available agenda for the Health Policy Committee.

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

Thank you,

Senator Gayle Harrell

Senate District 31

Layle

Cc: Allen Brown, Staff Director

Anhar Al-Asadi, Committee Administrative Assistant

The Florida Senate **APPEARANCE RECORD** Bill Number or Topic Deliver both copies of this form to Senate professional staff conducting the meeting Amendment Barcode (if applicable) OR Waive Speaking: Information Speaking: Against PLEASE CHECK ONE OF THE FOLLOWING:

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. 2020-2022 Joint Rules.pdf (flsenate.gov)

I am a registered lobbyist,

representing:

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

I am appearing without

compensation or sponsorship.

S-001 (08/10/2021)

I am not a lobbyist, but received

(travel, meals, lodging, etc.),

sponsored by:

something of value for my appearance

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 294							
INTRODUCER:	Senator Harrell							
SUBJECT:	Collaborative Pharmacy Practice for Chronic Health Conditions							
DATE:	February 17	7, 2025	REVISED:	02/19/25				
ANAL	YST	STAFF	DIRECTOR	REFERENCE		ACTION		
1. Smith		Brown		HP	Favorable			
2.				AHS				
3.				RC				

I. Summary:

SB 294 amends Florida Statutes relating to collaborative pharmacy practice agreements. Under current law, collaborative pharmacy practice describes an arrangement in which a physician authorizes a pharmacist to provide specified patient care services relating to chronic health conditions to one or more of the physician's patients. The bill provides that the term "chronic health condition" does not include heart failure, coronary heart disease, and cardiac rhythm disorder.

In practice, this would ensure that those conditions remain excluded from any definition of the term that may be adopted in rule by the Board of Pharmacy.

The bill provides an effective date of July 1, 2025.

II. Present Situation:

Pharmacist Licensure

Pharmacy is the third largest health profession behind nursing and medicine.¹ The Board of Pharmacy (BOP), in conjunction with the Department of Health (DOH), regulates the practice of pharmacists pursuant to ch. 465, F.S.² To be licensed as a pharmacist, a person must:³

- Complete an application and remit an examination fee;
- Be at least 18 years of age;

¹ American Association of Colleges of Pharmacy, *About AACP*, *available at* https://www.aacp.org/about-aacp (last visited Feb. 13, 2025).

² Sections 465.004 and 465.005, F.S.

³ Section 465.007, F.S. The DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. *See* s. 465.0075, F.S.

- Hold a degree from an accredited and approved school or college of pharmacy;⁴
- Have completed a BOP-approved internship; and
- Successfully complete the BOP-approved examination.

A pharmacist must complete at least 30 hours of BOP-approved continuing education during each biennial renewal period.⁵

Pharmacist Scope of Practice

In Florida, the practice of the profession of pharmacy includes:⁶

- Compounding, dispensing, and consulting concerning the contents, therapeutic values, and uses of any medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the patient's prescribing health care provider or other persons specifically authorized by the patient;
- Transmitting information from prescribers to their patients;
- Administering specified vaccines to adults and influenza vaccines to persons seven years of age or older;⁷
- Administering epinephrine autoinjections;⁸
- Administering antipsychotic medications by injection; 9 and
- Screen an adult for HIV exposure.¹⁰

A pharmacist may not alter a prescriber's directions, diagnose or treat any disease, initiate any drug therapy, or practice medicine or osteopathic medicine, unless permitted by law.¹¹

Pharmacists may order and dispense drugs that are included in a formulary developed by a committee composed of members of the Board of Medicine (BOM), the Board of Osteopathic Medicine (BOOM), and the BOP.¹² The formulary may only include:¹³

• Any medicinal drug of single or multiple active ingredients in any strengths when such active ingredients have been approved individually or in combination for over-the-counter sale by the U.S. Food and Drug Administration (FDA);

⁴ If the applicant has graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the U.S., the applicant must demonstrate proficiency in English, pass the board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH licensed pharmacist.

⁵ Section 465.009, F.S.

⁶ Section 465.003(13), F.S.

⁷ See s. 465.189, F.S.

⁸ *Id*.

⁹ Section 465.1893, F.S.

¹⁰ Section 465.1861, F.S.

¹¹ Section 465.003(22), F.S.

¹² Section 465.186, F.S.

¹³ *Id*.

• Any medicinal drug recommended by the FDA Advisory Panel for transfer to over-the-counter status pending approval by the FDA;

- Any medicinal drug containing any antihistamine or decongestant as a single active ingredient or in combination;
- Any medicinal drug containing fluoride in any strength;
- Any medicinal drug containing lindane in any strength;
- Any over-the-counter proprietary drug under federal law that has been approved for reimbursement by the Florida Medicaid Program; and
- Any topical anti-infectives, excluding eye and ear topical anti-infectives.

A pharmacist may order the following, within his or her professional judgment and subject to the following conditions:

- Certain oral analgesics for mild to moderate pain. The pharmacist may order these drugs for minor pain and menstrual cramps for patients with no history of peptic ulcer disease. The prescription is limited to a six-day supply for one treatment of:
 - o Magnesium salicylate/phenyltoloxamine citrate;
 - o Acetylsalicylic acid (zero order release, long acting tablets);
 - o Choline salicylate and magnesium salicylate;
 - o Naproxen sodium;
 - o Naproxen;
 - o Ibuprofen;
 - o Phenazopyridine, for urinary pain; and
 - Antipyrine 5.4%, benzocaine 1.4%, glycerin, for ear pain if clinical signs or symptoms of tympanic membrane perforation are not present;
- Anti-nausea preparations;
- Certain antihistamines and decongestants;
- Certain topical antifungal/antibacterials;
- Topical anti-inflammatory preparations containing hydrocortisone not exceeding 2.5%;
- Certain otic antifungal/antibacterial;
- Salicylic acid 16.7% and lactic acid 16.7% in flexible collodion, to be applied to warts, except for patients under 2 years of age, and those with diabetes or impaired circulation;
- Vitamins with fluoride, excluding vitamins with folic acid in excess of 0.9 mg.;
- Medicinal drug shampoos containing lindane for the treatment of head lice;
- Ophthalmic. Naphazoline 0.1% ophthalmic solution;
- Certain histamine H2 antagonists;
- Acne products; and
- Topical antiviral for herpes simplex infections of the lips. 14

Collaborative Pharmacy Practice Agreements

Under s. 465.1865, F.S., a collaborative pharmacy practice agreement (CPPA) is a formal agreement in which a physician licensed under ch. 458 or 459, F.S., makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to provide specified patient care services for certain chronic medical conditions.

¹⁴ Fla. Admin. Code R. 64B16-27.220 (2025).

A CPPA specifies what functions beyond the pharmacist's typical scope of practice can be delegated to the pharmacist by the collaborating physician. Common tasks include initiating, modifying, or discontinuing medication therapy and ordering and evaluating tests.

Pharmacist Training for Collaborative Practice

To provide services under a CPPA, a pharmacist must be certified by the BOP. To obtain certification a pharmacist must complete a 20-hour course approved by the BOP, in consultation with the BOM and the BOOM, and:

- Hold an active and unencumbered license to practice pharmacy;
- Have a Ph.D. in pharmacy or have five years of experience as a licensed pharmacist;
- Have completed the BOP-approved, 20-hour course, eight hours of which must be live or live video conference that includes instruction in:
 - o Performance of patient assessments;
 - o Ordering, performing, and interpreting clinical and laboratory tests;
 - Evaluating and managing diseases and health conditions in collaboration with other health care practitioners; and
 - o Writing and entering into a CPPA.
- Maintains at least \$250,000 of professional liability insurance coverage; and
- Has established a system to maintain patient records of patients receiving services under a CPPA for five years from the patient's most recent service.¹⁵

Required Contents of CPPA

The terms and conditions of the CPPA must be appropriate to the pharmacist's training, and the services delegated to the pharmacist must be within the collaborating physician's scope of practice. A copy of the certification received from the BOP must be included as an attachment to the CPPA. A CPPA must include the following:

- The name of the collaborating physician's patient(s) for whom a pharmacist may provide services:
- Each chronic health condition to be collaboratively managed;
- The specific medicinal drug(s) to be managed for each patient;
- Material terms defined as those terms enumerated in s. 465.1865(3)(a), F.S.;
- Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests;
- Conditions and events in which the pharmacist must notify the collaborating physician and the manner and timeframe in which notification must occur;
- The start and ending dates of the CPPA and termination procedures, including procedures for patient notification and medical records transfers;
- A statement that the CPPA may be terminated, in writing, by either party at any time; and
- In the event of an addendum to the material terms of an existing CPPA, a copy of the addendum and the initial agreement.

A CPPA will automatically terminate two years after execution if not renewed. The pharmacist, along with the collaborating physician, must maintain the CPPA on file at his or her practice

¹⁵ Section 465.1865(2), F.S.

location and must make the CPPA available to the DOH or BOP upon request or inspection. A pharmacist who enters into a CPPA must submit a copy of the signed agreement to the BOP before the agreement may be implemented.¹⁶

Allowable Chronic Health Conditions

CPPAs in Florida allow a pharmacist to provide specific patient care services for chronic health conditions. Section 465.1865(1)(b), F.S., establishes that the term "chronic health condition" means:

- Arthritis;
- Asthma:
- Chronic obstructive pulmonary diseases;
- Type 2 diabetes;
- Human immunodeficiency virus or acquired immune deficiency syndrome;
- Obesity; or
- Any other chronic condition adopted in rule by the board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine.

The Board of Pharmacy has adopted the following list of chronic health conditions for which a pharmacist certified pursuant to s. 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending CPPA:

- Hyperlipidemia:
- Hypertension;
- Anti-coagulation management;
- Nicotine Dependence;
- Opioid use disorder;
- Hepatitis C
- Those chronic health conditions enumerated in s. 465.1865(1)(b), F.S.¹⁷

On May 23, 2024, the Boards of Pharmacy, Medicine, and Osteopathic Medicine held a Joint Rules Committee meeting to discuss adding heart disease to the list of chronic health conditions.¹⁸ The committee ultimately decided not to proceed with the proposed rule language.¹⁹

Prohibited Acts Regarding a CPPA

A pharmacist may not:

- Modify or discontinue medicinal drugs prescribed by a health care practitioner with whom he
 or she does not have a CPPA; or
- Enter into a CPPA while acting as a pharmacy employee without the written approval of the owner of the pharmacy.

A physician may not delegate the authority to initiate or prescribe a controlled substance listed in s. 893.03, F.S. or 21 U.S.C. s. 812, to a pharmacist.

¹⁶ Section 465.1865(3), F.S. and Fla. Admin. Code R. 64B16-31.003 (2025).

¹⁷ Fla. Admin. Code R. 64B16-31.007, F.A.C. (2025).

¹⁸ Florida Department of Health, *Senate Bill 294 Analysis* (Feb. 17, 2025) (on file with Senate Committee on Health Policy).

¹⁹ *Id*.

Continuing Education

A pharmacist who practices under a CPPA must complete an eight-hour continuing education (CE) course approved by the BOP that addresses CPPA-related issues each biennial licensure renewal, in addition to the CE requirements under s. 465.009, F.S. A pharmacist wishing to maintain CPPA certification must submit confirmation of having completed such course when applying for licensure renewal. A pharmacist who fails to complete this CE is prohibited from practicing under a CPPA.

CPPAs in Effect

According to the DOH 2023-2024 Annual Report, there are 39,486 licensed pharmacists in Florida. ²⁰ In fiscal year 2023-2024, 87 pharmacists became certified to provide care under a CPPA. ²¹

III. Effect of Proposed Changes:

Section 1 of the bill amends s. 465.1865, F.S., to exclude heart failure, coronary heart disease, and cardiac rhythm disorders from the definition of "chronic health condition." This would remove the authority of the Board of Pharmacy to include those conditions as "chronic health conditions" in rule.

Under current law and rule, pharmacists are not authorized to "collaboratively manage" heart failure, coronary heart disease, and cardiac rhythm disorders with a collaborating physician under a CPPA. This would not change upon the enactment of SB 294, but the bill would prevent the BOP from classifying those conditions by rule as chronic health conditions that may be included in a CPPA prospectively

Section 2 of the bill provides an effective date of July 1, 2025.

IV. Constitutional Issues:

A.	Municipality/County Mandates Restrictions:
	None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

²⁰ Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year* 2023-2024, at pg. 4, available at https://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/annual-reports.html (last visited Feb. 13, 2025).

²¹ *Id.*

	D.	State Tax or Fee Increases:
		None.
	E.	Other Constitutional Issues:
		None.
٧.	Fisca	I Impact Statement:
	A.	Tax/Fee Issues:
		None.
	B.	Private Sector Impact:
		None.
	C.	Government Sector Impact:
		None.
VI.	Techr	nical Deficiencies:
	None.	
VII.	Relate	ed Issues:
	None.	
VIII.	Statu	tes Affected:
	This b	ill substantially amends section 465.1865 of the Florida Statutes.
IX.	Addit	ional Information:
	A.	Committee Substitute – Statement of Changes: (Summarizing differences between the Committee Substitute and the prior version of the bill.)
		None.
	B.	Amendments:
		None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

By Senator Harrell

31-00563-25 2025294

A bill to be entitled

An act relating to collaborative pharmacy practice for chronic health conditions; amending s. 465.1865, F.S.; revising the definition of the term "chronic health condition" to exclude specified heart conditions for purposes of collaborative pharmacy practice for chronic health conditions; providing an effective date.

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

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Section 1. Paragraph (b) of subsection (1) of section 465.1865, Florida Statutes, is amended to read:

465.1865 Collaborative pharmacy practice for chronic health 14 conditions .-15

- (1) For purposes of this section, the term:
- (b) "Chronic health condition" means:
- 1. Arthritis;
- 2. Asthma;
- 3. Chronic obstructive pulmonary diseases;
- 4. Type 2 diabetes;
- 5. Human immunodeficiency virus or acquired immune deficiency syndrome;
 - 6. Obesity; or
- 7. Any other chronic condition adopted in rule by the board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine.

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The term does not include heart failure, coronary heart disease,

ı	31-0	0563-25									202	25294	
30	or a	cardiac	rhy	thm d	isor	der.							
31		Section	2.	This	act	shall	take	effect	July	1,	2025.		
1													

THE FLORIDA SENATE



Tallahassee, Florida 32399-1100

COMMITTEES:

Appropriations Committee on Higher Education, Chair Health Policy, Vice Chair Appropriations
Appropriations Committee on Health and Human Services
Children, Families, and Elder Affairs
Education Postsecondary
Environment and Natural Resources

SENATOR GAYLE HARRELL

31st District

February 4, 2025

Senator Burton 408 Senate Office Building Tallahassee, FL 32399

Dear Chair Burton,

I respectfully request that SB 294 –Collaborative Pharmacy Practice be placed on the next available agenda for the Health Policy Committee.

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

Thank you,

Senator Gayle Harrell

Senate District 31

Layle

Cc: Allen Brown, Staff Director

Anhar Al-Asadi, Committee Administrative Assistant

The Florida Senate

APPEARANCE RECORD

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Meeting Date Health Policy	Deliver both copies of this form to Senate professional staff conducting the meeting	Bill Number or Topic
Committee		Amendment Barcode (if applicable)
Name Chris Mand	Phone	904-355-1555
Address 4427 Herschel St	Email <i>j</i>	n land law e ad com
Street		
Jax 62	32210	
City State	Zip	
Speaking: For Against] Information OR Waive Speaking	ı: In Support
Р	LEASE 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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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. 2020-2022 Joint Rules. pdf (flsenate.gov)

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

2/18/202**6**

The Florida Senate **APPEARANCE RECORD**

SB 294	 Collaborative 	Pharmacy	Practice	Agreement

Meeting Date Health Policy		Deliver both copies of this form to Senate professional staff conducting the meeting		Bill	Number or Topic	
Name	Dr. Alan Ac	kermann DO FACC		3 Phone _	Amendme 05-903-9478	nt Barcode (if applicable)
Address		ayne Boulevard STI	E 204	a Email _	ackermann@mhs.r	net
	Aventura	FL	33180			Reset Form
	City	State	Zip			
	Speaking:	For Against	Information OR	Waive Speak	ing:	Against
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	n appearing withou npensation or spor		I am a registered lobbyis representing: Florida Chapter, An of Cardiology		something of travel, mea	obbyist, but received of value for my appearance Is, lodging, etc.), oy:

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. 2020-2022 Joint Rules.pdf (flsenate.gov)

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7 (The Florida Senate	794
2-18	APPEARANCE RECOR	D
Heath Polky	Deliver both copies of this form to Senate professional staff conducting the meeting	Bill Number or Topic
Committee		Amendment Barcode (if applicable)
Name Jarrad Owl	Phone	Jod-252-1166
Address 2355 PW	ic - Ro	Howlet Office Towns
Street City State	Zip	
Speaking: For Against	☐ Information OR Waive Speak	ing:
	PLEASE CHECK ONE OF THE FOLLOWIN	IG:
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:
Floris	En Medical As:	roitoisos

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. 2020-2022 Joint Rules.pdf (flsenate.gov)

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

The Florida Senate

2-18-2025

APPEARANCE RECORD

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Meeting Date

Deliver both copies of this form to

Bill Number or Topic

Mea	rith Pol	104	Senate professional staff conduc		
	Committee				Amendment Barcode (if applicable)
Name	David	Allen			401-2187
Address	STreet Street	2nd Ave	Snite 3200	Email david	allen C gray -
	Street				robinson . com
	Miami	FL	33131		
	City	State	Zip		
	Speaking: F	or Against	Information OR	Waive Speaking: Ir	Support Against
		PL	EASE CHECK ONE OF TH	le following:	
	n appearing without mpensation or sponsorshi	p. F	I am a registered lobbyist, representing: = 16 vida Sociut Systum M	ty of Mealth -	I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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The Florida Senate

APPEARANCE RECORD

294

February 18, 2025

Meeting Date		Deliver	both copies of this for	Bill Number or Topic			
Healt	h Policy	Senate professi	ional staff conducting	the meeting			
	Committee	and a state of the			Amendment Barcode (if applicable)		
Name	Barney Bisho	p III		Phone	-510-9922		
Name							
Address	1454 Vieux C	arre Drive		Email Barr	ney@BarneyBishop.com		
	Street						
	Tallahassee	FL	32308				
	City	State	Zip				
	Speaking: For	Against Information	o OR wa	aive Speaking:	In Support Against		
	PLEASE CHECK ONE OF THE FOLLOWING:						
	n appearing without npensation or sponsorship.	I am a reg	gistered lobbyist, ting:		I am not a lobbyist, but received something of value for my appearance		
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February 18, 2025

The Florida Senate PPEARANCE RECORD

SB	294
SD	234

S	В	294

Bill Number or Topic Meeting Date Deliver both copies of this form to Health Policy Senate professional staff conducting the meeting Amendment Barcode (if applicable) Committee 850-222-5702 Chris Lyon Phone Name Email clyon@llw-law.com 106 East College Avenue, Suite 1500 Street 32301 Tallahassee FL State Zip City Waive Speaking: In Support Against OR Speaking: For Against Information PLEASE CHECK ONE OF THE FOLLOWING: I am not a lobbyist, but received I am a registered lobbyist, I am appearing without something of value for my appearance compensation or sponsorship. representing: (travel, meals, lodging, etc.), Florida Osteopathic Medical sponsored by: Association

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. 2020-2022 Joint Rules.pdf (flsenate.gov)

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CourtSmart Tag Report

Room: KB 412 Case No.: - Type: Caption: Senate Committee on Health Policy Judge:

Started: 2/18/2025 1:47:52 PM

Ends: 2/18/2025 2:36:43 PM Length: 00:48:52

1:47:57 PM Chair Burton Calls Meeting to Order

1:47:58 PM Roll Call

1:48:03 PM Quorum Present

1:48:23 PM Opening Remarks, Chair Burton

1:49:38 PM Tab 1 SB 126 - Prescription Hearing Aids by Senator Bradley

1:49:44 PM Senator Bradley 1:50:40 PM Chair Burton 1:50:44 PM Public Testimony

1:50:54 PM Alexander Evertz Waives in Support **1:51:17 PM** Theresa Bulger Speaks for Information

1:51:52 PM Senator Bradley
1:52:08 PM Roll Call for SB 126
1:52:20 PM Reported Favorably

1:52:45 PM Tab 2 SB 152 - Protection from Surgical Smoke by Senator Davis

1:53:12 PM Senator Davis 1:54:17 PM Chair Burton 1:54:22 PM Public Testimony

1:54:28 PM Megan Moroney, Florida Nurses Association

1:57:08 PM Eva Lim **2:00:13 PM** Saundra Falk

2:03:25 PM Jack Cory, Florida Nurses Association Waives in Suppport

2:04:25 PM Waives in suppport read into report-Chair Burton

2:04:53 PM Senator Davis
2:05:37 PM Reported Favorably

2:06:06 PM Tab 3 SB 264 - Step-therapy Protocols by Senator Harrell

2:06:19 PM Senator Harrell
2:10:20 PM Chair Burton
2:10:22 PM Senator Gaetz
2:10:57 PM Senator Harrell
2:12:34 PM Public Testimony
2:12:37 PM Tom Griffin
2:16:42 PM Carali McLean

2:19:56 PM Waives in Support Read into Report-Chair Burton

2:20:33 PM Senator Harrell
2:20:49 PM Roll Call for SB 264
2:21:18 PM Reported Favorably

2:21:26 PM Tab 4 SB 342 - Public Records/Agency for Health Care Administration by Senator Harrell

2:21:34 PM Senator Harrell Public Testimony

2:23:05 PM Kim Smoak, AHCA Deputy Secretary Waives in Support

2:23:15 PMSenator Gaetz2:24:51 PMSenator Harrell2:25:40 PMRoll Call for SB3422:25:59 PMReported Favorably

2:26:10 PM Tab 5 SB 294 - Collaborative Pharmacy Practice for Chronic Health Conditions by Senator Harrell

2:26:23 PM Senator Harrell
2:29:20 PM Senator Davis
2:29:52 PM Senator Harrell
Senator Harrell
Public Testimony

Walter in Company

2:31:05 PM Waives in Support Read into Report-Chair Burton Waives in Opposition Read into Report-Chair Burton

2:31:43 PM 2:34:56 PM 2:35:30 PM	Dr. Alan Ackermann American College of Cardiology, Florida Chapter Senator Harrell Roll Call for SB 294
2:35:59 PM 2:36:04 PM	Reported Favorably Vote Recordings
2:36:12 PM 2:36:30 PM 2:36:33 PM	Senator Trumbull Closing Remarks Adjourned